Green Ribbon Science Panel
Subcommittee #1 --- Alternatives Assessments (AB 1879)

ATTACHMENTS

Attachment 1-1 --- Statutory (AB 1879) Requirements for Alternatives Assessments (HSC section 25253)

Attachment 1-2 --- Alternatives Assessments *(excerpts from Draft Regulations, November 2010)*

Attachment 1-3 --- "Alternatives Assessment for Chemicals: From Problem-Evaluation to Solutions – Assessment and Implementation" *(Background paper for March 31 – April 1, 2011 Interagency Discussion on Alternatives Assessment, 3/24/2011)*

Attachment 1-4 --- "Alternatives Assessment Framework" *(Lowell Center for Sustainable Production, July 2006)*

Attachment 1-5 --- Excerpts from "Five Chemicals Alternatives Assessment Study" *(Toxics Use Reduction Institute, University of Massachusetts, June 2006)*
For complete study report go to: www.turi.org/library/turi_publications/five_chemicals_study

Attachment 1-6 --- "Guidance on the Preparation of an Application for Authorisation" *(ECHA-11-G-01, January 2011)*, and "Guidance for the Preparation of an Annex XV Dossier for Restrictions" *(ECHA, June 2007)*

See introductory memorandum from GRSP member Timothy Malloy which identifies the most relevant sections of each document.

Attachment 1-1

Statutory Requirements for Alternatives Assessments

(HSC section 25253)

Statutory (AB 1879) Requirements for Alternatives Assessments

Health and Safety Code section 25253

25253. (a)(1) On or before January 1, 2011, the department shall adopt regulations pursuant to this section that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern, in accordance with the review process specified in Section 25252.5. The department shall adopt these regulations in consultation with all appropriate state agencies and after conducting one or more public workshops for which the department provides public notice and provides an opportunity for all interested parties to comment.

(2) The regulations adopted pursuant to this section shall establish a process that includes an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives, as well as an evaluation of critical exposure pathways. This process shall include life cycle assessment tools that take into consideration, but shall not be limited to, all of the following:

(A) Product function or performance.
(B) Useful life.
(C) Materials and resource consumption.
(D) Water conservation.
(E) Water quality impacts.
(F) Air emissions.
(G) Production, in-use, and transportation energy inputs.
(H) Energy efficiency.
(I) Greenhouse gas emissions.
(J) Waste and end-of-life disposal.
(K) Public health impacts, including potential impacts to sensitive subpopulations, including infants and children.
(L) Environmental impacts.
(M) Economic impacts.

(b) The regulations adopted pursuant to this section shall specify the range of regulatory responses that the department may take following the completion of the alternatives analysis, including, but not limited to, any of the following actions:

(1) Not requiring any action.
(2) Imposing requirements to provide additional information needed to assess a chemical of concern and its potential alternatives.
(3) Imposing requirements on the labeling or other type of consumer product information.
(4) Imposing a restriction on the use of the chemical of concern in the consumer product.
(5) Prohibiting the use of the chemical of concern in the consumer product.
(6) Imposing requirements that control access to or limit exposure to the chemical of concern in the consumer product.
(7) Imposing requirements for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product.
(8) Imposing a requirement to fund green chemistry challenge grants where no feasible safer alternative exists.
(9) Any other outcome the department determines accomplishes the requirements of this article.

(c) The department, in developing the processes and regulations pursuant to this section, shall ensure that the tools available are in a form that allows for ease of use and transparency of application. The department shall also make every feasible effort to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers, and consumers can use to make consumer product manufacturing, sales, and purchase decisions.

Attachment 1-2

Alternatives Assessments

(excerpts from Draft Regulations, November 2010)

EXCERPTS FROM DRAFT REGULATIONS (NOVEMBER 2010)
ALTERNATIVES ASSESSMENTS

See pages 5 through 8 for the definitions of various terms contained in draft section 69305.3.

§ 69305.3. AA Evaluation and Comparison Process and Factors.

(a)(1) Each AA, required pursuant to section 69305.1(a), shall include all of the following:

(A) A Chemical Hazard Assessment,

(B) Except as provided otherwise in paragraph (2)(B), an Exposure Potential Assessment,

(C) A Multimedia Life Cycle Evaluation,

(D) Product Function and Performance Analysis, and

(E) Economic Impact Analysis.

(2)(A) A Chemical Hazard Assessment shall be performed to evaluate and compare the chemicals contained in the Priority Product or component(s) and all alternatives identified for consideration.

(B) An Exposure Potential Assessment shall be performed to evaluate and compare the potential for exposures to the chemicals contained in the Priority Product or component(s) and any alternative being considered that contains a chemical that exhibits one or more hazard traits. An Exposure Potential Assessment is not required if none of the alternatives being considered contain a chemical that exhibits a hazard trait.

(C) Concurrent with, or following completion of, the Chemical Hazard Assessment and Exposure Potential Assessment, if applicable, a Multimedia Life Cycle Evaluation shall be performed to evaluate and compare the multimedia impacts of the Priority Product or component(s) and all alternatives being considered during each life cycle segment identified for consideration.

(D) The results of the Chemical Hazard Assessment or, if applicable, the Exposure Potential Assessment, or both, may be used to screen out alternatives before proceeding with the Multimedia Life Cycle Evaluation. Likewise, the results of the Chemical Hazard Assessment, Exposure Potential Assessment, and/or Multimedia Life Cycle Evaluation may be used to screen out alternatives before proceeding with the Product Function and Performance Analysis and the Economic Impact Analysis.

(3) The Priority Product, or component(s), and all alternatives being considered shall be evaluated and compared for the same set of life cycle segments. The same methodologies, and a consistent set of factors, shall be used to evaluate and compare the Priority Product, or component(s), and all alternatives being considered. In identifying the list of factors to be used for this evaluation and comparison, the list of factors specified in subsections (b) through (f) shall be reviewed to determine which factors are pertinent to, and will be used for, the evaluation and comparison.

Consideration may also be given to any applicable safeguards provided by other federal or California State regulatory programs.

(b) Chemical Hazard Assessment. The following factors shall be reviewed to determine if they are pertinent for inclusion in the Chemical Hazard Assessment evaluation and comparison of the chemicals contained in the Priority Product or component(s) and all alternatives being considered:

(1) Physical chemical hazards,
(2) Adverse public health impacts,
(3) Adverse ecological impacts,
(4) Adverse air quality impacts,
(5) Adverse water quality impacts, and
(6) Adverse soil quality impacts.

(c) Exposure Potential Assessment. The following factors shall be reviewed to determine if they are pertinent for inclusion in the Exposure Potential Assessment evaluation and comparison of the potential for exposures to the chemicals contained in the Priority Product or component(s) and all alternatives that are being considered:

(1) Chemical quantity information.

(A) Quantities of the Chemical of Concern or alternative chemical(s) necessary to manufacture the Priority Product or component(s), or alternative, and

(B) Estimated volume and/or mass of the Chemical of Concern or substitute chemical that is or would be placed into the stream of commerce in California as a result of the product or component(s) or potential alternatives.

(2) Exposure limitation factors listed in section 69303.3(a)(1)(B).
(3) Consumer use factors listed in section 69303.3(a)(1)(C).
(4) Environmental release factors listed in section 69303.3(a)(1)(D).

[See page 4 for the draft text of referenced section 69303.3(a)(1)(B)-(D).]

(d) Multimedia Life Cycle Evaluation. The following factors shall be reviewed to determine if they are pertinent for inclusion in the Multimedia Life Cycle Evaluation and comparison of the multimedia impacts of the Priority Product or component(s) and all alternatives that are being considered:

(1) Materials and resource consumption impacts,
(2) Adverse air quality impacts,
(3) Adverse water quality impacts,
(4) Adverse soil quality impacts, and
(5) Waste and end-of-life impacts.

(e) Product Function and Performance Analysis. The following factors shall be reviewed to determine if they are pertinent for inclusion in the Product Function and Performance Analysis of the Priority Product or component(s) and all alternatives that

are still under consideration following completion of the Chemical Hazard Assessment, Exposure Potential Assessment, and Multimedia Life Cycle Evaluation.

(1) Function and performance factors attributed to the Chemical of Concern in the Priority Product or component(s), and any essential function and performance attributes that must be met by any potential alternatives,

(2) Useful life, expressed in single use or number of applications, days, months or years, of the Priority Product or component(s), and that of the potential alternatives,

(3) Functional equivalency of each alternative relative to the Priority Product or component(s), and

(4) Technological and economic feasibility of each alternative.

(f) Economic Impact Analysis. The economic impacts specified in section 69301.1(a)(30) shall be reviewed to determine if they are pertinent for inclusion in the Economic Impact Analysis of the Priority Product or component(s) and all alternatives that are still under consideration following completion of the Chemical Hazard Assessment, Exposure Potential Assessment, and Multimedia Life Cycle Evaluation. Evaluation and comparison of economic impacts shall take into account both internalized and externalized costs during the life cycle of the Priority Product or component and all alternatives being considered, and shall include an evaluation of the range of projected costs. Evaluation and comparison of externalized costs shall include costs to government agencies, the public, businesses, and consumers.

Draft Section 69303.3(a)(1)(B)-(D) *(referenced above in section 69305.3(c)(2)-(4))*:

(B) The potential for the public or the environment to be exposed to the Chemical(s) of Concern contained in the product, during the useful life of the product and end-of-life disposal or management of the product, considering the following factors:

1. Containment of the chemical within the product, including the long-term integrity of the containment mechanism or system,
2. Engineering and administrative controls,
3. Federal and California State regulatory restrictions that reduce the potential for exposure, and
4. Frequency and duration of exposure for each use scenario and end-of-life scenario.

(C) The types and extent of consumer uses that could result in public exposure to the Chemical(s) of Concern contained in the product, which in turn could result in adverse public health impacts, considering the following factors:

1. Household use.
2. Sensitive subpopulation potential use or exposure at:

a. Home,
b. Schools, child day care facilities, and other areas frequented by children on a regular basis,
c. Health care facilities, and
d. Recreational areas and facilities.

3. Consumers who purchase, use, or otherwise come in contact with the product.
4. Persons who come in contact with the product while providing or receiving a service.
5. Customers, clients and members of the general public who come in contact with the product or releases from the product in a workplace.

(D) Product uses or management or disposal practices that could result in releases to the environment of the Chemical(s) of Concern contained in the product, which in turn could result in any of the adverse impacts specified in section 69302.3 (a)(1)(C) through (a)(1)(F) [*same as impacts listed in section 69305.3(b)(3)-(6)*], considering the following factors:

1. Use, storage, transportation, and end-of-life management practices and locations.
2. Potential for release into, migration from, or distribution across environmental media, and potential for accumulation, persistence or toxicity in biological or environmental compartments or systems of the Chemical of Concern or its degradation products.

Draft Definitions for Key Terms Contained in Draft Section 69305.3:

"Adverse air quality impacts" means air emissions of any of the air contaminants listed below:

(A) Nitrogen oxides,
(B) Toxic air contaminants,
(C) Sulfur oxides,
(D) Greenhouses gases,
(E) Stratospheric ozone-depleting compounds,
(F) Other ozone-forming compounds, or
(G) Particulate matter, with an aerodynamic diameter of ten (10) micrometers or less.

"Adverse ecological impacts" means all of the following adverse effects on living organisms and their non-living environments:

(A) Acute or chronic toxicity in aquatic, avian, animal or plant species,
(B) Adverse impacts on aquatic and terrestrial ecosystems,
(C) Loss or deterioration of environmentally sensitive habitats,
(E) Impacts adversely affecting the ability of an endangered or threatened species to survive or reproduce,
(F) Impacts that directly or indirectly cause population loss, decline in population diversity, or changes in historical communities, and
(G) Impacts that directly or indirectly cause vegetation contamination or damage.

"Adverse public health impacts" means impacts that directly or indirectly cause any of the following effects on human health:

(A) Acute toxicity,
(B) Carcinogenicity,
(C) Developmental toxicity,
(D) Reproductive toxicity,
(E) Epigenetic toxicity,
(F) Genotoxicity, or
(G) Organ, tissue or cellular toxicity not otherwise described above.

"Adverse soil quality impacts" means all of the following adverse affects on soil function or soil chemical, physical or biological characteristics or properties:

(A) Chemical contamination,
(B) Biological contamination,
(C) Loss of biodiversity,
(D) Loss of organic matter,
(E) Erosion,
(F) Compaction or other structural changes, and

(G) Soil sealing.

"Adverse water quality impacts" means all of the following adverse effects on the beneficial uses, as specified in Water Code section 13050(f) or adopted in a Water Quality Control Plan pursuant to article 3 of chapter 3 and/or article 3 of chapter 4 of division 7 of the Water Code, of the waters of the State which include groundwater, fresh water, brackish water, marsh lands, wetlands, or coastal bodies or systems:

(A) Increase in biological oxygen demand,

(B) Increase in chemical oxygen demand,

(C) Increase in total dissolved solids,

(D) Increase in thermal pollution, and

(E) Introduction of, or increase in, any of the following:

1. Chemicals identified as priority toxic pollutants for California pursuant to section 303(c) of the federal Clean Water Act and listed in section 131.38 of Title 40 of the Code of Federal Regulations published in the Federal Register May 18, 2000,

2. Pollutants listed by California or the United States Environmental Protection Agency for one or more water bodies in California pursuant to section 303 (d) of the federal Clean Water Act,

3. Chemicals identified as contaminants that have primary Maximum Contaminant Levels (MCLs) under the federal Safe Drinking Water Act, and

4. Pollutants requiring monitoring and reporting in waste discharges to land that have Notification Levels (NLs) specified under the Waste Discharge and Water Reuse Requirements (WDRs/WRRs) of the Porter-Cologne Water Quality Control Act.

"Economic impacts" means an increase or decrease in one or more of the following:

(A) Jobs or businesses,

(B) The costs of doing business,

(C) The cost of goods to consumers,

(D) Capital investments,

(E) Resource costs,

(F) Energy costs,

(G) Operation and maintenance costs,

(H) Waste disposal and treatment costs, or

(I) Other relevant financial investments or liabilities not listed above.

"End-of-life" means the point when the product is discarded by the consumer or the end of the useful life of the product, whichever occurs first.

"Environment" means the land, air, water, soil, minerals, flora and fauna.

"Functionally equivalent" means that a product that has been altered by a chemical or component substitution, or that has replaced another product, meets or exceeds the intended performance and functionality of the original product.

"Life cycle" means the activities in the course of a consumer product's life span, which are its design, raw materials mining, resource inputs and other resource consumption, intermediate materials processes, manufacture, packaging, transportation, distribution, marketing, use, operation and maintenance, waste generation and management, reuse and recycling, and end-of-life disposal.

"Materials and resource consumption" means renewable and nonrenewable resources that are used for a consumer product during its life cycle.

A renewable resource is a resource that is replaced by natural processes at a rate that is equal to or faster than its consumption rate and includes solar, wind, timber, agriculture and water. A renewable resource may become a nonrenewable resource if the rate at which it is consumed exceeds the rate at which it is produced such that its continued use may drive the resource to exhaustion.

A nonrenewable resource is a resource that is formed over long periods of geologic time and includes petroleum, coal, metals (mined and recycled), minerals, and exhausted resources.

"Materials and resource consumption impacts" means all of the following:

(A) Water consumption and conservation,
(B) Production, in-use, and transportation energy inputs,
(C) Energy consumption and efficiency, and
(D) Reusability and recyclability.

"Physical chemical hazards" means all of the following:

(A) Flammability,
(B) Flash point,
(C) Explosivity limits,
(D) Auto-flammability temperature, and
(E) Oxidizing properties.

"Product function and performance" means the principal use(s) or application(s) of a product by a consumer, as intended by the manufacturer, including function and performance attributes, and safety and environmental standards required by federal or California law.

"Soil sealing" means the covering of the soil surface with a layer of impervious material or changing the nature of the soil so that it behaves as an impermeable medium.

“Toxic” means a substance may cause an adverse biological effect.

“Useful life” means the period of time during which a product can be used for its intended use, expressed in either terms of a single use, number of applications, days, months or years of use.

“Waste and end-of-life impacts” means impacts associated with all of the following:

(A) The amount of waste and byproducts generated, and any special handling required for the waste and byproducts, during the life cycle of the Priority Product or component and each alternative being considered;

(B) Disposal, treatment or use of waste and byproducts, including solid waste, wastewater and storm water discharge streams; and

(C) Disposal of the Priority Product in the trash, down the sewer, or down the storm drain that interferes with the proper operation of solid waste, wastewater or storm water treatment facilities, and that may result in the discharge of Chemicals of Concern to the environment.

Attachment 1-3

"Alternatives Assessments for Chemicals: From Problem-Evaluation to Solutions --- Assessment and Implementation"

(Background paper for March 31 – April 1, 2011 Interagency Discussion on Alternatives Assessment)

Alternatives Assessment for Chemicals: From Problem-Evaluation to Solutions-Assessment and Implementation

A background paper created expressly for use in the March 31-April 1, 2011 Interagency Discussion on Alternatives Assessment, EPA Potomac Yards Conference Facility, Crystal City, VA

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Note: The ideas and views in this background paper are meant to stimulate discussion about the process and application of chemicals alternatives assessments. They do not represent the opinions or positions of any particular agency or organization.

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Introduction

There is increasing scientific, regulatory, business, and public attention to concerns about chemicals in production processes and everyday products and their potential health impacts. Yet, toxicological and exposure data on most chemicals, and in particular potential impacts resulting from cumulative and aggregate exposures and exposures to vulnerable sub-populations, are often lacking. These data are needed to inform risk reduction policies, although many argue that we lack clear mandates to ensure safer chemicals and products. The focus has been on the identification of threshold values that represent "acceptable", or "negligible" risk, and reducing exposures with engineering controls to prevent excursions above these levels. . Consideration of whether functional, cost-effective and safer alternatives exist that could reduce or eliminate risks, while stimulating innovation, is not frequently part of this analysis.

Alternatives assessment is a process for identifying and comparing potential chemical and non-chemical alternatives that could replace chemicals or technologies of concern.

In some cases government agencies and markets do act in ways that force the replacement of a particular substance or substances of concern. However, without thorough consideration of the alternatives and their impacts in manufacture, use, and disposal, risk trade-offs can occur. This process is still primarily reactive, focused on avoiding chemicals of concern as their hazards come to light, rather than supporting a thoughtful and strategic evolution towards safer chemicals and materials.

Responding to concerns about these challenges, an increasing number of state and local governments and federal agencies are implementing regulatory mandates or voluntary initiatives that incorporate an alternatives assessment process to support a shift to safer chemicals, materials and products. Alternatives assessment is a process for identifying and comparing potential chemical and non-chemical alternatives that could replace chemicals or technologies of concern. An alternatives assessment process that is based on characterizing potential human, including worker, health and environmental impacts of technically and economically feasible options can provide critical support for informed decision making while stimulating innovation. Alternatives assessment is a key element of informed substitution, the considered transition to lower hazard chemicals (see Appendix A for a glossary of terms).

Alternatives assessment is a key element of informed substitution, the considered transition to lower hazard chemicals

The purpose of this background document is to inform a cross-agency and stakeholder dialogue that can help support collaboration and more consistent alternatives assessment processes to support informed substitution. We present a rationale for alternatives assessment processes, an overview of the history of activities that have lead to the use of alternatives assessments in various governmental settings, and case examples of alternatives assessment in practice. We also provide an initial framework for the practice of alternatives assessment. We then explore challenges to alternatives assessment practices and opportunities for greater collaboration to advance alternatives assessment.

Examples of tools and resources for performing alternatives assessment, as well as examples of how this methodology has been used by various government organizations are provided in the appendices. In addition, Appendix A presents the common terminology that is used throughout this document. Key terms are found in **bold** text.

Why Alternatives Assessment?

Many have criticized the current approach to chemicals assessment and management as resource intensive, slow, and reactionary. Significant resources are applied to collect data to make determinations of risk, debate the significance of the risk, and determine the most cost-effective responses, resulting in a relatively small number of chemicals being assessed or acted upon. The burden generally rests on government to demonstrate unreasonable risks. This is often a large challenge given limited data on chemical toxicity, use and exposure. With this approach, preventive actions may be delayed while debates over risk occur, often due to uncertainties in the underlying understanding of chemical toxicity and exposure. When they do occur, actions may focus primarily on exposure controls in a particular media or population to reduce risks to "acceptable" levels and not consider opportunities to eliminate the risk completely or the trade-offs that might occur. Further, different agencies have different jurisdictional responsibilities for aspects of a particular chemical's risks that can limit discussions about safer alternatives. Even with aggregate risk assessment requirements (as with pesticides) this approach cannot efficiently address myriad of chemicals used in commerce today. As the Leadership Council of the CDC/ATSDR- sponsored *National Conversation on Public Health and Chemical Exposures* (described below) noted,

> "Adequate protection of the public's health is hampered by deficient testing and information collection authority, fragmentation and segregation of critically related public health concerns into separate agency silos, lack of communication between agencies, limited transparency and accountability, inadequate funding, inappropriate placement of the burden to prove harm, and insufficient attention to the concerns of vulnerable communities.
>
> A fundamental shift of emphasis is needed in our nation's approach to chemical exposures toward the development, adoption, and evaluation of safer alternatives. Preventing and eliminating problems at the source before harm occurs is a fundamental and proactive public health goal. Given that it is impossible to have full scientific certainty regarding public health risks, however, policymakers need decision-making tools that employ scientific rigor and encourage a common-sense, precautionary approach."

The Leadership Council's call for a shift in focus will require a significant change in how we characterize and make decisions about chemicals in commerce. A major part of chemicals science and policy efforts have focused on understanding and characterizing environmental and public health problems. While this work is important and valuable, the focus on problems is often at the expense of efforts that focus on solutions. To define problems without a comparable effort at finding solutions greatly diminishes the value of applied environmental, occupational and public health science. Further, if agencies' actions promote the phase-out of a specific chemical, there is a responsibility to understand

alternatives and support a path forward that is environmentally sound, technically feasible and economically viable.

An alternatives assessment approach can help support responsible action and has several direct benefits to environmental and health policy, including:

1. Focusing on solutions rather than problems. Alternatives assessment reorients environmental protection discussions from problems to solutions. Instead of examining the risks of one chemical of concern, alternatives assessment focuses on choices and opportunities. It draws attention to what a government agency or proponent of an activity could be doing to solve the problem at hand. Such discussions consider what "function" a chemical provides and whether that function can be served in a less hazardous and more effective way. Examining choices permits a broader range of questions and considerations about a chemical or product, including its need.
2. Stimulating innovation and prevention. Alternatives assessment processes can lead to innovation and produce substantial cost-savings for firms and possibly job creation as well as health and environmental benefits for society, including workers. Alternatives assessment calls attention to current and "on-the-horizon" alternatives. Resources that might otherwise be directed solely to resource intensive processes of characterizing problems can focus on solutions.
3. Multi-risk reduction. Alternatives assessment can be an efficient means of reducing multiple risks, as well as avoiding risk trade-offs. Problem-based approaches generally examine one risk or problem at a time and are met with one solution at a time. These solutions may be inflexible (e.g., pollution control equipment to reduce exposures to certain levels) and require successive investments of technology to meet each new problem or reduction in exposure limits. Or they may address only one particular problem or set of policy goals and ignore others. For example, efforts to enhance renewable energy technologies, such as solar energy, can involve the use of toxic materials that may adversely affect workers or communities. By focusing on one risk at a time, solutions may fail to identify risk trade-offs that may occur as production process or chemical changes alter manufacturing processes along a whole supply chain. For example, actions to reduce air emissions of volatile organic compounds could result in substitution with flammable solvents that trades one health risk (cancer) for another (flammability). Another trade-off risk could occur where assessment of safety of a particular chemical or alternative in one agency may ignore risks that are not included in the "assessment lens" of that agency. For example, food additives like diacetyl may be considered "safe" to consumers during ingestion, but may be very toxic to workers in production.
4. Better product design. Ultimately a primary goal is to shift the discussion away from making substitutions for chemicals of concern currently used in products to making alternatives assessment a fundamental component of product design. The cheapest and most advantageous point to address chemicals of concern is in the design phase, avoiding their use in the first place. By applying alternative assessment techniques in product design, chemicals are reviewed for the potential hazard they pose to human health and the environment before they are used and safer alternatives can be selected. This policy is encompassed in the 12 Principles of **Green Chemistry**.

An alternatives assessment process can examine technology options that might have multi-risk reduction opportunities, by reducing the use of inherently toxic chemicals, reducing risks to workers, consumers, and the environment as well as water, energy and material use reductions. It can also identify where trade-offs may occur to stimulate actions to minimize those risks.

Ultimately, alternatives assessment can support multi-stakeholder engagement that identifies solutions to problems, supports responsible, informed action by government agencies and the private sector, and contributes to sustainable business practices.

History of Alternatives Assessment at the International, State, and Federal levels

The concept of chemical substitution has a long history internationally and in the United States. While there are many examples of policies to encourage or require substitution of chemicals of concern, there are few that include requirements or processes for alternatives assessment, although this has changed in recent years.

Internationally, the Swedish government instituted the "substitution principle" as a core principle of environmental policy in the 1970s. The 1985 Swedish Act on Chemical Products states that:

> "Anyone handling or importing a chemical product shall take such steps and otherwise observe such precautions as are necessary to prevent or minimize harm to human beings or to the environment. This includes avoiding chemical products for which less hazardous substitutes are available."

Denmark and Norway have instituted similar provisions in national policies and used this concept as the foundation of several regional treaties regarding chemical contamination in the North Sea and Baltic regions.

The 1987 Montreal Protocol on Substances that Deplete the Ozone Layer represents possibly the first global effort to identify substitutes for a group of chemicals of concern. The Chemical Technical Options Committee reviews alternatives for ozone depleting substances. The 2001 Stockholm Convention establishes a legally binding means to address threats to health and the environment caused by persistent organic pollutants (POPs). Annex F of the Stockholm Convention requires the POPs Review Committee (POPRC) to complete an alternatives profile for all new candidate substances as part of its Risk Management Evaluation. In 2009, the POPRC adopted a new alternatives assessment policy, which states that having effective, available and accessible alternatives are critical to any successful chemical phase-out strategy, particularly for developing and transition countries. The policy defines alternatives broadly as: "a different chemical, material, product, product design system, production process or strategy that can replace a candidate substance while maintaining sufficient level of efficacy." In 2006, the United Nations Environment Programme established the Strategic Approach to International Chemicals Management (SAICM) to support the 2020 goal that chemicals are produced and used in ways that minimize significant adverse impacts on human health and the environment. The SAICM Overarching Policy Strategy includes the objective "To promote and support the development and

implementation of, and further innovation in, environmentally sound and safer alternatives, including cleaner production, informed substitution of chemicals of particular concern and non-chemical alternatives."

At the European level, substitution is a key aspect of the European Union's Registration, Evaluation, and Authorization of Chemicals (REACH) legislation. Recently, the European Chemicals Agency (ECHA) published an initial list of chemicals that will be subject to the REACH authorization procedures, requiring firms to find substitutes for substances of concern unless they can provide clear justification for continued use (as well as a list of Substances of Very High Concern that may be subject to authorization) and has published a guidance on the process. The European Union commissioned several reports on chemical substitution that defined the concept in the following manner:

> "Substitution means the replacement or reduction of hazardous substances in products or processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organizational measures."

Further, the concept of substitution is mandated in a number of European occupational health and safety regulations referring to carcinogens and hazardous substances in the workplace, and the European Commission is currently completing a substitution guidance document for employers. Substitution is also implicit in European cosmetics and toys regulations, which restrict the use of certain chemicals (primarily CMRs or carcinogens, mutagens, and reproductive toxicants).

In the United States, perhaps the most comprehensive institutionalized example of a requirement for alternatives assessment at the national level is the Environmental Impact Statement (EIS) process under the National Environmental Policy Act (NEPA) and similar state programs. Under NEPA, federal agencies and private entities using public funds must undergo an EIS process for federally supported activities that might have a substantial effect on the environment. The goal of NEPA is to foster better decisions and "excellent action" through the identification of reasonable alternatives that will avoid or minimize adverse impacts.

NEPA regulations specify a process that the agency must follow before initiating an activity. Through an interdisciplinary approach, agencies must (1) comprehensively identify and examine environmental effects and values; (2) rigorously study, develop, and describe appropriate (reasonable) alternatives in comparative form, including not moving ahead with an activity; and (3) recommended courses of action. Agencies are instructed to undergo a "scoping process" to broadly define potential impacts and to examine them in detail including direct and indirect impacts, cumulative effects, effects on historical and cultural resources, impacts of alternatives, and options to mitigate potential impacts.

In the environmental area, the United States and Canada agreed in the 1978 Great Lakes Water Quality agreement that "the discharge of toxic substances in toxic amounts be prohibited and the discharge of any or all persistent toxic substances be virtually eliminated." The U.S.-Canada International Joint Commission noted in its Sixth Biennial report that to achieve the agreements goals, "if a chemical or group of chemicals is persistent, toxic and bioaccumulative, we should immediately begin a process to eliminate it. Since it seems impossible to eliminate discharges of these chemicals through other

means, a policy of banning or sunsetting their manufacture, distribution, storage, use and disposal appears to be the only alternative."

In the areas of occupational safety and health and food safety, discussion of substitution also has a long history. While substitution requirements are not explicitly built into the Occupational Safety and Health Act, the industrial hygiene hierarchy of controls identifies substitution as a first priority for protecting workers from harmful exposures. The hierarchy is mentioned in part of the first (1974) NIOSH Pocket Guide and Standards Completion Program and the OSHA Respiratory Protection Standard and substitution was the basis of the never implemented 1979 Generic Cancer Standard, which stated that known and probable carcinogens should be substituted based on technical feasibility. Similarly, the Delaney Clause of the Federal Food Drug and Cosmetics Act states that: "the Secretary of the Food and Drug Administration shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals."

The Pollution Prevention Act of 1990 resulted in renewed attention to chemical reduction and substitution. The Act "declares it to be the national policy of the United States that pollution should be prevented or reduced at the source whenever feasible." Following the passage of the Act, the Environmental Protection Agency established numerous programs, such as the Cleaner Technology Substitutes Assessments designed at identifying chemicals of concern and assessing safer alternatives to those substances. Several EPA pollution prevention programs have supported voluntary partnership efforts aimed at reducing problem chemicals and waste generation. In particular, the EPA established the Design for Environment (DfE) program. The DfE program has developed methods to identify alternatives to chemicals of concern through "informed substitution," which DfE defines as the considered transition from a chemical of particular concern to safer chemicals or non-chemical alternatives. DfE describes the goals of informed substitution as follows: to minimize the likelihood of unintended consequences, which can result from a precautionary switch away from a chemical of concern without fully understanding the profile of potential alternatives, and to enable a course of action based on the best information - on the environment and human health - that is available or can be estimated.

Similarly, the EPA's Green Chemistry program supports and rewards the design of inherently safer chemicals. In 2000, Paul Anastas and John Warner published the book 'Green Chemistry: Theory and Practice' which defined twelve principles of Green Chemistry. The 12 Principles of Green Chemical aim to alter the way products are manufactured in order to minimize their impact upon human health and the environment throughout their lifecycles. One principle specifically addresses the issue of safer alternatives:

> *'Design safer chemicals and products: Design chemical products to be fully effective, yet have little to no toxicity.'*

By promoting green chemistry, chemical manufacture and use activities are focused on safer alternatives and safer products at the product design stage, which can ameliorate many of the environmental, worker and public health concerns associated with the use of chemicals of concern.

During the past decade, there has been increasing pressure at the state and federal levels to reform chemicals regulations. Further, there is increasing discussion as to whether the current regulatory system is adequate to address chemical concerns. At the same time, increasing consumer pressures have pushed the marketplace to act in the absence of government policy, often without adequate data on substitutes.

States and local governments were the first to respond to these trends beginning in the early 2000s. The states have a long history of innovation in chemicals management and pollution prevention, dating back to the California Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as Prop 65) which prohibits businesses from discharging chemicals that have carcinogenic or reproductive toxicity effects into sources of drinking water. In recent years a number of states, particularly Washington, Maine, California, Oregon, Michigan, Minnesota, Connecticut, New York, Maryland, and Massachusetts, have moved forward with chemicals management policy reform efforts. These efforts have ranged from single chemical restrictions on mercury, phthalates, brominated flame retardants, and bisphenol-A, to procurement policies and broader chemical prioritization and substitution requirements. Because of this evolution of state policies, and the frequent lack of resources for implementation, ten states have combined efforts to form the Interstate Chemicals Clearinghouse (described more fully in Appendix F), which provides a mechanism to share data on chemical toxicity, uses, and alternatives. In the 2009-2010 legislative session, about 350 bills related to chemicals were introduced at the state or local level.

Similarly, at the federal level several legislative, regulatory, and voluntary initiatives have occurred during the past five years. The Consumer Product Safety Improvement Act of 2008 includes a ban on six phthalates and tightens the restrictions on lead in children's products. In 2009, the Obama administration issued principles for the reform of the Toxic Substances Control Act, including the principle that “green chemistry should be encouraged and provisions assuring transparency and public access to information should be strengthened.” Based on these principles, the EPA has initiated a comprehensive effort to enhance the Agency’s current chemicals management program within the limits of existing authorities. This effort includes: new regulatory risk management actions; development of chemical action plans for chemicals of concern; requiring information needed to understand chemical risks; and increasing public access to information about chemicals. At the same time, the Senate and House have introduced bills to reform the Toxic Substances Control Act. The Senate bill, the Safer Chemicals Act of 2010 (S. 3209), and the House bill, the Toxic Chemical Safety Act of 2010 (H.R. 5820), require EPA to categorize and prioritize chemicals based on hazard and exposure characteristics and mandates that chemical manufacturers make risk-based safety determinations in order to market a chemical. Both bills include provisions aimed at stimulating safer alternatives and green chemistry.

At the federal level, several pieces of legislation restricting individual chemicals of concern, such as bisphenol-A, have been introduced in Congress. The Safe Cosmetics Act of 2010 (H.R.5786) was introduced to increase FDA authority to require testing of cosmetics products, increase transparency and reduce chemicals of concern. Chemical Plant Security legislation drafts being discussed in the House and Senate contain provisions to require analysis of inherently safer technology options that would reduce accident potential. The Chemical Safety Board, established by Congress to investigate the root

causes of chemical accidents, strives to advance inherently safer technologies to reduce accident risks. In 2007, the National Institute for Occupational Safety and Health (NIOSH) initiated the Prevention Through Design Program (described more fully in Appendix H) to support the "designing out" of hazards in the early stage of the design process. In 2010 OSHA initiated a process aimed at identifying hazardous chemicals for which OSHA should develop exposure reduction strategies. Finally, Presidential Executive Order 13514 of 2009 on government procurement sets the principle that government should lead by example. It establishes an interagency sustainability taskforce, promotes green buildings, electronics stewardship, resource conservation and green house gas reductions through government purchasing and sets goals for pollution prevention and waste minimization through "reducing and minimizing the quantity of toxic and hazardous chemicals and materials acquired, used, or disposed of... implementing integrated pest management and other appropriate landscape management practices; and increasing agency use of acceptable alternative chemicals and processes in keeping with the agency's procurement policies."

Most recently the CDC in association with the Agency for Toxic Substances and Disease Registry (CDC/ATSDR) funded the *National Conversation on Public Health and Chemical Exposures* that has engaged stakeholders in a dialog about reducing chemical exposures. An independent, voluntary effort, the *National Conversation* was facilitated by RESOLVE, a neutral non-profit consensus building organization. The *National Conversation* was grounded in the vision that chemicals will be used and managed in ways that are safe and healthy for all people. It was launched in June 2009 and will be completed in April 2011 with the issuance of an Action Agenda. Participants included public health professionals and others bringing the experience and perspectives of government, communities, business, NGOs, and research institutions. Web dialogues, community conversations, and public comment opportunities encouraged public participation at key points throughout the process.

The first recommendation in the *National Conversation* Action Agenda directly addresses alternatives assessment; in addition, precautionary approaches are included in several other recommendations.

- Recommendation 1.1 calls for federal, state, tribal and local government agencies to promote the substitution of hazardous chemicals with less toxic alternatives through use of policy incentives, investment in research and development, enhanced efforts to develop effective hazard screening methods and dissemination of information the public can use in personal decision making. The recommendation further requests that agencies responsible for the review of individual chemicals and manufacturing processes establish guidelines for and mandate the timely identification and adoption or development of viable safer chemicals and manufacturing processes under existing or (where necessary) new authorities. It also suggests that federal agencies should coordinate in developing a program for the promotion of safer technologies, which would involve fostering relevant expertise in engineering, policy, and alternatives assessment. Finally, the recommendation suggests that companies systematically identify, evaluate, and either adopt or develop alternative technologies and approaches.

- Recommendation 1.5 calls for federal agencies to work in consultation with the public and private sector to develop standard scientific criteria and protocols to: 1) apply the precautionary approach to both existing and new chemicals; and 2) design, assess and promote safer chemical processes and products. Priority actions requested in this recommendation include identifying the most important and useful data to include in alternatives assessments that will serve to implement precautionary decisions; and refining the analytical approach for integrating the information collected, comparing alternatives, involving the public, and monitoring the consequences of decisions.

Parallel to government efforts, retailers and manufacturers are beginning to work to avoid known chemicals of concern in products and identify safer alternatives as a result of consumer pressure or regulations in some part of the world. In some cases, large retailers and product purchasers, and health care providers and purchasing organizations, have instituted chemicals policies, including restricted substances lists, with which their suppliers must comply. For example, Wal-Mart now requires that chemical product suppliers provide information on all intentionally added ingredients to a database where the chemicals are screened for their hazards and this information is provided to purchasers. SC Johnson has developed a scoring system called the Greenlist™ to evaluate substances in their products and promote a shift towards the use of safer ingredients. Other companies are developing processes to prioritize chemicals of concern and assess safer alternatives. In some cases, there are sector-wide lists of globally restricted substances, such as in the footwear and apparel industry.

This brief historical exploration demonstrates that alternatives assessment is not a new process, yet incorporation of alternatives assessment requirements in substitution policies is not very common. Efforts at chemical substitution have increased significantly during the past decade. However, there has been little attention to date to improved collaboration and coordination around alternatives assessment policies, processes, and tools that help support informed substitution.

Defining the Landscape: Achieving Informed Substitution Using Alternatives Assessment

Alternatives assessment is a process of identifying and comparing potential chemical and non-chemical alternatives to a chemical of concern to facilitate informed substitution. Alternatives assessments focus on the role of the chemical of concern in a specific process or product design to determine if the function of that chemical can be achieved using a chemical of lower hazard , finding a product redesign option that eliminates the need for the chemical, or redesigning the process to eliminate the need for the chemical of concern.

Many terms and phrases are used to describe the nuances of alternatives assessment and related processes. A summary of the most common terms used in this paper can be found in Appendix A.

A common element of the various governmental initiatives described in the History section of this paper involves seeking safer alternatives by identifying and avoiding chemicals of concern. This approach traditionally involves creating lists of chemicals of concern and enacting regulatory or non-regulatory policies to avoid or reduce those substances. While expedient, this approach has several

challenges associated with it, including the inconsistency and age of many lists and the potential for users to assume that chemicals not on these lists are therefore "safer". Chemicals not on regulatory lists or subject to regulation are often not well studied and may pose unknown hazards. In shifting away from known chemicals of concern, it is important not only to avoid hazardous substances but to ensure that alternatives are indeed safer, a process that we refer to as **informed substitution.**

Substitution is not limited to substitution of one chemical with another. And it can occur at the production process or product level.

Informed substitution focuses on identifying alternatives and evaluating their health, safety and environmental hazards, potential trade-offs, and technical and economic feasibility. Substitution is not limited to substitution of one chemical with another. And it can occur at the production process or product level. For example, a chemical process may be targeted for substitution, such as vapor degreasing using chlorinated solvents. Or at the product level, substitution may involve a design change that takes advantage of the characteristics of new or different materials. An example of this kind of substitution is in the redesign of electronics enclosures to eliminate the need for flame retardants altogether. A chemical process design change, for example production of pharmaceuticals, may eliminate several production steps thereby avoiding or reducing the use of high hazard chemicals (this is the approach of "**green chemistry**"). In some cases, a particular chemistry or the function it serves may be determined to be unnecessary.

Figure 1 illustrates the relationship between alternatives assessment, substitution planning and informed substitution.

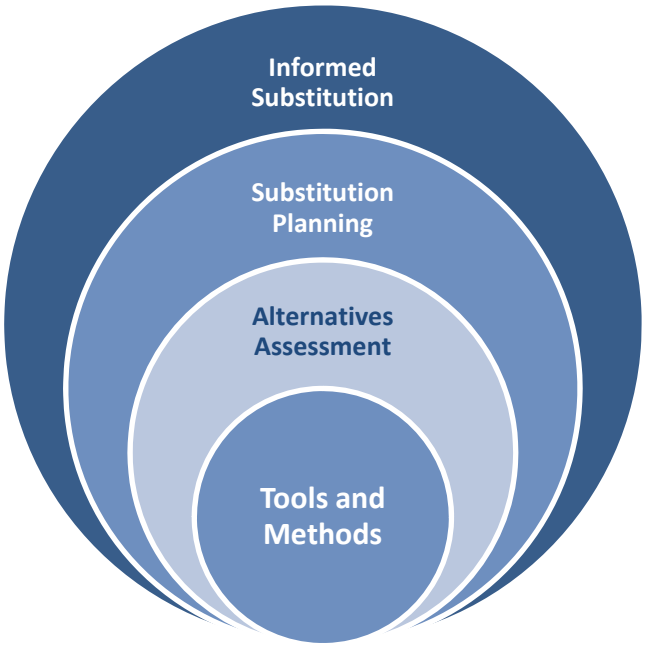

Figure 1 Relationship of Tools and Processes to Achieve Informed Substitution

The experience of pollution prevention programs such as the Massachusetts Toxics Use Reduction Program demonstrate that ideal "drop-in" substitutes often do not exist and adoption of safer substitutions often requires changes to production process or product design. As substitutions become more complicated to implement performance, economic, and risk trade-offs become more challenging to consider. In other cases, safer alternatives may not exist or may not be technically feasible, which creates a need for additional research, development and technical support to design and adopt safer and effective alternatives.

Implementation of process and product changes can be quite complicated. Hence, the process of alternatives assessment forms part of the broader framework of substitution planning, a powerful tool that supports informed substitution through setting goals, engaging stakeholders, and achieving implementation. Substitution planning is similar to the concept of "facility planning" for pollution prevention and source reduction.

Most often, alternatives assessment activities focus only on a small part of the substitution process: **comparative chemicals hazard assessment**. This approach may only peripherally consider the actual adoption of alternatives and the challenges that might occur either up or downstream of the production process.

As such, in 2006, the Lowell Center for Sustainable Production developed a framework for alternatives assessment intended to envision the three essential elements of alternatives assessment, including:

- Alternatives assessment foundations: the core of the process, where values and decision-rules are made explicit and may help to rapidly screen out certain alternatives from future consideration
- Alternatives assessment processes: the steps used to evaluate and compare chemicals, materials or products, including: identification of targets for action; characterization of end uses and functions of the substance; identification and evaluation of alternatives; and selection and implementation of preferred alternatives.
- Evaluation modules: the tools and methods to evaluate economic feasibility, technical performance, human health and safety impacts, and social justice impacts of alternatives.

The framework includes two evaluation paths: one for existing chemicals, materials, and products and one for the design of new chemicals, materials or products (see Figure 2). Both include a continuous review process to identify trade-offs, measure progress, and identify opportunities for improvement.

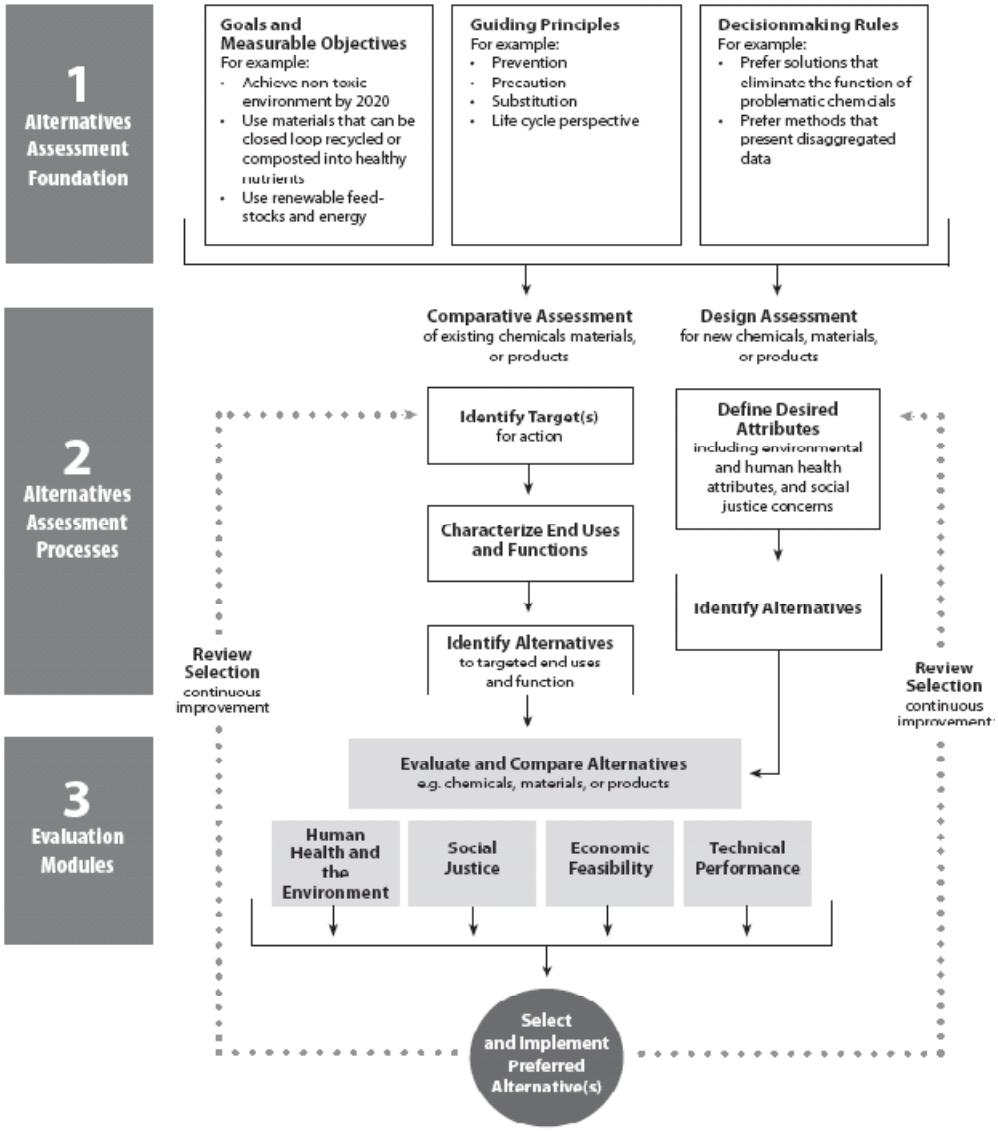

Figure 2 - Lowell Center for Sustainable Production Alternatives Assessment Framework

Alternatives assessment initiatives may occur at numerous levels of governance. For example, at a federal level, where greater toxicological resources exist, an alternatives assessment may focus on what alternatives exist for a particular chemical or functional use of a chemical. At the state and local levels (and within firms), an alternatives assessment may focus on whether and how a particular alternative would work in a particular production process or product line. At this level, technical assistance and incentives to promote adoption as well as consideration of facility level process change impacts become important.

The scope of an alternatives assessment can vary widely in terms of information needs, cost and technical expertise. Integration of increasing levels of specificity in terms of use and application, narrows the scope of the assessment, but requires more specific technical knowledge about the potential substitutes to facilitate adoption at the company level. Detailed knowledge of manufacturing

processes may not be available to government agencies, which indicates these agencies must involve affected businesses to ground their study results.

Some aspects of the evaluation stage of an alternatives assessment are fairly well-developed, such as determining economic and technical feasibility, though approaches may vary between agencies or firms. For example, the EPA's Cleaner Technologies Substitutes Assessment process included a module on technical assessment with a 17 step process for developing the protocol for evaluating products. In the area of economic assessment, several approaches ranging from traditional cost-benefit assessment, to net present value analyses to full cost accounting have been used. Few approaches have been developed to consider social performance – the socio-economic implications of adopting alternatives, including impacts on workers and communities, child labor, training, or customer health. UNEP has recently proposed guidelines for social life cycle assessment.

For comparative chemical hazard assessments, a myriad of tools have been developed by agencies and the private sector (see Appendix B - Resources). How these tools are used depends heavily on the particular agency, goals and legal/procedural mandates. For example, several state agencies and the EPA's Design for Environment Program conduct comparative hazard assessments. A few examples of these programs are provided in the appendices. Within those assessments a range of toxicological endpoints are evaluated for the current chemical in use and identified alternatives. Chemicals that appear on specific lists (such as known carcinogens) or that meet specific toxicological criteria (e.g., high persistence or bioaccumulation potential) are rated as a higher concern. While review approaches may differ, the types of toxicological endpoints and criteria for higher and lower concern have tended to remain relatively consistent across agencies. Exposure is generally a secondary consideration in these comparative hazard approaches, particularly when comparing chemicals for a particular functional use, and is usually defined in qualitative terms, based on physical chemical data, as well as fate and transport.

The degree to which upstream and downstream implications (lifecycle considerations) of alternative chemicals are considered is inconsistent across agencies. Some agencies conduct quantitative or qualitative risk assessments (to the extent that data exist) of alternatives, where mandates for achieving a particular level of safety or exposure control exists. Other agencies or programs may use quantitative or qualitative lifecycle assessment approaches for evaluating toxicity concerns, along with climate impacts and energy and materials use. The use of lifecycle tools to compare alternatives has occurred in programs where institutional purchasing is involved. Other tools, such as multi-criteria decision analysis, which combines consideration of health and safety attributes with economic and performance considerations, have also in some limited cases been used.

In addition to government-developed tools for comparative chemicals assessment, many private and non-profit entities have developed their own comparative chemicals assessment approaches. For example the non-profit organization Clean Production Action developed a comparative chemicals hazard assessment tool called the "Green Screen" to assign chemicals into higher and lower concern categories. Several companies and agencies are using this methodology, now in its second iteration.

This section has begun to identify alternatives assessment as a tool to support informed substitution. Informed substitution cannot occur without a careful consideration of alternatives. But informed substitution also requires structures for establishing goals and targets as well as implementation of alternatives and design of new chemicals and materials based on the principles of green chemistry.

Overview of current alternatives assessment activities and practices – Case Examples

Appendices C-H provide case examples of current initiatives on alternatives assessment at the local (City of San Francisco), state (Washington, Maine, Massachusetts and a multi-state collaboration called the Interstate Chemicals Clearinghouse, or IC2) and federal (the US Environmental Protection Agency's Design for Environment program and the National Institute of Occupational Safety and Health's Prevention Through Design program) levels.

The purpose of providing these case examples is to provide background that can inform discussions of collaboration and more effective coordination of approaches. It is important to note that alternatives assessment activities can occur as a direct result of legislative or regulatory mandates, an indirect result of such mandates, or as part of a compliance or innovation support initiatives.

Challenges to Informed Substitution and Alternatives Assessment Processes

Despite the increasing interest in alternatives assessment processes at the local, state, and regional levels, a series of challenges still exist to broader application in practice. These can be divided by data gaps; methodological challenges; lack of mandates and resources; technical barriers and jurisdictional boundaries. These challenges often intersect with each other. While these challenges are not insurmountable, it is important to address them in advancing alternatives assessment practice.

Data gaps

Basic data on chemical toxicity, uses, and exposures, as well as chemical product formulation are often not available. It is often difficult to obtain information on how particular chemicals are used, and what are their feedstocks and degradation products. Exposure data, particularly for chemicals with dispersive uses, may be difficult to obtain (particularly if use data are unavailable). Environmental or human biomonitoring data are often expensive to collect and methods have not been developed for detection of many chemicals. Chemical manufacturers and users may be unwilling to provide such information for competitive advantage purposes, and claims of confidentiality are often allowed under specific laws. As such, the toxicological, use, and exposure database for many chemicals is limited, particularly for newer chemicals that might serve as safer substitutes.

Agencies have varied in how they address data gaps. Some agencies use predictive modeling tools to estimate hazards or risks, while others must obtain additional data due to regulatory requirements to demonstrate unreasonable risks.

Methodological challenges

While there is some collaboration regarding the steps of alternatives assessment processes and some of the criteria for toxicological evaluation, there has been less coordination regarding the actual methodologies of alternatives assessment. Unlike risk assessment which has a well-defined four step process, no such consistent process currently exists for alternatives assessment, including the comparative chemicals evaluation process. Further, how "safer" is defined varies by jurisdiction, including the criteria for defining higher and lower concern. Finally, the scope of an assessment can result in varying results.

Lack of mandates and funding

Alternatives assessment processes are generally not mandated under federal laws, with the exception of the National Environmental Policy Act. Legislation such as the Pollution Prevention Act of 1990 while prioritizing source reduction provides no mandate for such activities. Agencies may undertake alternatives assessments as part of regulatory programs, enforcement actions or other discretionary activities. However, the lack of mandates can provide a disincentive to alternatives assessment, particularly when there are competing mandatory authorities for an agency or when alternatives assessment may conflict with a competing regulatory requirement for action (such as demonstrating unreasonable risk). When budgets are limited, agencies may be forced to focus attention on implementing the mandated activities on which they are reviewed in Congress and the Administration. Finally, the lack of mandates may not provide strong incentives for the regulated community to engage in evaluation and adoption of alternatives or unclear or conflicting mandates that do not require alternatives assessments (such as chemical restrictions) may result in regulated entities moving towards alternatives that are easy, drop-in substitutes but result in trade-off risks.

Similarly, there are limited human resources and expertise in agencies in conducting alternatives assessments, in part due to the lack of mandates and funding. As such, when questions of alternatives arise, agency staff may not understand how to assess or think about issues such as trade-offs and performance. The lack of expertise is compounded by a lack of education and training on alternatives assessment processes for policymakers and scientists, including those designing and manufacturing chemicals and chemical products.

The limitations in regulatory mandates and funding is similar to chemicals research funding, where a vast majority of funds are dedicated to detailed quantitative assessments of risks and not on development or assessment of alternatives. Such limits in funding and expertise extend to state and local agencies, where environmental and health agency budgets have been significantly reduced.

Technical barriers

As previously noted, chemical substitution is not a simple process, particularly for small and medium sized firms. Often alternatives are not available or require significant process change to work in practice (i.e., achieving comparable performance and cost). While state agencies have worked closely with manufacturing firms for almost two decades as part of pollution prevention education and outreach activities, this type of technical support has occurred less at the federal level. If the goal of alternatives

assessment is to support informed substitution, then the implementation side becomes increasingly critical and resources to support adoption may be necessary.

Jurisdictional boundaries

Under the current federal and most state systems chemical risks are addressed by a range of agencies that may or may not work in a coordinated fashion or have competing regulatory or jurisdictional interests. Different chemical types are regulated by different agencies (or divisions of agencies), such as pesticides, cosmetics, toys, food contact articles, consumer articles, pharmaceuticals, etc. in ways that may impede collaboration around safer substitutes. For example, while EPA may have authority to regulate chemicals in commerce under the Toxic Substances Control Act, it may only be able to look at alternatives for specific uses of a chemical, if other uses are regulated under another agency's authorities. Similarly, while one agency may only look at risks to the consumer or environment, a chemical change may affect workers. Unlike renewable energy and sustainability, there is no national strategy or approach focused on safer alternatives to chemicals of concern.

Constructing the Foundations/Backbone of Alternatives Assessment Practice

The application of informed substitution requirements as well as the actual assessment of alternatives is likely to differ to some degree across agencies as a result of differences in goals of implementing statutes, differences in regulatory thresholds, and institutional cultures. However, as in the case of other assessment approaches, such as risk assessment, foundations of practice and process can be developed and greater consistency in definitions and approach can be achieved. Further, efforts for greater collaboration and sharing of expertise across agencies and levels of government to identify roles and responsibilities, particularly where multiple agencies are working on similar problems allows for greater resource efficiency and opportunities to stimulate innovation that results in environmental, health and economic gains.

To begin the dialogue on more effective collaboration around alternatives assessment practice, it is important to lay out a "backbone," or framework, for alternatives assessment practice and collaboration. This backbone builds off of existing approaches, such as the protocol established in the interactive Interstate Chemicals Clearinghouse (IC2) Safer Alternatives Wiki (www.ic2saferalternatives.org) (see Appendix E for more information). It mirrors the process of facility or substitution planning undertaken by many firms. Stakeholder engagement, which often differs by agency, extends throughout this whole process. Various resources are available to assist in this process as well. Figure 3 illustrates the steps of the alternatives assessment process as developed by the IC2.

Figure 1 - IC2 Safer Alternatives Assessment process

Defining the goals, scope and boundaries

Defining the goals and scope and decision-rules of an alternatives assessment process is a critical first step. This scope setting helps define the range and types of alternatives that might be considered. These may differ depending on the agency. Is the goal to identify safer alternatives to a specific chemical of concern in a specific product type, to advance a clean technologies agenda, or to justify regulatory action on a particular chemical of concern? Is the goal simply to identify alternatives, or ensure their technical and functional viability in manufacturing? Is the scope based on a particular functional use of a chemical or a range of uses? Goals may also include achieving certain requirements with alternatives, such as biodegradation, closed loop recycling potential, biobased feedstocks or avoidance of certain types of chemical hazards, such as carcinogens. Finally, the scope may include to what degree lifecycle impacts of alternatives are evaluated or whether non-chemical or other innovative alternatives including not doing the activity (as is the case in NEPA) are considered. In the case of interagency evaluation of alternatives, the scope may include consideration of impacts that affect populations and media not generally regulated by a particular agency.

Identify and characterize chemical targets for action

It would be difficult to conduct alternatives assessments for all chemicals in commerce, given the thousands of unassessed chemicals. Hence, identification of priorities becomes an important first step in alternatives assessment processes. In some cases, chemicals of higher concern are defined by law. In others, agencies undertake prioritization processes. Agencies have collaborated for decades on identifying priorities for chemical assessment and in some cases for regulatory action. However, processes of prioritizing chemicals of concern have been varied (even within the same agency) and generally uncoordinated. This includes identification of hazard traits that would lead to increased concern about a substance, such as persistence and bioaccumulation (some which may be of lesser or greater concern to one agency or another).

Questions that need to be considered in identifying priorities include what the chemical is used for; whether concerns limited to a particular chemical or the entire class; what is the scientific evidence of concern; whether there are particular uses or exposures of concern to vulnerable populations; and if viable alternatives potentially exist? To answer these questions, there is a need for basic information on hazard traits and potential uses/exposures.

Identify and prioritize chemical uses

Chemicals serve particular functions and often the function of the chemical defines potential exposures and hazards. Chemical users select substances largely on their ability to perform a particular function. Some chemicals may have hundreds of functional uses. It may be possible to both identify and prioritize particular functional uses of chemicals that are regulated by multiple agencies (such as solvents) for identifying and comparing alternatives. This would allow for a more rapid comparison of multiple chemicals – some of which may be significantly safer – to achieve the same use. It is possible to prioritize both functional uses and uses of greatest concern of a particular chemical based on criteria such as: exposure potential based on the amount and how the chemical is used, priority industrial sector, priority product categories, pollution prevention and substitution potential, regulatory interest, chemical intensity (the need for potentially problematic chemicals to achieve the function), and necessariness of the functional use or chemical.

Identify and screen alternatives

At this phase an initial search to identify alternatives is conducted. These may involve only alternatives currently on the market or those that also may be "on the horizon". The identification of alternatives may happen through a variety of mechanisms, including literature reviews, stakeholder consultations, interviews with product and chemical manufacturers, etc. Depending on the scope of the assessment, this alternatives identification may include alternative product designs, materials, and services in place of product (for example integrated pest management). At this point, alternatives that are of high hazard (based on earlier decision-rules) or technically unacceptable may be eliminated from further evaluation. Alternatives that may require some level of technical or research support for implementation may be considered at this point.

Evaluate and compare alternatives

Comparative chemicals hazard assessment has been the focus of most alternatives assessment efforts to date. It includes consideration of hazards and potential exposures as well as how chemicals are ranked or characterized into high, medium or low concern or acceptable/unacceptable. This process also can involve processes to determine economic implications and technical viability of implementing alternatives. The extent to which minimum standards for alternatives are established is also a factor at this point.

Select alternatives

Once alternatives have been identified and assessed, it may be useful to determine which alternatives are safer. Agencies may make a determination about whether or not the alternative is indeed safer than the chemical of concern. Or they may simply present the information obtained in a

way that allows stakeholders to make their own determination. This step involves defining what is meant by the term "safer."

Promote and support adoption of alternatives

While alternatives may be available, they may be difficult to integrate into the market place for a variety of reasons: technical challenges in substitution or concern about performance in a particular production process, high initial costs of reformulation; or lack of incentives to substitute. Sometimes viable alternatives may not be currently available. If alternatives are not adopted or fail in implementation, the benefits of safer chemistry are lost, regrettable substitutions may take place, or skepticism about the value of alternatives assessment may occur. As such, it is useful for alternatives assessment processes to be linked to support for adoption. The tools to support adoption may include incentives such as: technical and training support to firms; establishing networks of firms to solve problems; setting up a "marketplace" for alternatives; providing financial incentives to support adoption; developing procurement requirements or regulatory requirements or regulatory relief. In cases where alternatives may not be available, challenge programs to develop alternatives could be initiated. This is one key area for multi-level collaboration between the federal, state and local levels of government.

Opportunities for Coordination and Collaboration

Advancing informed substitution through alternatives assessment provides many opportunities for new collaborations between federal, state and local agencies. These collaborations could form the basis of a more coordinated approach to alternatives assessment and implementation of safer chemicals and products. Some possible areas of collaboration include:

Stakeholder engagement

The *National Conversation on Public Health and Chemical Exposures* brought together a broad range of stakeholders and a key area of focus was the need to advance safer alternatives. A follow up activity could take the results of the group's efforts to bring together stakeholders to develop a plan for how alternatives assessment practice could be implemented more widely at a national, state or local level.

Scientific/technical collaboration networks

Agencies have varying scientific capacities for scientific assessment – toxicology, exposure assessment, economic and technical evaluation. Understanding and developing some type of database of these capacities may help facilitate alternatives assessment efforts and their application. Some agencies have undertaken efforts to integrate chemicals databases and understand opportunities for sharing expertise. One example is the Department of Homeland Security Risk Knowledge Management System.

Interagency taskforce

Interagency collaboration on chemicals and other environmental and health efforts is not new, for example the Interagency Testing Committee, the National Nanotechnology Initiative or the OMNE Committee coordinating efforts between EPA, NIOSH, MSHA and NIEHS. A newly re-established

committee, the Committee on Environment, Natural Resources, and Sustainability of the National Science and Technology Council of the White House may provide also provide a model. And models exist for federal, state and local collaboration such EPA's Forum on State and Tribal Toxics Action. The establishment of an interagency taskforce on safer chemicals may help facilitate greater cross-agency collaboration including:

- Establishing a national vision for safer chemicals, similar to that for clean energy that links environment, job creation, and economic development
- Identify barriers to alternatives assessment processes and strategies to overcome them.
- Establishment of interagency alternatives assessment guidelines or approaches to ensure consistency and collaboration of alternatives assessment efforts.
- Development of a national list of chemicals of high concern that would spur market demands for safer chemicals and products and identification of criteria for higher and lower concern chemicals
- Development of a national list of chemicals of lower concern or "green chemicals" that would spur use of safer chemicals. Information could also be included on what applications would be appropriate and how the determination of lower concern was reached.
- Identification of areas where competing environmental interests may result in risk trade-offs and where development of safer alternatives or actions in another agency would address a particular health and safety or ecological risk that may be regulated by another agency.
- Collaboration on regulatory and non-regulatory policy development to strengthen the value added of policies and programs and ensure efforts in one agency to advance safer materials do not adversely impact another.
- Coordination of R&D priorities and technical support or incentives for adoption of alternatives to chemicals of high concern
- Coordination of efforts to advance funding for assessment and adoption of safer materials.

Monograph or study on alternatives assessment methods

It would be useful to advance collaboration on alternatives assessment through the development of consistent approaches. One suggested approach is to generate an alternative assessment framework that identifies minimum, recommended and optimal levels of alternatives assessments. This approach would allow those organizations with less experience and resources to begin the alternative assessment process and to continually improve upon the quality of alternative assessments as they begin to demonstrate their worth and value. Those organizations with additional resources and expertise can conduct more thorough alternatives assessments with the same basic principles but more depth required.

Given the myriad of assessment methods, it may be useful to develop some type of monograph that outlines a roadmap to enhanced coordination. Several models for the development of such a study exist. An agency can pull together leading thinkers in the field to develop the approach and then seek comments from interested stakeholders, as was the case with the effort around Toxicity Testing in the 21st Century. A private facilitation organization or professional body could bring together stakeholders

professionals to develop such as approach as was the case with SETAC's development of the methodology for lifecycle assessment. Finally, the National Academy of Sciences could be funded to conduct a study that would outline a framework for the process and practice of alternatives assessment, as it did with the 1984 Red Book on Risk Assessment. The NAS has already developed a Statement of Task for such a study.

Conclusion

Alternatives assessment is a critical element of informed substitution. Yet, it is a relatively new tool to agencies, requiring new assessment approaches, capacities and skills, new policy frameworks, and new collaborations. As a result there are a variety of challenges to its application in process. However, there are many reasons to advance collaboration and consistency in approaches that have been outlined in this paper. Ultimately, if the goals of informed substitution and design of new chemicals based on green chemistry principles are to be achieved, a greater focus on developing, identifying, and assessing alternatives will be necessary. Small collaborative steps, built upon successful examples, can lead to broader efforts, enhanced practice and ultimately transitions towards more solutions-oriented chemicals science and policy.

Ultimately, if the goals of informed substitution and design of new chemicals based on green chemistry principles are to be achieved, a greater focus on developing, identifying, and assessing alternatives will be necessary.

Appendix A – Terminology Associated with Alternatives Assessments

There are many terms that may be used during a discussion about alternatives assessment that may be new or may have multiple meanings. To facilitate discussion, we suggest a list of terms and definitions as a reference.

- **Alternatives Assessment**: A process for identifying and comparing potential chemical and non-chemical alternatives that could replace chemicals or technologies of concern on the basis of their hazards, performance, and economic viability.
- **Chemical Hazard**: A stressor that can cause harm to human health or ecological systems based on inherent chemical and physical properties.
- **Comparative Chemicals Assessment**: The process of comparing chemical alternatives on the basis of their chemical hazards.
- **Green Chemistry**: Green chemistry is the design of chemical products and processes that reduce or eliminate the use or generation of hazardous substances throughout manufacture, use, and disposal. It is based upon the 12 Principles of Green Chemistry formulated by Warner and Anastas in the late 1990's which emphasizes the creation of safer chemicals and chemical processes in the design phase.
- **Informed Substitution**: A considered transition from a chemical of particular concern to safer chemicals or non-chemical alternatives. The goals of informed substitution are to minimize the likelihood of unintended consequences, which can result from a precautionary switch away from a chemical of concern without fully understanding the profile of potential alternatives, and to enable a course of action based on the best information - on the environment and human health - that is available or can be estimated.
- **Life Cycle Assessment**: LCA is a technique to assess the environmental aspects and potential impacts associated with a product, process, or service, by:
    - compiling an inventory of relevant energy and material inputs and environmental releases;
    - evaluating the potential environmental impacts associated with identified inputs and releases; and
    - interpreting the results to help you make a more informed decision.
- **Safer Alternative**: An option, including the option of not continuing an activity, that is healthier for humans and the environment than the existing means of meeting that need. For example, safer alternatives to a particular chemical may include a chemical substitute or a re-design that eliminates the need for any chemical addition.
- **Safer Chemical**: A chemical that, due to its inherent chemical and physical properties, exhibits a lower propensity to persist in the environment, accumulate in organisms and induce adverse effects in toxicological studies. Synonyms: lower hazard, inherently low hazard; 'green' chemical
- **Substitution Planning**: The process of setting goals and priorities, evaluating alternatives, identifying preferred alternatives and supporting their implementation.
- **Risk**: The chance of harmful effects resulting from exposure to an environmental stressor. Risk is a function of both hazard and exposure.

Appendix B - Resources Available on Alternatives Assessment

Note: This list is a work in progress that will be updated regularly with additional information.

Existing Alternatives Assessments

- *Alternatives to Deca-BDE in Televisions and Computers and Residential Upholstered Furniture,* Washington Department of Ecology and Department of Health, December 2008 (accessible at http://www.ecy.wa.gov/pubs/0907041.pdf).
- Massachusetts Toxics Use Reduction Institute's (TURI) *Five Chemicals Alternatives Assessment Study*, June, 2006 (accessible at http://www.turi.org/industry/alternatives_research/five_chemicals_study).
- *An Overview of Alternatives to Tetrabromobisphenol A (TBBPA) and Hexabromocyclododecane (HBCD)*, Gregory Morose, March, 2006 (accessible at http://sustainableproduction.org/downloads/AternativestoTBBPAandHBCD.pdf)
- *Washington State Polybrominated Diphenyl Ether (PBDE) Chemical Action Plan:* Final Plan, Washington Department of Ecology and Department of Health, January 2006 (accessible at http://www.ecy.wa.gov/pubs/0507048.pdf).
- *Decabromodiphenylether: An Investigation of Non-Halogen Substitutes in Electronic Enclosure and Textile Applications*, prepared by Pure Strategies for the Lowell Center for Sustainable Production, April, 2005 (accessible at http://sustainableproduction.org/downloads/DecaBDESubstitutesFinal4-15-05.pdf).
- *An Investigation of Alternatives to Miniature Batteries Containing Mercury*, Catherine Galligan and Gregory Morose, prepared for the Maine Department of Environmental Protection. December 2004 (accessible at http://sustainableproduction.org/downloads/MaineDEPButtonBatteryReportFinal12-17-04.pdf).
- *An Investigation of Alternatives to Mercury-Containing Products*, Catherine Galligan, Greg Morose, and Jim Giordani, prepared for the Maine Department of Environmental Protection. January 2003 (accessible at http://sustainableproduction.org/downloads/An+Investigation+Hg.pdf).
- *Washington State Mercury CAP*, Washington Department of Ecology and Department of Health, January 2003 (accessible at http://www.ecy.wa.gov/pubs/0303001.pdf).
- *The Use of Di-2-Ethylhexyl-Phthalate in PVC Medical Devices: Exposure, Toxicity and Alternatives* Joel Tickner, Lowell Center for Sustainable Production, 1999 (accessible at http://sustainableproduction.org/downloads/DEHP+Full+Text.pdf).
- Intergovernmental Forum on Chemical Safety - Substitution and Alternatives Case Studies, Examples and Tools (accessible at http://www.who.int/ifcs/documents/standingcommittee/substitution/en/index.html).

Existing Chemical Prioritization and Evaluation Programs

- *Washington State Chemical Action Plan (CAP) Program*, Washington Department of Ecology and Department of Health, http://www.ecy.wa.gov/programs/swfa/pbt/caps.html, including for

example the Lead CAP, September 2009 (accessible at http://www.ecy.wa.gov/pubs/0907008.pdf).

- *Children's Safe Products Act (CSPA) Report*, Washington Department of Ecology, July 2009 (accessible at http://www.ecy.wa.gov/pubs/0907014.pdf)
- Washington Department of Ecology CSPA chemical selection process, pilot rule process, comments and response to comments, accessible at http://www.ecy.wa.gov/programs/swfa/rules/ruleChildPilotPhase.html

General Guidance - additional resources providing guidance on the alternatives assessment process

- The Interstate Chemicals Clearinghouse (IC2) has created a dynamic wiki tool for states and other agencies to obtain guidance on the process of assessing safer alternatives (www.ic2saferalternatives.org)
- The EPA Design for Environment (DfE) program released "*Alternatives Assessment Criteria for Hazard Evaluation*", November 2010. This guidance goes through the step-by-step process that DfE is using in conducting alternatives assessments for chemicals as part of the EPA's Chemical Action Plans (accessible at http://epa.gov/dfe/alternatives_assessment_criteria_hazard_eval_nov2010_final_draft2.pdf).
- *Decision-Making under TURA: Process Overview and Reference Guide*, Toxics Use Reduction Institute Methods and Policy Report No. 28, 2010, University of Massachusetts Lowell (accessible at http://www.turi.org/library/turi_publications/decision_making_under_tura_process_overview_and_reference_guide_2010).
- Lowell Center for Sustainable Production alternatives assessment framework and other resources, accessible at http://www.chemicalspolicy.org/alternativesassessment.lowellcenter.php.
- *Alternatives Assessment for Toxics Use Reduction: A Survey of Methods and Tools*, Toxics Use Reduction Institute Methods and Policy Report No. 23, 2005, University of Massachusetts Lowell (accessible at http://www.turi.org/library/turi_publications/turi_methods_policy_reports/alternatives_assessment_for_toxics_use_reduction_2005)
- UNEP has recently proposed guidelines for social life cycle assessment. See: http://www.unep.fr/scp/publications/details.asp?id=DTI/1164/PA

Hazard Display Methods - methods for displaying data to facilitate decision making

- EPA's DfE process (www.epa.gov/dfe): The DfE program released "*Alternatives Assessment Criteria for Hazard Evaluation*" in November 2010. This guidance goes through the step-by-step process that DfE is using in conducting alternatives assessments for chemicals as part of the EPA's Chemical Action Plans (accessible at http://epa.gov/dfe/alternatives_assessment_criteria_hazard_eval_nov2010_final_draft2.pdf).
- Healthy Building Network Pharos Project - a tool to evaluate building materials (accessible at www.pharoslens.net).

- P2OASys - Pollution Prevention and Options Assessment System created and maintained by TURI (accessible at http://www.turi.org/home/hot_topics/cleaner_production/p2oasys_tool_to_compare_materials).

Screening Methods - tools for more quickly identifying preferable chemicals

- Clean Production Action's Green Screen for Safer Chemicals, which provides guidance for categorizing chemicals based on their inherent hazard to assist in identifying safer alternatives (accessible at http://www.cleanproduction.org/Greenscreen.php)
- EPA's Design for the Environment process - DfE Screens for Safer Chemicals Ingredients, which allows users to identify chemicals that have passed the DfE evaluation process. This database is accessible at http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm
- EPA launched ToxCast (accessible at http://www.epa.gov/ncct/toxcast/) in 2007 to develop ways to predict potential toxicity and to develop a cost-effective approach for prioritizing the thousands of chemicals that need toxicity testing.
- German Institute for Occupational Safety developed the Column Model to provide industry with a practical aid for the identification of possible substitutes (accessible at http://www.dguv.de/ifa/en/pra/spalte/index.jsp).
- Swedish KemI PRIO model (accessible at http://www.kemi.se/templates/PRIOEngpage____4160.aspx) - The criteria for the "PRIO substances" have been selected based on the Swedish Environmental Quality Objective for a Non-Toxic Environment (Government Bill 2000/01:652), and in consideration of the EU chemicals legislation REACH (Registration, Evaluation and Authorisation of Chemicals).

Databases - examples of sources of data to assist in making decisions

- Substitution Support Portal (accessible at http://www.subsport.eu/), an internet portal that is intended to be a resource on safer alternatives to the use of hazardous chemicals.
- ISTAS RISCTOX Database (in Spanish) - A database containing information about uses of substances, hazardous properties, and alternatives (accessible at http://www.istas.net/risctox/)
- TURI Laboratory CleanerSolutions database of cleaning products (accessible at http://www.cleanersolutions.org/) provides performance data on safer alternatives to substances used in various surface cleaning and preparation activities common to industrial and institutional applications.
- The IC2 is creating a priority chemical characteristic and use database that will allow users to: search for chemicals on one or more state lists, identify source lists for the chemicals, identify hazards and toxic characteristics associated with the chemicals, and link to additional resources that include information on the chemicals. This database is in the process of being created. More information about it can be found at http://www.newmoa.org/prevention/ic2/projects/
- Danish EPA Advisory List for Self-Classification of Dangerous Substances - includes over 20,500 substances that have been identified by Quantitative Structure-Activity Relationship (QSAR) models (accessible at

http://www.mst.dk/English/Chemicals/Substances_and_materials/Lists+of+substances/Selvklassificeringfarligstof.htm)

- OECD eChemPortal - The global portal to information on chemical substances developed by the Organization for Economic Cooperation and Development in 2008 provides free public access to information on properties of chemicals including physical/chemical properties, environmental fate and behavior, ecotoxicity and toxicity (accessible at http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en)

Published papers

- The Journal of Cleaner Production Special Issue, Volume 19, Issue 5 (March 2011), which can be accessed at http://www.turi.org/library/turi_publications/other_publications/turi_staff_publications/journal_of_cleaner_production_special_issue, contains several articles that discuss the use of the alternatives assessment process, including:
    - *Safer alternatives assessment: the Massachusetts process as a model for state governments*, Pamela Eliason, Gregory Morose, Toxics Use Reduction Institute, University of Massachusetts Lowell
    - *Applying the precautionary principle to consumer household cleaning product development*, Cara A.M. Bond (Seventh Generation)
    - *Selecting safer building products in practice*, Jennifer Atlee (GreenBuild)
    - *An abbreviated alternatives assessment process for product designers: a children's furniture manufacturing case study*, Kathryn H. Winnebeck (New York State Pollution Prevention Institute)
- Lavoie, E. T., L. G. Heine, et al. "*Chemical Alternatives Assessment: Enabling Substitution to Safer Chemicals*." Environmental Science & Technology 44(24): 9244-9249. Accessible at http://dx.doi.org/10.1021/es1015789
- *Chemical Alternatives Analysis: Methods, Models and Tools*, Revised Final Report to the Department of Toxic Substances Control, August 2010, Brandon Kuczenski, Roland Geyer, Bren School of Environmental Science and Management, University of California, Santa Barbara

Models

- PBT Profiler - developed by EPA to evaluate persistence, bioaccumulative and aquatic toxicity potential of organic substances, based on analog modeling (accessible at http://www.pbtprofiler.net/)
- EPA's AIM model is an online method that identifies closely related chemical structures that have experimental (measured) toxicological data in a specific set of publicly available databases (accessible at http://www.epa.gov/oppt/sf/tools/aim.htm)
- The Ecological Structure Activity Relationships (ECOSAR) Class Program is a computerized predictive system that estimates the aquatic toxicity of industrial chemicals. The program estimates a chemical's acute (short-term) toxicity and chronic (long-term or delayed) toxicity to aquatic organisms such as fish, aquatic invertebrates, and aquatic plants by using Structure

Activity Relationships (SARs). (accessible at http://www.epa.gov/oppt/newchems/tools/21ecosar.htm)

- EPA's OncoLogic™ model evaluates the likelihood that a chemical may cause cancer (accessible at http://www.epa.gov/oppt/sf/pubs/oncologic.htm)
- EPA's EPI Suite™ estimates physical / chemical properties (melting point, water solubility, etc.) and environmental fate properties (breakdown in water or air, etc.) which can indicate where a chemical will go in the environment and how long it will stay there (accessible at http://www.epa.gov/oppt/exposure/pubs/episuite.htm).

Sources for Scientific Literature on Chemicals

- Toxnet (accessible at http://toxnet.nlm.nih.gov/) is maintained by the National Library of Medicine, with access to databases on toxicology, hazardous chemicals, environmental health, and toxic releases.

On-going Alternatives Assessment Partnerships

- US EPA's Design for Environment Flame-Retardant Alternatives for DecaBDE Partnership, accessible at http://www.epa.gov/dfe/pubs/projects/decaBDE/index.htm
- US EPA's Design for Environment BPA Alternatives in Thermal Paper Partnership, accessible at http://www.epa.gov/dfe/pubs/projects/bpa/index.htm
- US EPA's Design for Environment Flame Retardants in Printed Circuit Board Partnership, accessible at http://www.epa.gov/dfe/pubs/projects/pcb/index.htm

Appendix C –Local initiative on alternatives assessment application – City of San Francisco

The presence of toxic chemicals in consumer products and manufacturing processes affects all cities and counties. Local governments are responsible for developing and maintaining costly waste water and solid waste management infrastructure in the hopes of preventing the contamination of natural ecosystems. In addition, County healthcare systems are increasingly burdened by the rising costs of diseases that likely are associated with environmental exposures to chemicals. Ultimately, a city's reliance on such end-of-pipe strategies is costly and inadequate to protect the public from modern chemical threats.

Until recently, local governments found little opportunity to prevent toxic chemicals from being used in production. San Francisco adopted a policy framework based on the Precautionary Principle that has allowed the City to reduce the presence of toxic chemicals in the chain of commerce by looking upstream to the design of products entering into its local borders. The Precautionary Principle Ordinance is explicit about the shared responsibility of citizens, business groups, and governments to make decisions that prevent harm before potentially irreversible damage is done. The mechanism described in the ordinance to achieve this outcome is that of alternatives assessment. Below are three examples of how the City utilized alternatives assessment to guide policy decisions.

Pesticides – As part of the adoption of an Integrated Pest Management (IPM) Ordinance, and in order to prevent a complete ban on the use of chemical pesticides on City property, the Board of Supervisors directed staff to evaluate all potential chemical pesticides used by City staff and create a list of "reduced risk" products that would be allowed for use under specified circumstances. Stakeholders included city gardeners and pest control operators, product manufacturers, IPM consultants, and nonprofit activist organizations. Information on hazard characteristics (criteria) were combined with cost, performance, and "level of community concern" to create the Reduced Risk List.

Results:

- Elimination of organophosphate pesticides and pesticides listed as surface water contaminants
- 81% reduction in pesticide use overall (lbs.)
- 65% reduction in use of most toxic products (active ingredients)
- 83% reduction in RoundUp (active ingredient)
- The list has tremendous community buy-in, is reviewed annually, and creates a means for continuous evaluation of safer alternatives as new information and products become available.

Pressure treated wood – Due to concerns over arsenic leaching out of play structures constructed with treated wood in City parks, the Board of Supervisors adopted an ordinance to prevent the use of arsenic treated wood in City construction projects. In preparing the language of the ordinance, staff performed an alternatives assessment to determine the availability of safer alternatives. Stakeholders included city carpenters, wood preservative manufacturers, trade associations, and nonprofit activist

organizations. Again, hazard-based criteria were combined with cost and performance information to determine the availability of safer alternatives.

Results:

- Alternatives were identified (CBA, ACQ) that did not contain arsenic (or similarly toxic chemicals) for most treated wood applications.
- The assessment found that arsenic-treated wood was the safer alternative for use in submerged marine environments (i.e. pier pilings). This is because arsenic prevents copper from leaching out of the wood and copper is of greatest concern for toxicity to marine organisms. Thus, a complete ban was not put in place and an exception was allowed for marine settings.

Professional Garment Cleaning - The California Air Resources Board has required dry cleaners in California to switch out their perchloroethylene (perc) based machines due to concerns over health effects and air quality. Many garment cleaning businesses are selecting hydrocarbon based solvents which meet the legal standard for an alternative to perc. San Francisco wished to identify the safest alternative technology for professional garment cleaning. Stakeholders included local garment cleaners, academic institutions, state environmental health officials, city regulatory agencies, and equipment manufacturers. An alternatives assessment was done that looked at hazard-based criteria, costs, performance, and regulatory requirements for each cleaning system.

Results:

- Creation of a color-coded summary of impacts of each technology that was translated into Korean and Chinese for use by local business owners as they make their equipment selection.
- Designation of Wet Cleaning as the “safest alternative” which was included in Green Business Program designations across California.
- $15,000 incentive for conversion of perc-based systems to Wet Cleaning.
- 9 Wet Cleaners are now established in San Francisco

Appendix D – State Initiatives to Prioritize and Act on Chemicals of Concern in Children's Products – Washington and Maine

Due to the large number of chemicals in commerce without adequate toxicity characterization data, coupled with a limited federal policy for chemical management in the United States, many states are grappling with the challenge of identifying toxic chemicals that may pose a risk to human health and the environment. Specific populations (e.g., children, elderly) are particularly sensitive to these toxic chemicals. In 2008, the Children's Safe Product Act (CSPA) was passed in Washington State and the Act to Protect Children's Health and the Environment from Toxics Chemicals in Toys and Children's Products was passed in Maine. Both laws included specific requirements to identify chemicals of concern in children's products. In addition, both Maine and Washington have conducted alternatives assessments of decabromodiphenyl ether (decaBDE). The two states' processes for chemical prioritization and action, described below, are relatively similar and agency staff were in regular contact during the implementation process.

Chemical prioritization:

Washington:

The CSPA required the Department of Ecology (Ecology) to identify High Priority Chemicals (HPCs) and Chemicals of High Concern to Children (CHCCs). To implement this legislation, a methodology was developed to identify HPCs from authoritative scientific and regulatory sources on the basis of toxicity criteria. Another set of chemicals of concern was then identified from authoritative sources, based on their potential exposure to children. CHCCs were defined as HPCs that also appear in biomonitoring studies (i.e., human tissues), or relevant exposure media (e.g., indoor air, house dust, drinking water, consumer products). The CHCCs were then subjected to a prioritization process, based on the strength and weight of evidence of toxicity and exposure data. Although the methodology was constrained by specific requirements in the CSPA, the intent of this work was to identify HPCs and CHCCs that might guide future regulatory actions and inform chemical management policies, aimed at protecting children's health.

Based upon this process, Washington identified 67 priority CHCCs and is in the process of establishing regulations and identifying reporting requirements for products that contain any of these 67 chemicals. Once completed, products manufactured or sold within Washington State that contain any of the 67 CHCCs must be reported to Ecology. This reporting requirement will be phased in beginning in 2012 and will start with the largest companies first.

In 2010, Ecology submitted amendments to the CSPA that would give Ecology the authority to require alternative assessments for those products containing CHCCs. As part of the proposed amendments, businesses would be required to conduct an alternatives assessment to evaluate whether viable alternatives to the CHCCs exist and can be used in the children's products. In addition Ecology, in consultation with other state and federal agencies and interested parties such as businesses and the environmental community, would develop guidance on alternative assessment requirements to assist in this process. This Legislature did not approve Ecology's request; however, Ecology is considering

continuing with the alternative assessment process and has applied for money from the US EPA to conduct a stakeholder process to identify necessary components in an alternatives assessment.

Maine:

Maine's 2008 legislation required the Department of Environmental Protection (DEP) to identify chemicals of high concern based upon authoritative lists and specific sources of toxicity related information. The sources identified were similar to those used by Washington State. In June 2009, Maine published its chemicals of high concern list[i]. In December 2010, DEP identified two priority chemicals, bisphenol A and the chemical class nonylphenols. As is the case with the Washington State legislation, any children's products containing either of the priority chemicals must be reported to the DEP. Maine's legislation gives DEP the authority to prohibit the use of any product containing a priority chemical if it determines a safer alternative exists and includes guidance on what constitutes a safer alternative.

Alternative Assessments:

Washington:

In 2007, the Washington State Legislature passed a ban on certain classes of polybrominated diphenyl ether flame retardants including decaBDE. A ban on decaBDE in certain applications would only take effect if, after conducting an alternatives assessment, Ecology determined a viable alternative existed while still maintaining fire safety. Ecology published its alternatives assessment report in December 2008 which indicated a safer alternative to decaBDE existed. The ban on decaBDE took effect in Washington State on January 1, 2011. While conducting the alternatives assessment, Ecology found that these assessments are complicated and required a wide range of technical expertise including chemists, toxicologists, manufacturing engineers, economists, etc. In addition, given the resources available, Ecology had to depend primarily upon technical studies done by other, authoritative organizations. Ecology learned that, within these constraints, alternative assessments are possible and that it is a technique which provides immediate benefits to human health and the environment by removing toxic chemicals from the production process. By removing toxic chemicals as inputs into products, considerable time and resources are saved by not having to deal with toxic chemicals which are released into the environment and can pose long-term cleanup problems. Source removal is the most cost effective manner for dealing with costs associated with toxic chemicals and alternative assessments are a strong tool which assists in this process.

Maine:

In January 2007, Maine's DEP and Center for Disease Control & Prevention (Maine CDC), released their Third Annual Report to the Maine Legislature on Brominated Flame Retardants. In the report, DEP and Maine CDC recommended that decaBDE be banned in certain applications. They indicated that safer alternatives to decaBDE exist and provided technical evidence to support their conclusions. The report was able to reach this conclusion because one author is a nationally recognized expert on brominated flame retardants and, therefore, was familiar with decaBDE and potential alternatives.

In September 2007, the Maine Legislature passed An Act to Protect Pregnant Women and Children from Toxic Chemicals Released into the Home banning the use of decaBDE in the recommended applications. The last restriction came into effect on January 1, 2010. The basis for this decision was the alternatives assessment conducted by DEP and the Maine CDC, proving the importance alternative assessments have upon subsequent policy decisions.

Appendix E - State Experience in Assessing and Implementing Alternatives - Massachusetts Toxics Use Reduction Program

The Massachusetts Toxics Use Reduction Act, enacted in 1989, targets toxics use and waste generation at the source—the industrial and manufacturing processes that generate it. This strategy affords better protection for the public and workers because it can prevent waste from being generated in the first place. Since the inception of this act companies in Massachusetts have reduced their use of toxics by over 40% and reduced emissions to the environment by over 90%. The key to the success of this program is the requirement for affected companies to a conduct good faith evaluation of the reasons for using the toxic chemicals in the first place. Toxics Use Reduction (TUR) planning includes mapping the processes associated with the use of the toxic chemical, and investigating the potential to, among other things, modify the process or product, or find alternatives to the toxic chemicals of concern. As part of this planning process, certified professionals help companies assess whether identified options are technically and economically feasible.

The success of Massachusetts in reducing its overall use and emissions of toxic chemicals is due in large part to the active participation and adoption of alternatives by the companies affected by this Act (i.e., companies using over reporting threshold amounts of the over 600 listed toxic chemicals). One of the ways the Massachusetts TUR Program supports these companies' successes is by providing onsite technical assistance to identify options and evaluate their effectiveness. Specifically, the Office of Technical Assistance provides confidential onsite guidance on TUR opportunities at the request of companies looking for safer alternatives to their current practices. In addition, the Toxics Use Reduction Institute (TURI) maintains a laboratory which provides free identification of potential safer alternatives to common cleaning and surface preparation solutions used by various industries, and performance testing of those alternatives to enhance the ability of companies to find feasible safer alternatives they can adopt. TURI also connects academic researchers with the more difficult TUR challenges faced by companies to research and develop safer chemicals and materials for specific applications. Finally, TURI provides ongoing training and education to the TUR planners, including opportunities for peer training and networking, to ensure that these professionals are able to provide effective and innovative options for specific challenges faced by companies.

The basic TUR planning steps constitute the main thrust of the alternatives assessment approach taken by the TURI. Specifically, in July 2005, the Massachusetts Legislature requested that TURI perform an alternatives assessment for five chemicals of concern identified by a coalition of public health, labor and environment advocacy groups. The chosen chemicals included lead, formaldehyde, perchloroethylene, hexavalent chromium, and di(2-ethylhexyl) phthalate. For each chemical, TURI was charged with identifying significant uses in manufacturing, consumer products, and other applications; reviewing health and environmental effects; and evaluating possible alternatives.

TURI developed a methodology for assessing alternatives to these five chemicals that allowed it to quickly determine priority uses and alternatives to assess and to research the pertinent decision criteria, which included performance, technical, financial environmental and human health parameters.

The Institute conducted its research in a phased manner. Phase I focused on understanding the concerns associated with the chemicals being studied, including profiling the inherent hazards associated with the chemical of concern and identifying its functional uses. In Phase II, TURI identified and prioritized possible chemical, material and process alternatives for the specific applications of the chemicals of concern being investigated.

This phase included pre-screening possible chemical alternatives based on a subset of minimum criteria. In this Phase of the study TURI focused its assessments on the most feasible alternatives for each specific priority use, by conducting a high level evaluation of the potential for alternatives to be adopted. Factors considered included:

- Performance criteria specific to the use of the chemical,
- Availability of the alternative,
- Location of the manufacture of the alternative,
- Current and potential future costs of the alternative,
- Known environmental, health and safety risks or benefits as compared to that of the chemical of concern, and
- Information about pending or existing global restrictions that might materially affect the ability of an industry to market its products internationally was considered.

The final phase of the study was the assessment of the potential alternatives being considered. As with the TUR planning process, TURI not only evaluated alternatives that were possible chemical substitutes, but also considered product reformulations using different materials (for example, use of non-rigid polymers that preclude the need for phthalate plasticizers) and process alternatives (for example, changing the upstream process that currently requires vapor degreasing to use lubricants that either don't require cleaning, or are easier to remove using water-based surfactants).

In Phase III, TURI focused its assessment on a broader range of chemical hazard criteria, and also incorporated a more rigorous evaluation of technical and economic feasibility of potential alternatives. In addition, where appropriate, life cycle considerations were incorporated into the assessment in a qualitative manner. TURI analyzed a total of sixteen different use categories and approximately one hundred different alternatives in this study.

The active involvement of stakeholders was key to the success of this project. The involvement of a wide range of stakeholders throughout the project resulted in a more accurate assessment, more valuable results, and increased understanding of the issues, challenges and perspectives among stakeholders. Stakeholder contributions to this project also revealed in detail the substantial investment companies have made in developing safer products.

Appendix F - Interstate Collaboration on Chemical Prevention – the Interstate Chemicals Clearinghouse Safer Alternatives Wiki

State representatives gathered in 2008 in Lowell Massachusetts to discuss the need for shared resources and a common language with respect to assessing the availability of safer alternatives for chemicals of concern. This group decided to work collaboratively to create a protocol for conducting alternatives assessments. The intent was to create a flexible and adaptive set of steps that form the shared understanding of what constitutes a safer alternative to a chemical of concern. The goal was not to dictate precisely how to conduct the assessment, but rather to lay out basic steps generally agreed upon at that meeting, and to provide a set of resources to draw from when a unique alternatives assessment is performed.

This work was adopted by the Interstate Clearinghouse on Chemicals (IC2) – an association of state, and local governments that promotes a clean environment, healthy communities, and a vital economy through the development and use of safer chemicals and products. The goals of the IC2 are to:

1. Avoid duplication and enhance efficiency and effectiveness of state, local, and tribal initiatives on chemicals through collaboration and coordination;
2. Build agency capacity to identify and promote safer chemicals and products;
3. Ensure that state, local, and tribal agencies, businesses, and the public have ready access to high quality and authoritative chemicals data, information, and assessment methods.

In particular, the IC2 supports agencies in their development and implementation of programs to promote the use of safer chemicals. The work of the IC2 to create a common understanding and protocol of the alternatives assessment process can be viewed at the IC2 Safer Alternatives wiki: www.ic2saferalternatives.org. Figure 4 illustrates the overall alternatives assessment protocol developed by the IC2.

Figure 2 - IC2 Safer Alternatives Assessment process

Appendix G – Federal Effort to Promote Informed Substitution - EPA Design for the Environment Program

EPA's Design for the Environment (DfE) Program works in partnership with industry, environmental groups, and academia to reduce risk to people and the environment by promoting informed substitution through its Safer Product Labeling and Alternatives Assessment programs. The drivers for DfE programs are two-fold: to create incentives for the development and application of inherently safer chemicals (e.g., promote green chemistry) and to reduce the use of chemicals that may pose a hazard to human health and/or the environment. For more than 15 years, through partnership projects, DfE has evaluated human health and environmental concerns associated with traditional and alternative chemicals and processes in a range of industries. These analyses have empowered hundreds of businesses to select safer chemicals and technologies. DfE focuses on industries that combine the potential for chemical risk reduction with a strong motivation to make lasting, positive changes.

DfE's Alternatives Assessment Program helps stakeholders identify safer alternatives to chemicals of national interest, such as EPA priority chemicals[ii]. The alternatives assessments provide a basis for informed decision making by developing an in-depth comparison of potential human health and environmental impacts.

Alternatives Assessment Partnerships bring together EPA scientists, environmental organizations, industry leaders, academia, and others to evaluate the environmental and health impacts of potential alternatives to priority chemicals. DfE alternatives assessments are designed to characterize chemical hazards based on a full range of human health and environmental information. A recent publication in Environmental Science and Technology (Lavoie, Heine et al) explains the approach. DfE has also developed draft criteria - Alternatives Assessment Criteria for Hazard Evaluation - that describe in detail our approach to evaluating human health and environmental impacts.

Specifically, for each chemical evaluated, DfE compiles a dossier summarizing all available test data – public and confidential. Each chemical is evaluated for the level of the following endpoints:

- Acute mammalian toxicity
- Carcinogenicity
- Mutagenicity/genotoxicity
- Neurotoxicity
- Repeated dose toxicity
- Sensitization
- Irritation/corrosivity
- Endocrine activity
- Aquatic toxicity
- Environmental persistence
- Bioaccumulation

In addition DfE scrutinizes potential metabolites and breakdown products, and considers data on environmental and human exposures. For most of these endpoints, a determination is made as to the level of hazard: “High”, “Moderate”, or “Low”. For chemicals without adequate data, EPA experts evaluate the potential hazards based on chemical structure and the comparison to appropriate analogs. For some endpoints, such as aquatic toxicity, persistence and bioaccumulation, models can be particularly helpful.

The outcome of an Alternatives Assessments Partnership is a report that summarizes the results of the evaluation of each alternative, so that profiles can be compared. The report provides stakeholders with the information they need to choose safer chemicals, as well as avoid unintended consequences of switching to a poorly understood substitute.

The DfE Safer Product Labeling Program uses EPA's chemical expertise and resources to carefully evaluate products and to label only those that have met the program's protective standards. Design for the Environment labels a variety of chemical-based products, like all-purpose cleaners, laundry detergents, and carpet and floor care products.

Before a product is approved for use of the DfE logo, every chemical in the product is evaluated against DfE's Standard for Safer Cleaning Products. According to the Standard, each ingredient in a formulation is evaluated based on its "functional class." A comparison of the hazard profiles of each alternative within the functional class helps identify the chemicals that are on the safer end of the human health and environmental hazard spectrum. The methodology used is similar to that used in the alternatives assessment program, although the evaluation of chemicals varies based on functional use class. This approach, which uses many of the same methods developed for the alternatives assessment program, allows us to identify and promote the selection of those ingredients with the lowest hazard, while retaining product performance.

The presence of data gaps remains a significant challenge for both the Safer Product Labeling and Alternatives Assessment programs. Evaluating chemicals that lack data can be more costly and time-consuming, as it requires the engagement of additional expertise within EPA. It can also be a challenge to identify potential alternatives because of trade secret concerns and limited information on technical viability. Another important challenge is the lack of safer chemistries for some chemical use categories, indicating that there may be a need for green chemistry challenges.

As the Agency identifies priority chemicals for action, DfE Alternatives Assessments will be among the tools considered for risk management. EPA will choose DfE tools such as Alternatives Assessment where they have significant potential to advance green chemistry and safer product design through stakeholder partnerships. The Agency encourages multi-agency collaboration and coordination to advance the science and policy of alternatives assessment.

Appendix H - Protecting Workers through Safe Workplaces – NIOSH Prevention through Design Program

One of the best ways to prevent occupational injuries, illnesses, and fatalities is to eliminate hazards and minimize risks early in the design or re-design process and incorporate methods of safe design into all phases of hazard and risk mitigation. Although a long history of designing for safety for the general public exists in the U.S., less attention has gone to factoring the safety, health and well-being of workers into the design, re-design and retrofit of new and existing workplaces, tools and equipment, and work processes. The National Institute for Occupational Safety and Health (NIOSH) currently leads a nationwide initiative called Prevention through Design (PtD). PtD addresses occupational safety and health needs by eliminating hazards and minimizing risks to workers *throughout the life cycle* of work premises, tools, equipment, machinery, substances, and work processes including their construction, manufacture, use, maintenance, and ultimate disposal or re-use.

PtD activities are centered on four overarching areas of research, education, practice and policy. NIOSH published the PtD Plan for the National Initiative in December 2010. Research focuses on design factors that effectively reduce occupational morbidity, mortality and injury; metrics that assess the impact of these design factors; methods that diffuse effective designs; and economic and business issues including financial analysis of the impact of Prevention through Design on the business process. PtD research is also investigating the financial and business value of health and safety design interventions. A major hurdle to the adoption of PtD is the perception that the cost/benefit ratio is unfavorable. This void may prevent business executives from making informed decisions about the benefits of applying PtD principles to their workplace planning and purchasing actions.

Education focuses on motivating and equipping professional communities to continually increase their knowledge of design features that have a positive impact on worker safety and health. Acquisition of PtD knowledge and skills will occur through enhanced design and engineering curricula as well as through improved professional accreditation programs that value PtD issues and include them in their competency assessments. An important step in the widespread implementation of Prevention through Design (PtD) is to introduce PtD requirements into the civil engineering program criteria approved by the Accreditation Board for Engineering and Technology (ABET).

Practice focuses on identifying and sharing successful procedures, processes, equipment, tools and results through on-line databases and other media. Practice also includes demonstrating the value of including workers' health and safety in design decisions and exploring links with the movements toward green and sustainable design. For worker health and safety, sustainable design enhances indoor environmental quality and optimizes operational and maintenance practices. PtD is developing a systems-based approach for including PtD in capital projects. This activity addresses the need to develop a framework and methodology for use by H&S professionals, engineers and operations managers as they participate in new process, equipment and facility reviews.

Practice also includes the development of processes and tools to evaluate the health, environment and safety hazards of chemical agents and products in the workplace and either eliminate or substitute

those that can be hazardous to workers while minimizing exposure risks to the remaining hazardous agents. A significant barrier to the implementation of "Prevention through Design" (PtD) to minimize exposure risks to chemical agents is the lack of occupational exposure limits (PELs, RELs, TLVs, WEELs, etc.) for the vast majority of chemicals in commerce. Health hazard banding, i.e., the process through which the hazards of a material are collected, evaluated in terms of potential adverse effects from occupational exposure routes, and communicated in terms of health hazard band ranges, offers possibilities for addressing all of the rate limiters for OEL development. A hazard banding approach may be the most appropriate way to define OELs for families of materials where the data or resources are too limited to allow for a comprehensive and conclusive assessment of risk.

Health hazard banding has additional benefits when supplementing the formal OEL-setting process since it can provide a screening and summary tool for depicting existing data for a material that can increase the rigor, consistency and transparency of the data analysis and rationale. It highlights areas where data are missing. It also provides guidance for materials for which there are not yet sufficient data to develop a formal guideline value. Finally, health hazard banding is a logical approach for initiating Control Banding (i.e., linking to control-focused solutions). PtD has developed an intramural and extramural team of experts to develop the process, tools, and algorithms for implementing a hazard banding approach at NIOSH and at companies. OSHA is interested in hazard banding to supplement the PEL development process. And AIHA has approached NIOSH about a partnership to develop an ANSI standard.

Policy focuses on creating demand for safe designs for workers and incorporating these safety and health considerations into guidance, regulations, recommendations, operating procedures, and standards. Management systems and consensus standards are important factors in driving industry behavior. Significant progress has been made in including PtD into standards.

Endnotes

[i] Accessible at http://www.maine.gov/dep/oc/safechem/highconcern/

[ii] Accessible at http://www.epa.gov/opptintr/existingchemicals/pubs/ecactionpln.html

Attachment 1-4

"Alternatives Assessment Framework"

(Lowell Center for Sustainable Production, July 2006)

Version 1.0 | July 2006

Alternatives Assessment Framework

of the Lowell Center for Sustainable Production

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This paper was produced by the Lowell Center's Chemicals Policy Initiative, whose objectives are to significantly advance policy dialogue on reforming chemicals policy in the United States; assist in the development of sustainable chemicals management outside the US; encourage the development and use of safer alternatives by creating and promoting a comprehensive framework for alternatives assessment; and identify tools and appropriate ways of assisting green chemistry innovation and safer supply chain management of chemicals .

Glossary of Terms

Chemical	Any "element, chemical compound or mixture of elements and/or compounds."[2] A chemical "mixture," also known as a chemical "preparation," includes multiple chemicals.
Hazard	"Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent."[3]
Material	The "basic matter (as metal, wood, plastic, fiber) from which the whole or the greater part of something physical (as a machine, tool, building, fabric) is made."[4] Human-made materials like petroleum-based plastics are synthesized from specific chemicals.
Material economy	The physical matter upon which we base our lives.
Product	Something "produced by physical labor or intellectual effort."[5] Products made from physical matter (as opposed to intellectual products) are made of chemicals and/or materials. The terms "products" and "articles" are often used interchangeably.
Risk	"The probability of an adverse effect in an organism, system or (sub) population caused under specified circumstances by exposure to an agent."[6]
Safer Alternative	An option, including the option of not doing something, that is healthier for humans and the environment than the existing means for meeting that need. For example, safer alternatives to the use of a hazardous chemicals include: replacing the chemical with an inherently less hazardous chemical; eliminating the need for the chemical through material change, product re-design, or product replacement; or eliminating the chemical by altering the functional demands for the product through changes in consumer demand, workplace organization, or product use.

Preface

To create an economy that sustains life, we need to develop a materials economy that protects ecosystems and human health. We need products made from non-toxic materials that are biodegradable, materials that can be closed loop recycled, and production processes powered by renewable energy. We need material systems that sustain life, where the outputs from extracting or growing raw materials, manufacturing chemicals and materials, and manufacturing products are ultimately benign inputs into ecological cycles. Reconfiguring our material economy will require changes in the design of chemicals, materials, products (including services), and economic systems (e.g., transportation systems, building systems, production systems, etc.) and changes in our culture.

If we want to transition our current economic and materials systems towards a more sustainable economy, we need to learn how to make decisions that move us towards more sustainable materials. How do we distinguish and define the specific properties of safer and cleaner, and, ultimately, truly sustainable products and services? How do we know whether one alternative chemical, material, or product is superior from an environment, health and safety perspective from another?

The Lowell Center for Sustainable Production Alternatives Assessment Framework represents a small, first step towards creating an approach that allows us to answer these questions. In recent years, various research projects have been undertaken to develop frameworks, approaches, and tools for assessment of substitutes at the chemical, material, and product levels. However, no consistent framework or methodology has been developed and widely adopted that guides the process of alternatives assessment. This is a problem because many governments and firms, even when they want to move towards safer materials, often lack tools or guidance on how and what they should look at in assessing alternatives – the process of alternatives assessment.

We do not see this framework as a static process but rather one that is continuously being revised and updated. We look forward to engaging with others on how to make alternatives assessment a robust yet practical framework for evaluating and identifying safer chemicals, materials, and products.

"Can one distinguish and define the specific properties of a technics directed toward the service of life: properties that distinguish it morally, socially, politically, esthetically from the cruder forms that preceded it? Let us make the attempt."

LEWIS MUMFORD,
TECHNICS AND CIVILIZATION, 1934

Alternatives Assessment Framework

INTRODUCTION

The Lowell Center for Sustainable Production has developed the Alternatives Assessment Framework with the goal of:

> **Creating an open source framework for the relatively quick assessment of safer and more socially just alternatives to chemicals, materials, and products of concern. "Open source" means the collaborative development, sharing, and growth of methods, tools, and databases that facilitate decision making. "Relatively quick assessment" means that the process results in robust decisions informed by the best available science, while avoiding paralysis by analysis.**

Safer alternatives are options that are healthier for humans and the environment than the existing means of meeting needs, including the option of not undertaking an activity. For example, safer alternatives to the use of a hazardous chemical include replacing the chemical with an inherently less hazardous chemical; eliminating the need for the chemical through material change, product re-design, or product replacement; or eliminating the chemical by altering the functional demands for the product through changes in consumer demand, workplace organization or product use.[7]

Why Alternatives Assessment?[8]

The vast majority of environmental science has focused on understanding and characterizing environmental and public health problems. Millions of dollars are invested annually in investigating issues ranging from the mechanism of action of a small number of toxic compounds and the fate and transport of substances in environmental media to the effects of contaminants on environmental resources and the technologies for measuring, monitoring, and managing those pollutants. While much of this work is important and valuable, the focus on problems is often at the expense of investigations that focus on solutions. To define problems without a comparable effort at finding solutions greatly diminishes the value of environmental science.

Given the many gaps in scientific knowledge and the many uncertainties surrounding environmental risks and the reality that risk assessments are slow, resource intensive, and result in attention to only a small universe of risks, alternatives assessment provides an efficient and effective route to positive solutions. An alternatives assessment approach offers several direct benefits for environmental policy including:[9]

Focusing on solutions rather than problems. The most important aspect of alternatives assessment is that it reorients environmental protection discussions from problems to solutions. For example, chlorinated solvents provide a service of degreasing and cleaning. Once we understand this service, it is possible to think of a range of alternatives, such as ultrasonic cleaning or less toxic aqueous cleaners or even redesigning a metal part so that the need for cleaning is eliminated altogether.

Stimulating innovation and prevention. Alternatives assessment processes can lead to innovation and produce substantial cost savings for firms as well as health and environmental benefits for society. Alternatives assessment calls attention to current and "on-the-horizon" alternatives. Resources that might otherwise be directed solely to the expensive and time-consuming process of characterizing problems can then focus on solutions.

Multi-risk reduction. Alternatives assessment can be a more efficient means of reducing multiple risks in the long term. Problem-based approaches generally examine one risk or problem at a time and are met with one solution at a time. These solutions are often inflexible (e.g., pollution control equipment) and require successive investments of technology to meet each new problem and standard. Alternatives assessments can examine a broader range of factors and options. For example, a traditional risk-based approach might narrowly examine the risks of a particular agricultural pesticide while an alternatives assessment would examine the availability of safer pesticides, alternatives to pesticides altogether (organic agriculture), or alternative structures such as smaller farms that might reduce dependence on pesticides. In a specific firm, an alternatives assessment might examine technology options that would benefit both worker and environmental health or ways to reduce toxic substance, energy, and water use simultaneously.

Alternatives assessment forms an essential component of a necessary shift from primarily problem-based environmental policy to solutions-based policy. We define solutions-based policy as holistic, integrated policy designed to prevent risks at their source, avoid risk shifting, establish far-reaching, long-term environmental goals, and stimulate innovation in safer and cleaner forms of production, products, and activities. We will only reach the goal of sustainable production and consumption if we change our environmental protection focus from figuring out how bad the situation will be to seeking alternatives to problematic activities and designing the conditions for a more sustainable future.

To achieve this shift in focus towards safer alternatives and solutions, government agencies, companies, and other stakeholders need tools and approaches to guide the development, assessment, and comparison of options. The Lowell Center Alternatives Assessment Framework provides a guide for conducting alternatives assessments. The Framework establishes the fundamental processes in any alternatives assessment but the actual tools and criteria for doing the assessment

will vary across chemicals, materials, and products. Flexible yet robust methods of assessing alternatives are critical if we are to move beyond analysis to action.

The Lowell Center Alternatives Assessment Framework

The Lowell Center Alternatives Assessment Framework is designed to evaluate and identify environmentally[10] and socially preferable alternatives. "Alternatives" encompass production processes, chemicals, materials, products,[11] economic systems (such as transportation systems), and functions, as well as eliminating the need for a current activity or the function of a product. The Lowell Center Alternatives Assessment Framework consists of three core elements:

1. Alternatives Assessment **Foundation**
2. Alternatives Assessment **Processes**
3. Alternatives Assessment **Evaluation Modules**

We believe that any comprehensive alternatives assessment must include each of these core elements. Figure 1 illustrates the core elements of the Framework and how they overlap.

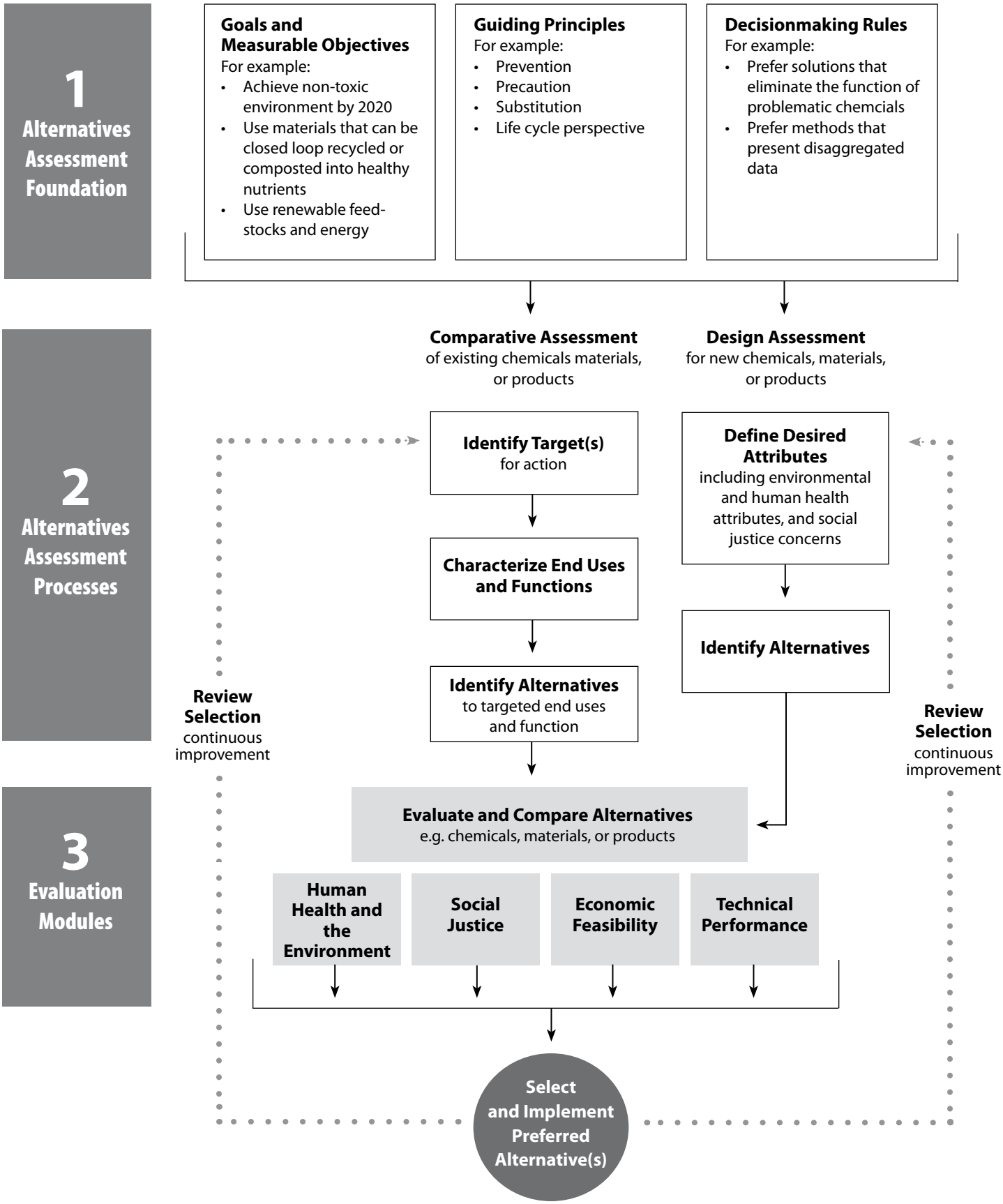
At the base of the Framework is the **Foundation**, where values are made explicit by clearly articulating the Principles, Goals, and Rules that guide decisions made during the assessment of alternatives. At the center of the Framework is the **Assessment Processes**—the methods, tools, and criteria used to evaluate which chemicals, materials, or products are safer and socially preferable. The Comparative Assessment Process and the Design Assessment Process are two separate yet overlapping tracks, depending on whether the subject of evaluation is an existing product or a product under development. Necessary to the Assessment Process are the **Evaluation Modules**, which evaluate the economic feasibility, technical performance, human health and environment impacts, and social justice impacts of alternatives.

These Evaluation Modules consist of methods, tools, and databases that facilitate relatively quick yet scientifically robust decisions. The modules are open source in that they are transparent and publicly available for the development, improvement, and/or use of all potential users. The Lowell Center envisions the Alternatives Assessment Framework as supporting the open and dynamic development of goals, methods, tools, and databases that lead to environmentally and socially preferable products, materials, and chemicals.

Defining the Terrain of Chemicals, Materials, and Products[12]

Throughout the Alternatives Assessment Framework we use the terms, "chemicals," "materials," and "products" as core areas of alternatives assessment work. As physical matter in our economy, chemicals, materials, and products are interrelated (for definitions of these terms see Glossary). Typical solid consumer products, such as the chairs we sit upon, are manufactured from materials, which in turn are constituted from chemicals. However, in other cases, chemical manufacturing processes generate chemicals as products.[13] Thus, products consist of materials and/or chemicals, materials consist of chemicals, and chemicals are constituents of materials or products. Figure 2 below illustrates the nested relationships between these types of matter.

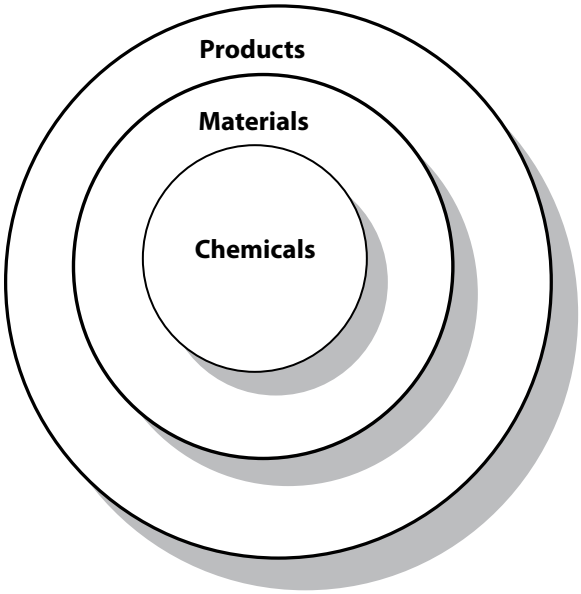
Figure 1 **Alternatives Framework: Detailed Summary**



Most products have this nested relationship. Consider carpet tiles as an example. Carpet tiles are made from a combination of backing and face materials. The face material is typically a nylon, either nylon 6 or nylon 6,6. Common backing materials include polypropylene, styrene butadiene rubber (SBR) and polyvinyl chloride (PVC). Nylon 6 is made from the chemical caprolactum; SBR is made from a mixture of chemicals styrene and butadiene, and the material natural rubber; polypropylene is made from the chemical propylene; and PVC is made from the chemicals ethylene and chlorine.

The distinction between chemicals, materials, and products emerges as most significant when evaluating and selecting solutions. For example, a solution to the substitution of a chemical of concern in a product, such as pentabrominated diphenyl ether (pentaBDE) in the foam cushions of a chair may be another chemical, or it may be a different material (e.g. metal or wood) that does not require a flame retardant. Similarly, post-consumer recycling systems are primarily developed around the material constituents of products rather than the individual chemicals.

Figure 2 **Nested Relationship Among Chemicals, Materials, and Products**



ALTERNATIVES ASSESSMENT FOUNDATION

Values are inherent in any technology assessment or comparison—be it a production process, chemical, material, product, or service. Personal and social values enter into the design and use of all decision-making methods and tools. The question is not how to design out values but rather how to make them explicit. Thus, any comprehensive Framework must define the Guiding Principles that inform the analysis, the Goals that the analysis process is designed to achieve, and Decision Making-Rules (see Figure 3 for an overview of this foundation and examples of Principles, Goals, and Decision-Making Rules).

Guiding Principles

When developing and using methodologies for informing decisions, practitioners make decisions. They make assumptions; create formulas; choose which formula(s) to use; and create new formulas even when others exist. Embedded in these decisions are values. These value-based decisions are often grounded in guiding principles and decision-making rules.

Guiding Principles for making environmental choices are common. Sometimes they are profession specific. Notable examples include The 12 Principles of Green Chemistry and The 12 Principles of Green Engineering (see *www.ChemicalsPolicy.org/organizations.shtml*). In industrial hygiene there is the hierarchy of controls.[14] In waste management there is the hierarchy of waste management.[15]

Figure 3 **Alternatives Assesment Foundation**

Goals and Measurable Objectives
For example:
- Achieve non-toxic environment by 2020
- Use materials that can be closed loop recycled or composted into healthy nutrients
- Use renewable feed-stocks and energy

Guiding Principles
For example:
- Prevention
- Precaution
- Substitution
- Life cycle perspective

Decisionmaking Rules
For example:
- Prefer solutions that eliminate the function of problematic chemicals
- Prefer methods that present disaggregated data

Other times these principles are firm specific, driven by a particular firm's mission. In all cases, they provide the foundations of the analyses and implementation that follow.

The Guiding Principles that inform the Lowell Center's design and application of the Alternatives Assessment Framework are:

- **Prevention:** any change to a chemical, material, or product that reduces, avoids, or eliminates the use of hazardous substances or generation of hazardous byproducts across its life cycle, so as to reduce risks to the health of workers, consumers, or the environment, without shifting risks between workers, consumers, or parts of the environment.[16]

- **Precaution:** preventive action to reduce threats of harm to human health or the environment, even if the exact nature and magnitude of the harm are not fully understood.[17]

- **Substitution:** "the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organizational measures."[18]

- **Life cycle perspective:** broad consideration (qualitative or quantitative) of environmental, social and/or economic issues across the life cycle of a chemical, material, or product.[19]

- **Transparency.** Openness and explicitness regarding methods, tools, and data sources. Transparency requires:
  - Publicly available data, including full disclosure of chemicals and materials in products to the fullest extent possible.
  - Clearly stated methodological steps, scope of analysis, data sources, assumptions, value judgments, and comprehensive discussion of uncertainty factors and missing data.

- **Stakeholder Participation.** Appropriate involvement of stakeholders in defining goals, developing methods, and selecting tools for implementing alternatives assessment.

- **Open Source.** A decision-making framework that is open, flexible, and easily adapted to meet evolving needs. The scope of work that needs to be completed to create a comprehensive Alternatives Assessment Framework is larger than any one single effort.

- **Enhancing, not delaying, decisions.** Methods and tools that facilitate making relatively quick decisions based upon robust data. These should be solutions based, identifying and leading to options that stimulate innovation.

- **Continuous improvement.** Successful implementation through continuous improvement and planning. Alternatives decisions are not final. They are steps along the path to sustainability. This means "don't let the perfect be the enemy of the good."

- **Values matter.** Explicitness about values, including the methods developed, tools used, and how data are analyzed. Examples of value judgments that emerge in alternative assessments include:
  - whether to use conservative, most likely case or worst case assumptions in analyses.
  - whether to emphasize the hazards or the risks of chemicals.
  - whether to emphasize pollution prevention or pollution control measures to manage toxic chemicals.
  - long-term goals and steps necessary to achieve them.
  - threshold of harm needed to trigger action.
  - priority action areas.
  - whether to use aggregated or disaggregated data.
  - how to aggregate data.

Goals and Measurable Objectives

Organizations and institutions perform alternatives assessments for a reason. They may want to inform the choices they make regarding chemicals, materials, products, suppliers, or production processes or to support the superiority of existing products. Once goals are agreed upon, the appropriate methods and tools for achieving the goals become clearer.

The process for defining goals differs widely depending upon whether it is a government entity, business, or non-governmental organization that is defining the goals. The Guiding Principles section above identifies principles critical to how goals should be developed, including transparency and collaboration with diverse stakeholders.

Examples of clearly articulated goals include:

Sweden. In 1999 the Swedish Parliament adopted fifteen national environmental quality objectives, the majority of which are to be attained by the year 2020.[20] Among the objectives are:

- "A Non-Toxic Environment" "The environment must be free from man-made or extracted compounds and metals that represent a threat to human health or biological diversity"[21] and

- "Reduced Climate Impact," which calls for achieving the goals of the UN Framework Convention on Climate Change.[22]

Herman Miller. The office furniture maker Herman Miller has committed to using the cradle-to-cradle protocol[23] in the design of all future products. President and CEO Brian Walker has established a Design for Environment goal that by 2010, 50 percent of all sales of products must meet the cradle-to-cradle protocol goals of:

- eliminating very problematic materials.
- designing for disassembly.
- maximizing recycled content and recyclability.
- eliminating PVC plastic.

Ecology Center of Ann Arbor. In its report on sustainable plastics in the automotive sector, this environmental group defined environmentally sustainable plastics as:

- having no hazardous chemicals associated with the life cycle of the material.
- being capable of either a) closed-loop recycling (recycled into the same product) or b) degrading into healthy nutrients for the soil.
- being manufactured from renewable raw materials and energy (without the use of genetically modified organisms—GMOs).[24]

Setting goals often involves setting interim measurable objectives to achieve those goals. For example, Sweden set the following measurable objectives to achieve the goal of A Non-Toxic Environment:[25]

- "By 2010, data will be available on the properties of all deliberately manufactured or extracted chemical substances handled on the market."
- "By 2010, finished products will carry health and environmental information on any dangerous substances they contain."
- Phase-out substances of very high concern, including: carcinogens, mutagens, and reproductive toxicants by 2007; cadmium by 2010; and very persistent and very bioaccumulative organic substances by 2010.

In setting measurable objectives—or benchmarks—organizations define priorities for identifying safer alternatives. Metrics or indicators are critical to understanding whether certain options and activities move the organization towards its ultimate goals and provide a means of measuring progress.

Decision-making Rules

Decision-making rules are typically derived from the Guiding Principles and Goals and are implemented during the Assessment Processes and in the Evaluation Modules. Some decision-making rules will be universal across Assessment Processes, while others will be specific to certain cases. Examples of decision-making rules include:

- Treat all chemicals lacking data as if they were chemicals of moderately high concern.
- Prefer solutions that eliminate the function of a problematic chemical, material, or product.
- Prefer methods that present disaggregated data. Such methods would present data across evaluation categories or hazards in their actual value terms—rather than creating a single number to compare across options—allowing a more transparent evaluation of trade-offs between options.
- Accept hazard assessment data as sufficient for determining whether to avoid a chemical.
- Avoid alternatives that are the direct source of persistent, bioaccumulative toxics (PBTs) across their lifecycle.
- Brainstorm a wide range of alternatives based on a detailed understanding of the function or service that the chemical, material, or product provides, the need it fills, and how that function can be achieved in a sustainable manner. Such an analysis should consider not only those alternatives that are available but those that may be on the horizon.
- When data are not available on chemical hazards, use modeling results from structural activity relationships in the short term, paired with a commitment from stakeholders, including chemical manufacturers, to develop additional data in the longer term.

Each organization needs to develop decision rules that provide the foundation for first narrowing the range of alternatives to be compared and then evaluating those alternatives.

ALTERNATIVES ASSESSMENT PROCESSES

The Lowell Center's Alternatives Assessment Framework has been designed to assist both in the selection and in the design of chemicals and technologies. The process used to evaluate alternatives will vary depending upon whether the assessment begins as a comparison of existing alternatives— "the Comparative Assessment Process"—or begins from the design of a new technology—"the Design Assessment Process." Figure 4 illustrates the stages of these two alternatives assessment processes.

THE COMPARATIVE ASSESSMENT PROCESS

The Comparative Assessment Process involves six steps:

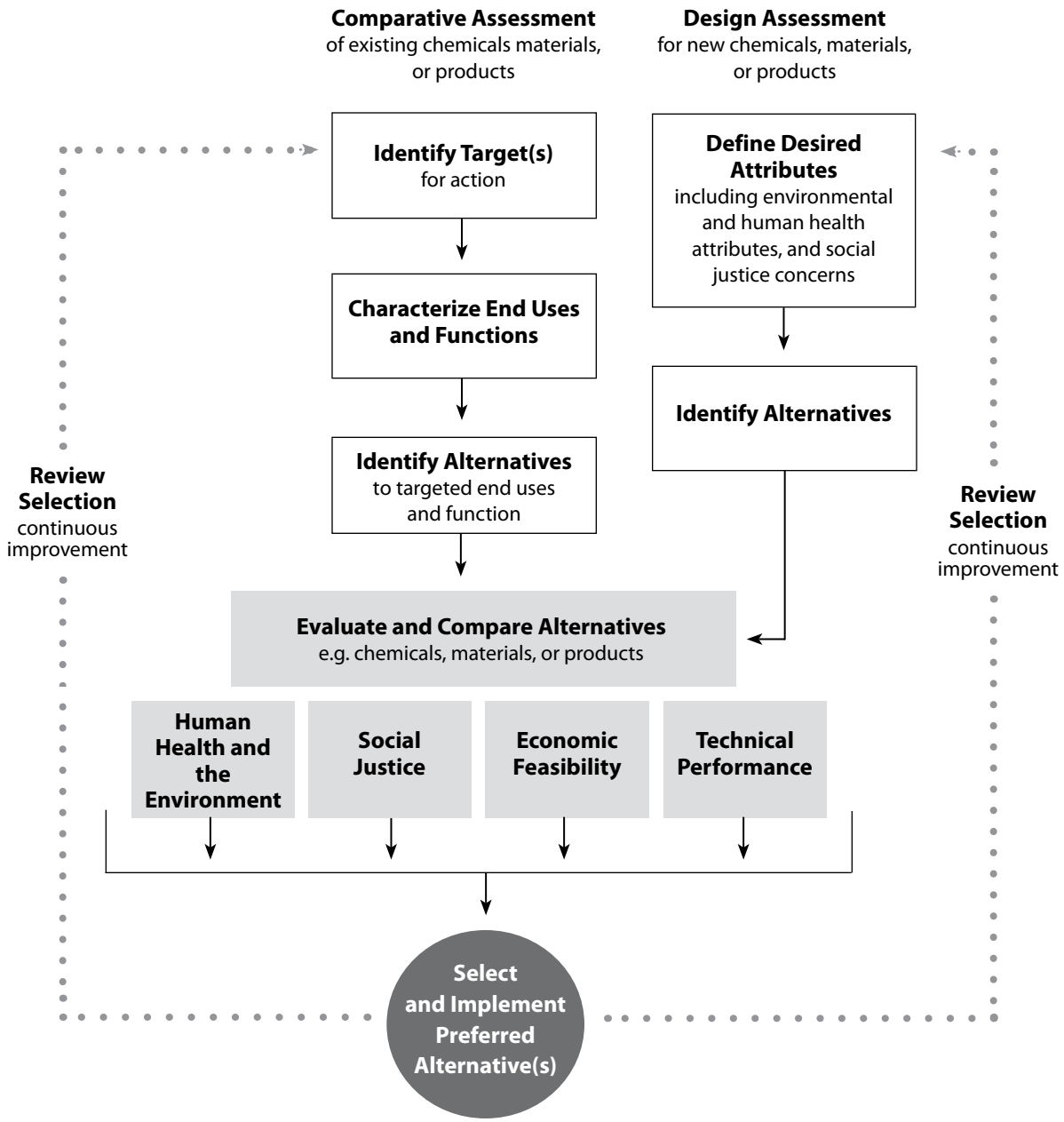
1) Identify Target(s) for Action
2) Characterize and Prioritize End Uses
3) Identify Alternatives
4) Evaluate and Compare Alternatives
5) Select Preferred Alternative(s)
6) Review Selection

The first step, **Identify Targets for Action**, can be a chemical, material, product, system, production process, or function. Of particular interest to the Lowell Center are assessments that begin with chemicals as targets for action—e.g., trichloroethylene—and then seek out safer alternatives that may include alternative chemistries, production processes, or product re-design. Chemicals

as initial targets for action are of particular interest because there is increasing professional and public interest in performing comparative assessments of alternatives to hazardous chemicals—especially persistent, bioaccumulative, and toxic chemicals.[26]

The second step is **Characterize and Prioritize End Uses and/or Functions** of the technology for assessment. Often a particular chemical or material may be used in many end uses. For example, the primary end use and function of di-2-ethylhexyl phthalate (DEHP) is as a plasticizer (softening

Figure 4 **Alternatives Assessment Processes**



agent) for polyvinyl chloride (PVC) plastic. In this stage the user should understand the function of the chemical and how it flows through a facility or product supply chain.

Because most analyses cannot address every end use, specific end uses of high interest need to be prioritized for assessment. While a chemical such as DEHP may have hundreds of end uses, a single or a small number of end uses may constitute up to 80 percent or more of the total chemical use. In the case of DEHP, plasticizer use in PVC accounts for 90 percent of its end uses.

The third step is **Identify Alternatives** to the priority end uses that are on the market or in development (also referred to as "on the horizon"). This may involve a broad market survey and literature review as well as interviews with appropriate experts who have a broad perspective. To achieve the greatest environmental and social improvement, it is important to view a wide range of alternatives. For instance, alternatives need to be considered that include: drop-in replacements, eliminating the function or need entirely, changing systems, and replacing products with services. Alternatives that are not yet readily available but may be available in the foreseeable future (or have technical or cost issues) should not be eliminated at this point.

The fourth step, **Evaluate and Compare Alternatives**, is the most complex and challenging part of the Alternatives Assessment Framework. The Framework is designed to encourage the selection and use of a series of different "evaluation modules" that can be used to compare alternatives. These include modules for evaluating and comparing human health and the environment impacts, social justice impacts, economic feasibility, and technical performance. These are described below in Section 3.

It is here that the creation of an open source system for filling in the necessary methods, tools, and databases is critical. In Figure 4, the "Evaluate and Compare Alternatives" box—as well as the specific evaluation factors below it—are shaded to emphasize that further module development needs to be done in each of these areas. Especially challenging is defining the criteria for comparing chemicals, materials, or products across multiple attributes (toxicity, biological degradation, eutrophication, global warming, etc.) and across lifecycles. Also challenging is the development of economic analysis tools that do not discourage longer term investments in safer materials by focusing primarily on short-term costs.

In the fifth step, the decision maker will **Select Preferred Alternative(s)**. The preferred solution may be a single technology or there may be multiple acceptable technologies. For example, there may be many preferred options to the use of DEHP as a plasticizer in PVC plastics.

In selecting the preferred alternative, decision makers often need to prioritize among attributes. This is because there are few cases when an alternative is superior for all attributes: technical, social, economic, and environmental performance.

There is no generally agreed on way to compare technical, health and safety, and economic trade-offs. However, companies and public institutions use a variety of approaches to integrate environmental and/or social performance attributes into their selection of chemicals, materials,

and products. Most large organizations have established procedures for comparing products based on economic and technical performance. In many cases, these procedures prioritize technical performance and sometimes cost above other considerations.

Such comparisons will likely involve qualitative and/or quantitative comparisons. An example of a quantitative comparison is to assign each performance attribute a ranking (e.g., on a scale of 1-4) and assign a weight to each attribute depending on its importance to the organization. Each alternative receives a total numeric score that allows cross comparisons. Another way may be a +/- or pro/con system. A hybrid of these as well as group/stakeholder deliberations may be the best approach.

Approaches to integrating environmental and social attributes into alternative selection processes include:

- using the evaluation modules discussed below to assess both social and environmental attributes.
- creating summary tables from the evaluation modules to support the selection process (see for example, the US EPA's Cleaner Technologies Substitute Assessment selection chapter).[27]
- inserting additional line items for environmental/social attributes into the organization's existing matrix for alternatives selection.
- using environmental/social attributes as "pre-screens" for alternatives. "Pre-screens" means the alternative must meet certain threshold(s) of environmental/social attributes to even be considered as a viable alternative.
- designing an iterative comparison and selection process whereby all attributes are optimized over time. In this approach, while trade-offs among attributes are accepted in the present, the goal is to optimize all performance attributes (environment, social, economic, and technical) over time. In this process the decision may mean selecting a firm which has the less preferred product today because it is more likely to produce the most optimal product for all attributes tomorrow. In this approach organizations are building continuous improvement and innovative capacity of product manufacturers into the selection process.

In many cases firms are using a combination of these approaches depending on the product in question, their goals, and their approaches to selecting products. In all cases, the selection process should include an implementation planning process, whereby details of process and product changes, research needs, communications needs, investments, training, and other administrative and organizational changes needed to implement the selected alternative as well as timelines and processes are clearly outlined. This step should include a discussion of the stakeholders within and outside of the firm or agency that should be involved in the implementation process.

The final step, **Review Selection**, reflects the fact that no technology—be it a chemical, material, or product—is typically perfect in terms of environment and social acceptability. Over time, specific chemical, material, and product selections will need to be re-visited and re-evaluated based upon emerging science and changing social expectations. Alternatives assessment is part of the journey towards sustainable technologies, and as such, will always be an iterative process.

THE DESIGN ASSESSMENT PROCESS

The **Design Assessment Process** differs from the Comparative Assessment Process because it begins with the intention to develop new chemicals, materials, products, or systems. This evaluation focuses on the positive attributes that designers want rather than selecting among options that are currently available on the market. The Design Assessment Process involves five steps:

1) Define Desired Attributes
2) Identify Alternatives
3) Evaluate and Compare Alternatives
4) Select Preferred Alternative(s)
5) Review Selection

The first step in the Design Assessment Process is to **Define Desired Attributes** that are wanted in the physical matter being designed, be it a chemical, material, product, or system. Examples include: the 12 Principles of Green Chemistry;[28] the 12 Principles of Green Engineering;[29] materials/products that can either be closed loop recycled or composted at the end of their use life; products that are durable, easily repaired/upgraded, or disassembled; and products/materials with high recycled content.

An important consideration in this step is consideration of necessity. Products are frequently designed without considering their necessity for society (whether they provide a benefit or fulfill an important human need) and whether the potential risks associated with the manufacture of that product should be incurred by society. An example is the use of antimicrobials in handsoaps, where research has indicated that they may not provide added protection over normal soap and water, but may actually contribute to antimicrobial resistance when widely distributed in the environment.[31] Another example is the use of mercury switches in children's disposable cereal box toys. The toys are not necessary for meeting an important human need but yet may contribute to mercury contamination and waste problems.

In the second step, **Identify Alternatives**, alternatives are identified that meet the desired attributes. The final three steps—Evaluate and Compare Alternatives and Select Preferred Alternative(s)—are the same as in the Comparative Assessment Process.

EVALUATION MODULES

The comparison of alternative solutions is a critical component of the Alternatives Assessment Framework. Further development of the Framework will require creating new and refining existing modules that facilitate the evaluation and comparison of alternatives. These modules will be combinations of methods, tools, and databases.

We use the "module" concept to emphasize that the components of alternatives assessments need to be designed to allow for flexibility, adaptability, appropriate use, and continuous improvement. We want modules that users can plug in to meet their specific needs.

While there may be other areas of interest in evaluating alternatives, the Lowell Center Alternatives Assessment Framework identifies the need for evaluation modules in four areas:

- Impacts on human health and the environment
- Social justice impacts
- Technical performance
- Economic feasibility

This section differs from the preceding sections in that it outlines a sketch of possible directions for action rather than a proposed set of actions because at this moment in time there are no clear choices as to which methods and tools are most appropriate (for given applications) for each of the evaluation modules. This is especially true for the Human Health and the Environment module and the Social Justice module, where methods and tools are more novel and less widely used than the methods/tools available for evaluating Technical Performance and Economic Feasibility. We emphasize the open source nature of this framework because we recognize that significant research and development is needed to create the tools needed for performing comprehensive Human Health and the Environment and Social Justice evaluations.

Human Health and the Environment

No dominant method has emerged for evaluating and comparing chemical or material hazards. Rather there are many assessment methods and tools that are available for defining and comparing the hazards associated with chemicals including:

- The "Evaluation Matrix" developed for the German Federal Environmental Agency.
- "Quick Scan" developed by The Netherlands.
- "PRIO" developed by the Swedish Chemicals Inspectorate (KemI).
- "The Column Model" developed by the German Institute for Occupational Safety (BIA).
- The "Pollution Prevention Options Analysis System" (P2OASys) developed by the Massachusetts Toxics Use Reduction Institute.
- The "Cradle to Cradle Design Protocol" developed by McDonough Braungart Design Chemistry (MBDC). The MBDC Cradle to Cradle Design Protocol also encompasses material and product assessment.
- The "Chemicals Assessment and Ranking System (CARS) designed by the Zero Waste Alliance.
- The "P2 Framework Models" developed by the US Environmental Protection Agency, which includes "EPI Suite," ECOSAR Aquatic Toxicity," "OncoLogic," and the "PBT Profiler."
- The Cleaner Technologies Substitutes Assessment (CTSA) method developed by the US EPA DfE Program and the University of Tennessee Center for Clean Products and Clean Technologies.
- The US EPA's chemical alternatives assessment developed in *Furniture Flame Retardancy Partnership: Environmental Profiles of Chemical Flame-Retardant Alternatives for Low-Density Polyurethane Foam* (2005).
- The "GreenList" Process developed by the SC Johnson Company.

Some of these tools are proprietary—CARS, MBDC Protocol, and P2OASys—while others are publicly available.

A significant challenge to the evaluation of alternatives is that the hazards posed by many chemicals have never been comprehensively tested. The US Environmental Protection Agency's (US EPA) High Production Volume (HPV) Challenge Program is a start in the direction of compiling better test data on roughly 2,000 chemicals used or imported into the United States in quantities equal to or greater than one million pounds per year. In addition, the US EPA has developed a set of tools—the "P2 Framework Models"—for predicting the likely hazards of a chemical based upon structure activity relationships. These tools and the HPV data, while imperfect, represent an important step towards developing more comprehensive hazard data on chemicals.

For product assessment the dominant method is life cycle assessment or LCA. The strengths of LCA include that it is a well-defined method, applies a life cycle perspective to a defined functional unit, and can be quite effective in assessing attributes for which there is readily available and quantifiable data that can be translated into common units (e.g., climate change gases). The weaknesses of LCA include: lack of transparency (a single number answer can hide the values, assumptions inherent in the analysis and trade-offs between options), difficulty in establishing boundaries for analysis, orientation towards the hazards of pollutants rather than the hazards of chemicals in production (which fosters a pollution control rather pollution prevention mindset), generally poor handling of recycling issues, and significant costs.

The shortcomings of LCA highlight the need to clearly define the applications for which LCAs are most appropriate (e.g., evaluating impacts of energy use) and for developing methods that are better suited to evaluating hazards of chemicals, materials, and products.

Social Performance

Social performance assessments over the past 15 years have focused on corporate behavior. For example, the Global Reporting Initiative (GRI) has developed social (as well as economic and environmental) performance indicators for individual corporations. The social indicators encompass four broad areas of concern: a) labor practices and decent work; b) human rights; c) society; and d) product responsibility. "Labor practices and decent work" covers employment, labor/management relations, health and safety, training and education, and diversity and opportunity. "Human rights" covers strategy and management, non-discrimination, freedom of association and collective bargaining, child labor, forced and compulsory labor, disciplinary practices, security practices, and indigenous rights. "Society" covers community, bribery and corruption, political contributions, competition, and pricing. "Product responsibility" covers customer health and safety, products and services, advertising, and respect for privacy. [31]

Prior to the emergence of social performance indicators for corporations, the trend in social performance assessments in the material economy focused on technology assessments, especially of technological systems with broad societal significance like nuclear power.[32] These technology assessments focused on how technologies affect communities, social interactions, and political institutions. The current debates over the use of genetically modified organisms (GMOs) and nanotechnology follow in this tradition of broad technology assessment.

An important next task in the development of this Alternatives Assessment Framework is to develop a social justice module that builds from the work on social performance indictors and technology assessments and applies it to the assessment of alternative chemicals, materials, and products.

Technical Performance

Technical performance assessments are essential to ensuring that alternative solutions meet or exceed the performance of existing products. An alternative is not viable if it does not achieve this end. The depth of technical performance assessment needed will vary with the end user, the degree to which readily available and tested products are already on the market, and the availability of technical data. Exhaustive technical assessments are not needed or useful in every situation.

Market Assessments seek to determine if alternatives exist on the market. At the most basic level, the mere presence of an alternative on the market and in competition with the product, chemical, or material of concern for exactly the same end use can be sufficient to state that technically viable alternatives exist. For some government decisions, market assessments are sufficient for their needs.

Research and Development (R&D) Assessments assess the likelihood that a technically viable alternative is in the R&D pipeline. R&D assessments are similar to market assessments in that they seek to identify the availability of products, although in the R&D pipeline rather than already on the market. The need for R&D assessments emerges when alternatives to products of concern either do not exist on the market or exist but are unacceptable due to cost, technical performance, social justice impacts, or environmental/human health impacts.

Detailed Technical Assessments by Product End Users are often required to determine if the product meets the needs of the end user. As noted above, the need for exhaustive technical assessments will vary depending on market adoption of an alternative and the availability of relevant technical data. The US EPA in its performance assessment module (of the Cleaner Technologies Substitute Assessment methodology) developed a 17-step process for evaluating technical performance that consisted of: 1) developing a performance protocol for evaluating products (11 steps); 2) developing supplier and observer data sheets for collecting consistent data across suppliers and products; and 3) testing and comparing performance results (4 steps).[33]

Technical Assessments for Regulatory Decisions. What is the technical and environmental performance of alternatives for an entire industry sector? When writing regulations the US EPA performs exhaustive assessments of technologies that are available or in development for meeting specific environmental performance goals within an industry sector. For example, when developing water effluent regulations for the pulp and paper industry in the 1990s, the US EPA produced a 200 page report on the availability, technical performance, cost, and environmental performance of pollution prevention technologies for the pulp and paper industry.[34]

Economic Feasibility

The level of economic assessment needed for informing alternatives selection will vary with end users—including regulators, institutional/business, consumers, and technology change advocates (such as non-governmental organizations). Economic feasibility assessments are performed at a variety of levels, ranging from quick market assessments to detailed industry-wide cost/benefit analyses:

Market Assessment. Does the alternative exist on the market? At the most basic level the mere presence of a product on the market means it is economically viable for some segment(s) of the economy. The market viability of an alternative will range from niche premium markets to direct price competition with the product of concern.

Cost Assessment. How much does the alternative cost relative to the chemical, material, or product of concern? Cost assessments will range from direct price comparisons to life cycle cost assessments (also known as "environmental cost accounting" or "total cost accounting"). A direct price comparison assesses the economic viability of an alternative simply in terms of product price—more, less, or the same -- relative to the product of concern. Life cycle costing is a holistic assessment of the comparative cost of alternatives to products of concern, including: product price; operation, maintenance, and repair costs over the life of the product; cost of regulatory compliance, disposal and other potential liabilities; and the use of long-term financial indicators (e.g., net present value, internal rate of return, and profitability index). The US EPA promotes the development and use of environmental accounting tools through its Environmental Accounting Project and developed a module for performing cost assessments as part of its Cleaner Technologies Substitute Assessment methodology.[35]

Cost/Benefit Analysis. What are the costs and benefits of technology change (often defined in terms of regulatory compliance) for an entire industry sector? Regulatory agencies, especially environmental regulatory agencies like the US EPA, frequently perform detailed analyses of the costs of technology change to comply with a new regulation as well as the environmental benefits of implementing the regulation. The US EPA refers to these as "regulatory impact analyses." These cost/benefit analyses forecast industry-wide impacts for a handful of regulatory scenarios based upon the level of pollution allowed.

Compliance cost variables may include industry-wide (i.e., across an entire industry sector such as pulp and paper manufacturing) capital costs, operations and maintenance costs, annualized costs, plant closing, and job loss for each regulatory alternative. As an example, the monetized compliance benefits when the US EPA calculated the benefits of updated water effluent regulations for the pulp and paper industry included human cancer risk reductions, acute health benefits, agricultural benefits, aquatic health benefits, and avoided costs for sludge disposal. In the monetization of benefits, many benefits remain unquantified due to lack of data. For example in the case of the pulp and paper analysis the following benefits were not quantified: non-carcinogenic effects of exposure to hazardous air pollutants and water pollutants other than dioxin; chronic effects of exposure to volatile organic compounds; effects of exposure to sulfur emissions; as well as the many intangibles including benefits of in-stream uses like swimming; near-stream uses like picnicking and wildlife observation; aesthetic benefits of residing, working, or traveling near water; and intergenerational equity benefits.

Notes on Economic Assessments

A challenge in performing economic assessments is that the price of alternatives is not static. As demand grows and manufacturers achieve economies of scale, prices decline. Additionally, institutional consumers that purchase in large volumes receive volume purchasing discounts and can also drive firms to innovate—developing new price competitive products—to capture new market share. If a large institutional consumer has a strong interest in a particular alternative—for example detergents made without nonylphenol ethoxalates—they are likely to receive them at a reasonable cost if they can ensure a large and regular purchase. Similarly in the case of regulatory compliance, regulatory agency forecasts of cost compliance may often be inflated in comparison to actual costs of compliance as implementing firms innovate and suppliers drop the prices of their products.

Limitations of the cost-benefit analysis appear when the methods ignore the reality that the cost of replacing a high hazard chemical may serve as insurance against a company's brand being scandalized in the public because of the use of a hazardous chemical. In the auto industry some producers follow a "zero faults approach"—i.e., avoid chemical scandal—because the costs of tarnishing brand image are in the long term much higher than eliminating the use of the high hazardous chemical. Thus the choice between a cost-benefit analysis or a zero (chemical) faults approach is a strategic decision. It might be that in the long term the zero faults approach is more economically beneficial to a firm than a cost-benefit approach.

SUMMARY

The Lowell Center Alternatives Assessment Framework is an effort to bring the disparate elements of alternatives assessment efforts under a single open-source umbrella. Values, long-term vision and goals, toxicity concerns, and social justice impacts have often been ignored in current efforts to identify and compare safer alternatives. The Lowell Center Alternatives Asssessment Framework is an initial step at defining a comprehensive approach for creating more environmentally appropriate and socially just products.

The Lowell Center considers this publication of the Alternatives Assessment Framework a first edition. As an open source tool we encourage people in firms, organizations, and governments to use it, adapt it, and expand on it. The Lowell Center is following up this publication with projects to more fully develop several of the evaluation modules and to apply the Framework. As we begin to apply this framework and work with others, we hope to develop and deepen the approaches. We hope that as others use this or similar frameworks, they will share their expansions and alternations. At some future date, the Lowell Center will reissue this document, more fully developed by further experience.

ENDNOTES

1 The outcomes of that meeting as well as the background research that informs this Alternatives Assessment Framework can be found at: *http://chemicalspolicy.org/downloads/alternativesassessmentfinalreport_000.pdf*.

2 OSHA Hazard Communication Standard (HCS), Subpart Z, Toxic and Hazardous Substances, 29 CFR 1910.1200, Section "c", "Definitions."

3 Organisation for Economic Co-operation and Development (OECD), 2003, *Descriptions of selected key generic terms used in chemical hazard/risk assessment* (Paris: OECD).

4 G&C Merriam Company, 1976, *Webster's Third New International Dictionary* (Springfield, MA: G&C Merriam Company).

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6 Op cit., OECD, 2003.

7 For example, see the definition of "substitution" in: J. Lohse, et al., 2003, *Substitution of hazardous chemicals in products and processes*, compiled by Ökopol GmbH and Kooperationsstelle Hamburg for the European Union Directorate General Environment, Nuclear Safety and Civil Protection of the Commission of the European Communities (Hamburg: Ökopol GmbH), p. i.

8 See J. Tickner and K. Geiser, 2004, The precautionary principle – stimulus for solutions and alternatives-based environmental policy. *Environmental Impact Assessment Reviews*. Vol. 24. pp. 801-824.

9 Mary O'Brien, 2000, *Making better environmental decisions: an alternative to risk assessment* (Cambridge: MIT Press).

10 "Environmental" is broadly construed here to include human health and the natural environment.

11 "Products" includes both tangible goods as well as services.

12 This section is excerpted in part from M. Rossi, J. Tickner, and S. Edwards, 2004, "Setting the context for the Lowell workshop on designing safer alternatives: chemicals, materials + products" (Lowell: Lowell Center for Sustainable Production).

13 Examples of chemicals as product include: intermediates, process aids (e.g., chlorinated solvents in degreasing), disinfectants, cleaning products, etc. In such instances, chemicals are considered either singly or often as a mixture of chemicals.

14 Industrial hygiene hierarchy of controls: substitute to reduce or eliminate exposure, engineering controls (e.g., ventilation), and personal protection controls (e.g., goggles or masks).

15 Waste management hierarchy: prevent, reuse, recycle, incinerate, and landfill.

16 Adapted from the definition of "toxics use reduction" as defined by the Massachusetts Toxics Use Reduction Act of 1987.

17 Adapted from Wingspread Statement on Precautionary Principle (January 25, 1998); see C. Raffensperger and J. Tickner (eds.), 1999, *Protecting public health and the environment: Implementing the precautionary principle* (Washington, DC: Island Press), Appendix A.

18 J. Lohse, et al., 2003, *Substitution of hazardous chemicals in products and processes*, compiled by Ökopol GmbH and Kooperationsstelle Hamburg for the European Union Directorate General Environment, Nuclear Safety and Civil Protection of the Commission of the European Communities (Hamburg: Ökopol GmbH).

19 See for example: J.A. Todd and M.A. Curran (eds.), 1999, *Streamlined life-cycle assessment: a final report from the SETAC North America streamlined LCA workgroup* (Pensacola: SETAC).

20 Swedish Environmental Objectives Council, 2004, *Sweden's environmental objectives—a shared respon-sibility* (Bromma, Sweden: Swedish Environmental Protection Agency), p. 6. See also, www.miljomas.nu/english/english.php

21 Ibid, p. 10.

22 Ibid, p. 9.

23 Developed by McDonough Braungart Design Chemistry (MBDC).

24 The Ecology Center, 2005, *Moving towards sustainable plastics: a report card on the six leading automakers* (Ann Arbor: The Ecology Center).

25 Quoted bullets are from Chapter 4 in: Swedish Environmental Objectives Council, 2004, *Sweden's environmental objectives are we getting there?* (Bromma, Sweden: Swedish Environmental Protection Agency).

26 See "Defining the Terrain of Chemicals, Materials, and Products" section of the Introduction for further details on the distinction between chemicals, materials, and products.

27 Source: *http://www.epa.gov/dfe/pubs/tools/ctsa/ch10/ch10.htm*.

28 P. Anastas and J. Warner, 1998, *Green chemistry: theory and practice* (New York: Oxford University Press).

29 P.T. Anastas and J.B. Zimmerman, 2003, 12 principles of green engineering, *Environmental Science and Technology*, 37 (3): 94A-101A.

30 Levy, S. B. 2001. Antibacterial Household Products: Cause for Concern. Emerging Infectious Diseases 7(3, Supplement): 512-515

31 Global Reporting Initiative (GRI), 2002, *Sustainability reporting guidelines*, *http://www.globalreporting.org/guidelines/2002/GRI_guidelines_print.pdf.*

32 For example, see Langdon Winner, 1986, *The whale and the reactor: a search for limits in an age of high technology* (Chicago: The University of Chicago Press).

33 See US EPA Cleaner Technologies Substitute Assessment performance assess module at *http://www.epa.gov/dfe/pubs/tools/ctsa/ch7/mod7-2.pdf*

34 US EPA, Office of Pollution Prevention and Toxics, 1993, *Pollution prevention technologies for the bleached kraft segment of the U.S. pulp and paper industry* (EPA/600/R-93/110).

35 For environmental accounting see *http://www.epa.gov/opptintr/acctg/resources.htm* and for the US EPA Cleaner Technologies Substitute Assessment cost analysis module see *http://www.epa.gov/dfe/pubs/tools/ctsa/ch7/mod7-3.pdf*.

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Alternatives Assessment Framework
of the Lowell Center for Sustainable Production

The Lowell Center for Sustainable Production

uses rigorous science, collaborative research, and innovative strategies to promote communities, workplaces, and products that are healthy, humane, and respectful of natural systems. The Lowell Center is composed of faculty, staff, and graduate students at the University of Massachusetts Lowell who work collaboratively with citizen groups, workers, businesses, institutions, and government agencies to build healthy work environments, thriving communities, and viable businesses that support a more sustainable world.

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Attachment 1-5

Excerpts from
"Five Chemicals Alternatives Assessment Study"

(Toxics Use Reduction Institute, University of Massachusetts Lowell, June 2006)

For the complete study report go to:
www.turi.org/library/turi_publications/five_chemicals_study

Executive Summary

Five Chemical Alternatives Assessment Study

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Overview

In July 2005, the Commonwealth of Massachusetts requested that the Toxics Use Reduction Institute perform an alternatives assessment for five chemicals: lead, formaldehyde, perchloroethylene (PCE), hexavalent chromium, and di(2-ethylhexyl) phthalate (DEHP). For each chemical, the Institute was charged with identifying significant uses in manufacturing, consumer products, and other applications; reviewing health and environmental effects; and evaluating possible alternatives. The Institute was also directed to evaluate possible effects on Massachusetts employment and economic competitiveness associated with adoption of alternatives. The study was conducted within a single fiscal year, and had a total budget of $250,000.

Rather than attempt to study all uses of each chemical, the Institute selected priority categories of use for each chemical. Likewise, for each use studied, the Institute chose a subset of possible alternatives for analysis. The Institute analyzed a total of sixteen different use categories and approximately one hundred different alternatives.

This report presents factual information on each alternative. The study does not provide a ranking of the alternatives; rather, it provides information that will allow users to make informed decisions and, in some cases, to design additional research to fill remaining information gaps. An important aspect of this alternatives assessment is its transparency: all information collected by the Institute is available for users to assess in the context of their specific applications, concerns and needs. Where the Institute was not able to obtain full information for a given parameter, this is clearly noted.

The results of this study will serve as a guide for those seeking safer substitutes to the five chemicals discussed here. In every case, at least one alternative was identified that was commercially available, was likely to meet the technical requirements of many users, and was likely to have reduced environmental and occupational health and safety impacts compared with the base chemical. In addition, the methodologies piloted in this study should prove useful as a model for future efforts at alternatives assessment. Alternatives assessment is a relatively new and highly promising methodology for analyzing products and processes that affect human health or the environment. The present study helps to demonstrate the viability of alternatives assessment as a useful tool to support decision-making about chemicals and their alternatives.

Approach and Methodology

During the year, five teams of Institute staff and outside experts performed parallel alternatives assessments using a common process and methodology. The project was divided into three phases. In the first phase, the Institute identified uses of the five chemicals within Massachusetts, and prioritized a subset of those uses to analyze in depth. In the second phase, the Institute identified alternatives and, again, chose priority alternatives for further study. In the third phase, the Institute conducted detailed research on each of the priority alternatives, gathering information on the health and environmental, technical, and economic aspects of each alternative. For each phase of the analysis, the Institute relied on information from experts and publicly available resources. The Institute also consulted extensively with stakeholders, including industry representatives, government agencies, and public health, environmental and labor advocates.

Prioritization of Chemical Uses

Each of the five chemicals considered in this study has a wide range of uses. The Institute selected a subset of these uses based on the importance of each use in Massachusetts, the potential availability of alternatives, the extent of possible exposures for workers and the general population, and the potential utility for Massachusetts businesses and citizens of the alternatives assessment. To maximize the value of this pilot project, the Institute also made an effort to include a mix of uses relevant for industry, small business, and consumer products. The Institute placed a low priority on uses where alternatives are already being readily adopted, or where significant research on alternatives is being carried out by others.

For hexavalent chromium and DEHP, the uses selected for this study represent a large percentage of total use of these chemicals in Massachusetts manufacturing. Lead and formaldehyde, on the other hand, have a multitude of uses beyond those examined here. For perchloroethylene, the study incorporated uses of particular relevance for small businesses and consumer exposures. The assessments conducted for this study can be used as a model for future assessments of other uses.

Prioritization of Alternatives

Alternatives to toxic chemicals may include drop-in chemical substitutes, material substitutes, changes to manufacturing operations, changes to component/product design, and other technological or market solutions. The Institute identified more than 200 possible alternatives for the chemical uses of interest, then applied a health and environmental screen to all alternatives. The screen excluded any chemical that was a known or probable human carcinogen, failed a persistence, bioaccumulation, and toxicity (PBT) screen, or was included on the 1999 More Hazardous Chemicals list developed by the Massachusetts Toxics Use Reduction program's Science Advisory Board. Of the options that passed this initial screening, the Institute prioritized alternatives for further study based on additional information about viability, health and environmental effects, economic considerations, and importance to stakeholders. The Institute also chose to prioritize products or materials manufactured in Massachusetts. When several alternative chemicals or materials could be grouped together, the Institute selected a representative of that grouping for detailed consideration.

The individual chapters provide detailed information on the process by which the Institute chose the list of alternatives to assess for each chemical use. It is important to note that inclusion of an alternative in the assessment does not imply an endorsement of that alternative. Similarly, exclusion of an alternative from the assessment does not imply that it has been rejected. In some cases, alternatives have been excluded from this assessment simply because they have been studied in depth in another context.

Some alternatives, particularly those comprised of single chemicals, were assessed as generic alternatives. Other alternatives vary considerably depending on the precise formulation or manufacturer. In these cases the Institute assessed a representative product. The choice of a particular manufacturer's product as representative does not constitute an endorsement of that product, or indicate that other similar products are not worthy of consideration.

Alternatives Assessment

The alternatives assessment included consideration of health and environmental effects, technical feasibility, and financial feasibility.

- **Health and environmental effects.** The Institute evaluated a subset of environment, health and safety (EH&S) endpoints. The Institute did not perform a detailed toxicological review for each alternative. Rather, the study relied on information obtained from authoritative bodies, emphasizing the most recent validated data or data that has been referenced by a US government agency. Where this type of information was not available, or where more recent studies called into question the results previously published by authoritative bodies, supplementary information was noted. The Institute relied on the U.S. EPA PBT Profiler software to gain information on persistence, bioaccumulation potential and toxicity. In cases in which it was necessary to evaluate chemicals in mixtures, the assessment considered each of the chemical constituents, excluding those making up 1% or less by mass of the mixture.
- **Technical feasibility.** The study identified and assessed application-specific performance requirements that must be met for each feasible alternative. The performance information that the Institute was able to obtain varied considerably among uses. For some uses information was obtained from published studies or directly from technical experts or several users of the alternatives. For other uses the Institute relied on information provided

by product manufacturers. The type of performance information that was available for a given alternative will affect the degree and nature of follow-up that may be necessary for users to draw conclusions about technical feasibility for individual applications.

- **Financial feasibility.** Data sources for financial information included manufacturers, stakeholders, the Chemical Economics Handbook and other standard reference sources. In many cases, particularly for emerging alternatives, no hard cost information was available. In other cases, sufficient cost information exists to conclude that the alternative is either more or less costly than the current chemical use. The Institute recognizes that cost comparisons today may be of limited relevance for emerging technologies and technologies that are gaining in popularity, since learning curves, economies of scale, and other factors can reduce costs over time.

It is important to note that this study was not designed to assess the relative safety of one alternative over the other. Rather, alternatives were compared to the study chemical as a baseline. This report provides information in the three assessment areas for each alternative and invites readers to use and supplement this material as appropriate for the specific considerations and requirements that they face. Users should use the material presented here for guidance in conducting their own assessments, taking into account the values, priorities, and situation-specific requirements that are most relevant for their organizational, industrial, or policy goals.

Economic Impact Assessment

In addition to collecting financial information as part of each alternatives assessment, the Institute convened a group of economists and other experts to discuss broader economic patterns, including the possible impacts on employment and competitiveness from adopting alternatives in Massachusetts.

Lead and Lead Compounds

Lead is a naturally occurring metal with a high density and low melting point. It is ubiquitous in manufactured products in many forms: as a pure metal, as an alloy with other metals, and in compounds. It is valued for its electrical conductivity, high density, and ability to stabilize plastics.

Lead poses a serious threat to human health and the environment. Acute human health effects of high lead exposures can include gastrointestinal distress, brain and kidney damage, and death. Chronic effects of lead exposure include anemia, damage to the nervous system, effects on blood pressure and kidney function, and interference with vitamin D metabolism. The U.S. Environmental Protection Agency (EPA) has classified lead as a probable human carcinogen, and the International Agency for Research on Cancer (IARC) has classified inorganic lead as probably carcinogenic to humans (Group 2A). Fetuses, infants and children are particularly vulnerable to adverse effects from lead exposure, including irreversible neurological damage. There is no known safe threshold for lead exposure in children.

Lead is extremely persistent in both water and soil. Combustion of leaded gasoline was a major source of anthropogenic lead releases in the past. Industrial releases from smelters, battery plants, chemical plants, and disturbance of older structures containing lead based paints are now major contributors to total lead releases.

The Institute selected three priority uses of lead to assess in detail: ammunition, weighting applications, and heat stabilizers for PVC wire and cable coatings. These applications were chosen based on stakeholder interest, importance to Massachusetts industry and consumers, and likely

availability of alternatives. Ammunition used at indoor and outdoor firing ranges is a significant source of occupational lead exposure and environmental contamination. Automotive wheel weights and fishing sinkers were chosen as representative of a large number of lead uses that rely on its high density. Wire and cable heat stabilization is the category with the largest use of lead among Massachusetts manufacturers. The results of these assessments are summarized below.

Ammunition for shooting ranges

Most practice shooting ranges currently use lead ammunition. Range operators and shooters can be exposed to high airborne lead levels in indoor shooting ranges. Use of lead ammunition at outdoor shooting ranges can produce environmental contamination.

Most of the major ammunition manufacturers now market lead-free bullets. A few smaller ammunition manufacturers specialize in the production of lead-free ammunition.

The Institute examined five possible alternatives to lead ammunition for use in shooting ranges: bismuth, copper, iron, tungsten, and zinc. For each alternative, the Institute examined human health, environmental, technical, and cost criteria.

- **Human health.** The alternative materials are all superior to lead from a human health perspective for the criteria the Institute considered (carcinogenicity, developmental toxicity, and occupational exposure).
- **Environment.** In general, the alternatives are more desirable from an environmental standpoint, with the exception of aquatic toxicity for copper and zinc.
- **Technical criteria.** Technical criteria of interest for this application include density, frangibility, and barrel wear.
    - Greater bullet density is advantageous for most ammunition applications, since high bullet weight and small bullet size are both desired characteristics. Tungsten has greater density than lead, while the other alternatives have lower density than lead. However, the density of bismuth is very close to that of lead. One manufacturer produces bismuth bullets that match the weight of many lead bullets.
    - Many lead-free bullets are frangible, which means they fragment into small particles upon impact with a target. Frangible bullets are safer than lead bullets for use at indoor firing ranges because they reduce or eliminate the dangers associated with ricocheting bullet fragments. This is of particular concern when firing at steel targets at close range. Frangible bullets can also limit damage to steel targets. Bismuth, iron, tungsten/nylon, and powdered copper can all be used to make frangible bullets. Solid copper bullets are not frangible and may ricochet more readily than lead bullets. Some zinc bullets break apart upon entering a target, but their probability of ricochet is not known.
    - Barrel wear is the erosion of barrel material by bullets. All of the alternative materials except tungsten are similar to lead from the perspective of barrel wear.
- **Cost.** All the alternatives currently have a higher purchase price than lead bullets. However, all the alternatives are superior to lead bullets from the perspective of operating costs. Firing ranges face numerous costs associated with the use of lead ammunition. These can include costs of air monitoring, blood lead level testing of range operators, maintenance of containment and filtration systems, purchase of replacement filters, range cleaning, and lead

disposal. By switching to lead-free ammunition, firing ranges can reduce or eliminate costs in these areas. In addition, lead bullets and bullet fragments must be either recycled or disposed of as hazardous waste. Alternative bullets, in contrast, can be disposed of as non-hazardous waste if they are not recycled. Frangible bullets also reduce wear and damage on bullet traps and backstops.

Weighting applications

The Institute chose wheel weights and fishing tackle as two examples of the larger category of lead used in weighting applications.

Fishing sinkers

Nearly 2,500 metric tons of lead are used each year in the United States to produce fishing sinkers. Many of these sinkers are lost during use. One study found that anglers lost, on average, one sinker every six hours of fishing.

Lead sinkers are lethal to waterbirds, such as loons and swans. One study found that the most common cause of death in adult breeding loons was lead toxicity from ingested fishing sinkers.

A number of states have placed limits on the use of lead fishing sinkers. In Massachusetts, lead sinkers are prohibited for use in the Quabbin and Wachusett Reservoirs, the two bodies of water that support the core of the state's loon population. Use of lead sinkers is restricted in several other states in the Northeast, and is restricted or banned in several countries.

Many anglers produce their own lead sinkers at home. This activity can expose individuals and family members to airborne lead particles or vapors.

The Institute examined five possible alternatives to lead for use in fishing sinkers: bismuth, ceramic, steel, tin, and tungsten. For each alternative, the Institute examined human health, environmental, technical/performance, and cost criteria.

- **Human health.** All the alternative materials are superior to lead from the perspective of the human health criteria the Institute examined (carcinogenicity, developmental toxicity, and occupational exposure).
- **Environment.** The alternatives are generally superior to lead from an environmental standpoint as well. All of the alternatives are clearly less hazardous to waterfowl and other aquatic species than lead.
- **Technical criteria.** The principal technical criteria of interest for this application are density, hardness, malleability, melting point, and corrosion resistance.
    - Tungsten is more dense than lead; all the other alternatives are less dense than lead.
    - Harder materials are preferable for use in many sinkers. All the alternatives are harder than lead; pure tin is about equal to lead in hardness, while tin alloy is harder than lead.
    - Greater malleability is an advantage for sinker applications where the sinker is crimped on to the fishing line. Tin has malleability equal to that of lead; all of the other alternatives are less malleable than lead.
    - Low melting point is considered an advantage because it allows individuals to produce sinkers at home, although home production of lead sinkers also creates

human health hazards. Bismuth and tin have lower melting points than lead; ceramic, steel, and tungsten have higher melting points.

  - Carbon steel is less resistant to corrosion than lead. Stainless steel and all the other alternatives are similar to lead in this regard.

- **Cost.** The alternatives generally have a higher retail price than lead sinkers, although some steel sinkers are competitive in price with lead sinkers. Studies conducted in the 1990s suggested that fishing sinker purchases represent less than 1% of total expenditures by anglers on their sport, so an increase in fishing sinker costs would be unlikely to have a significant effect on users.

Wheel weights

Wheel weights often fall off automobile wheels, leading to lead contamination of the environment. Worker exposure is a concern in the installation of wheel weights.

There is a thriving market in lead-free wheel weights. European and Japanese automobile manufacturers have already switched to lead-free wheel weights and U.S. automobile manufacturers are currently in the process of making the switch. Asian auto manufacturers now primarily use steel weights. Zinc weights are used widely in Europe, and US auto manufacturers are using zinc weights for automobiles destined for export to Europe. General Motors and Ford are in the process of converting to steel weights.

Despite these developments, the U.S. market in replacement wheel weights continues to use lead weights almost exclusively. This market in replacement weights accounts for 80% of total wheel weight use in the U.S.

The Institute examined four possible alternatives to lead wheel weights: copper, steel, tin, and zinc. For each alternative, the Institute examined human health, environmental, technical/performance, and cost criteria.

- **Human health.** All of the alternative materials are superior to lead for the human health criteria the Institute examined (carcinogenicity, developmental toxicity, and occupational exposure).

- **Environment.** For the most part the alternatives are superior environmentally, although zinc is inferior for aquatic toxicity in salt water, and copper is inferior for aquatic toxicity in both fresh and salt water.

- **Technical criteria.** The principal technical criteria of interest for this application are density, malleability, and corrosion resistance.

  - All of the materials considered in this analysis are less dense than lead. Thus, in order to achieve the same mass, the weights made from alternative materials must be somewhat larger than their lead counterparts. This adjustment does not typically pose engineering difficulties for weights used on passenger vehicles.

  - The malleability of lead makes it possible to shape wheel weights to match the curve of the wheel diameter. The malleability of copper and tin is similar to that of lead; steel and zinc are less malleable. Manufacturers can compensate for lower malleability by creating segmented weights.

  - The corrosion resistance of the alternative materials is generally similar to that of lead; tin is superior to lead in this regard because it does not require coating.

- **Cost.** Copper and tin weights are expected to cost more than lead weights at initial purchase; zinc weights cost about the same as lead weights, and steel weights have equal or lower cost. The end of life costs for all the alternatives are lower than those for lead.

Heat stabilizers for PVC wire and cable coatings

Lead heat stabilizers used for polyvinyl chloride (PVC) constitute the largest use of lead compounds in Massachusetts manufacturing, and the wire and cable industry is the largest user of these compounded resins.

Significant progress has been made in the identification and adoption of alternatives. Many lead-free heat stabilizers are commercially available, and resin compounders are working proactively with wire and cable companies to encourage their adoption. Regulatory requirements prohibiting the use of lead and other hazardous substances in electrical and electronic equipment in the European Union have created an incentive for U.S. manufacturers to develop lead-free alternatives. The Institute is engaged in on-going collaborative projects to help Massachusetts industries to gain and maintain a competitive edge in producing lead-free wire and cable, as well as lead-free electrical and electronic equipment.

The Institute did not conduct a complete technical assessment for alternative heat stabilizers. Each application has unique technical requirements, and stabilizers are formulated with many different combinations of chemicals to suit each application. Furthermore, heat stabilizers will be examined as part of a collaborative project between the Institute and the U.S. EPA to conduct a detailed life cycle assessment for three specific wire and cable applications. However, many Massachusetts wire and cable companies plan to adopt lead-free alternatives before that study will be complete. Thus, stakeholders determined that it would be useful for the Institute to analyze the environmental health and safety profiles of chemicals that are widely used in alternative stabilizers.

The Institute gathered information on five categories of alternative heat stabilizers: calcium-zinc, barium-zinc, magnesium-zinc, magnesium aluminum hydroxide carbonate hydrate, and magnesium zinc aluminum hydroxide carbonate. From these categories, the Institute selected five representative heat stabilizer products and conducted an environmental health and safety assessment of their constituent materials. Many of these constituent materials were found to be superior to lead from a human health and environmental perspective. Costs of mixed metal heat stabilizers have decreased in recent years, such that a transition to a mixed metal heat stabilizer may be cost neutral. Where a cost differential exists, it is estimated at 10% or less.

Formaldehyde

Formaldehyde is a naturally occurring chemical found in small quantities in the human body. Products that are made from or contain formaldehyde include many resins, permanent press fabric treatments, lawn fertilizers, cosmetics and disinfectants. Wood adhesives used to make plywood, particleboard and other manufactured wood products are the dominant end use for this chemical. The plastics industry also uses formaldehyde-based resins extensively. Formaldehyde is also used as a sterilant and tissue preservative. It is used to preserve animal specimens used in secondary school and college biology classes. It is also used to preserve human and animal tissue in medical and scientific laboratory settings. Embalmers use formaldehyde to preserve human remains for burial.

Formaldehyde exposure through consumer products or industrial activity is very hazardous to human health. Formaldehyde is highly irritating, acts as a potent sensitizer, and is known to cause cancer in humans. In 2004 IARC moved formaldehyde from Group 2A (probable human carcinogen) to Group 1 (known human carcinogen). Ingestion of formaldehyde or exposure to very high air concentrations can cause death.

The Institute assessed alternatives to formaldehyde in three categories of use: sanitary storage in barbering and cosmetology, preserved educational specimens for dissection, and building panels.

Sanitary storage in barbering and cosmetology

The Massachusetts Board of Cosmetology requires cosmetology salons to use dry sanitizer made from paraformaldehyde (a polymerized solid form of formaldehyde) in drawers where instruments are stored. The perforated plastic containers containing para-formaldehyde emit formaldehyde as it de-polymerizes into formaldehyde gas, filling the cabinets and drawers where hair brushes are kept, and subsequently entering the salon and classroom air as drawers are opened. Use of this dry sanitizer has placed a consistent source of formaldehyde in salons and cosmetology training schools, including vocational high schools.

The Institute identified and evaluated two possible alternatives to the use of dry sanitizer in drawers. The first option is a process change: storage of implements in a disinfected, dry, covered container or drawer without the use of any additional sterilant. The second option is to use ultraviolet (UV) light cabinets for sanitary storage.

The Massachusetts Board of Cosmetology is the only such board in the U.S. that requires use of dry sterilants. In contrast, the National-Interstate Council of State Boards of Cosmetology (NIC) does not recommend use of formaldehyde-based dry sterilants due to their carcinogenic potential. In place of dry sterilants, the NIC recommends an alternative procedure of proper cleaning, wet disinfection, drying and storage. The disinfection and storage practices recommended by the NIC are reiterated in the rules of many other Boards of Cosmetology and in the field's primary textbook and practice guidance.

Process change

One practical alternative to use of dry sterilant is simply to store implements in a disinfected, dry, covered container that is isolated from contaminants. This option would produce cost savings, because it would eliminate the need for cosmetology salons to purchase dry sterilant.

Simple elimination of dry sterilant, without any other change in procedures, is superior to use of dry sterilant from the human health, environmental, and cost perspectives. It is equivalent from a technical perspective.

UV light cabinets

Another option is for cosmetology salons to use UV light cabinets. A disadvantage of this technology is that although UV germicidal light is effective at killing pathogens, it must strike all surfaces and this is difficult to achieve on a brush. The cabinets may also become reservoirs of pathogens if they are not regularly cleaned and disinfected.

Use of UV storage cabinets is superior to use of dry sterilant from a human health and environmental perspective, although there is the potential for UV light exposure if the cabinets are misused. This system has a higher cost than dry sterilant.

Preserved educational specimens for dissection

Secondary school and college students in anatomy classes dissect preserved specimens, including fetal pigs, frogs, cats, sharks and other species. Traditionally, educational specimens have been preserved with a formalin solution (a 37% solution of formaldehyde in water). Formaldehyde kills the bacteria that would otherwise decay the tissue. It also polymerizes the tissue, helping to maintain its texture, structure and color. This application does not account for a large percentage of formaldehyde use, but it poses particular public exposure concerns. Students, laboratory instructors and technicians are exposed to formaldehyde through their repeated contact with these specimens.

The Institute evaluated two categories of alternatives: use of specimens that are formaldehyde-free, and the technological alternative of video and virtual dissection.

Specimens in alternative solution

Using specimens of grass frogs as a typical application, an outside expert evaluated the technical performance of three alternative preservatives: Formalternate by Flinn Scientific, Wardsafe by Ward Scientific, and Streck Tissue Fixative (S.T.F.) Preservative by Nebraska Scientific. Formalternate is a combination of propylene glycol, ethylene glycol phenyl ether and phenol. Wardsafe is primarily glutaraldehyde. S.T.F. is a mixture of diazolidinyl urea, 2-bromo-2-nitropropane-1, 3-diol (Bronopol), zinc sulfate, and sodium citrate. Different species may be preserved in different solutions by the same company. All these alternative products are readily available from well-established companies.

- **Health.** All three alternatives are superior to formaldehyde-containing specimens from the perspective of carcinogenicity, sensitizing potential, and capacity to cause irritation. Some ingredients of the alternatives can cause skin, eye and respiratory irritation, and some can act as sensitizers, but they are less hazardous than formaldehyde on all these measures. Evaluating the health effects of Formalternate and S.T.F. is complicated by the fact that they are chemical mixtures. Glutaraldehyde, used in Wardsafe, has high acute toxicity, but is present at low concentrations in the specimen.
- **Environment.** Some of the chemicals used in the alternative fixatives are more toxic to fish and other species than is formaldehyde. In general, the low volatility and small amounts of preservative in the alternative specimens suggests that exposure for humans and the environment are likely to be very low. Life cycle considerations for the alternatives include the use and disposal of some ingredients, such as phenol and zinc sulfate, which are potential environmental pollutants.
- **Technical criteria.** All of alternatives match or exceed the important technical and performance criteria for educational specimens: color, texture, and stiffness of the specimen

tissue. The color of the alternative specimens was as good as or better than the formalin-preserved specimen. The specimens varied in texture but all had acceptable characteristics.

- **Cost.** The prices of alternative specimens are similar to each other and generally less expensive than the formalin-fixed specimen.

Process change: Video dissection

Another alternative is to use video/virtual dissection instead of physical dissection of a preserved specimen.

- **Health and Environment.** Video/virtual dissection does not pose any of the health or environmental hazards for students or instructors associated with dissection of preserved specimens.
- **Technical criteria.** Video/virtual dissection offers different pedagogic opportunities from those afforded by physical dissection. Some instructors believe that video dissection is not an adequate substitute for dissection of preserved specimens, although it may be a useful supplement. However, the educational utility of video and/or virtual dissection may vary with the class or instructor. A complete assessment of the educational benefits of each option was beyond the scope of this study.
- **Cost.** The cost of video/virtual dissection programs is variable. Low or no-cost materials are available, as are more expensive programs. In contrast to preserved specimens, these represent a one-time cost.

Hardwood plywood and structural use building panels

Adhesives used to make plywood, particleboard and other manufactured wood products account for the majority of formaldehyde consumed world wide each year. The components of wood panels vary depending on their intended use. Plywood and other products that are "exterior-grade" or need to withstand wet conditions are usually made with phenol-formaldehyde resin. Particleboard and medium density fiberboard, often used for making furniture and cabinetry, are made with less expensive urea-formaldehyde resins, which have higher levels of formaldehyde emissions. Melamine-formaldehyde resins and polyacetal resins are also used in wood products and laminates and in molded plastic parts.

The Institute examined three alternatives that are currently available: Columbia Forest Products soy-based resin hardwood plywood panels, Homasote's recycled paper panel boards, and Viroc's wood fiber Portland cement panels. The Institute also assessed one emerging alternative that is not yet on the market, JER EnviroTech's plastic-wood fiber panel.

Hardwood plywood

The Columbia Forest Products soy-based resin hardwood plywood panel (Purebond) is a hardwood veneer core plywood panel. It can be used to make cabinets, built-in furniture, paneling, shelving, doors and other uses requiring a high end wood product.

- **Human health.** Purebond is superior to formaldehyde-resin plywood from the perspective of carcinogenicity and irritation/sensitizing properties. It eliminates potential formaldehyde exposures for users. However, its production involves use of epichlorohydrin as an intermediate. Epichlorohydrin is classified as a probable human carcinogen and poses other

hazards to human health and the environment. This chemical could be a hazard to workers and the environment during production.

- **Environment.** The formaldehyde-based resin in conventional plywood has minor ecotoxicity. Purebond is similar to formaldehyde-resin plywood for this parameter.
- **Technical Criteria.** Technical characteristics of interest for this application include appearance/construction, strength of the glue bond when moist, fire resistance, warp resistance, and product availability. Purebond is similar to formaldehyde-containing plywood for the parameters of appearance/construction, fire resistance, and product availability. It has a glue bond superior to that of urea-formaldehyde plywood under conditions of moisture. Its warp resistance has not been assessed fully.
- **Cost.** Purebond is currently available at a similar cost to formaldehyde-resin plywood.

Structural use panels

The Institute assessed two alternatives that could be used in place of softwood plywood for structural use panels: Homasote's recycled paper panel boards, and Viroc's wood fiber Portland cement panels.

Homasote's recycled paper panels and Viroc's wood fiber Portland cement panels may be used in place of softwood plywood and oriented strand board (OSB) in exterior sheathing, roof decking and floor decking. Viroc is used extensively in Europe.

- **Health.** Viroc and Homasote do not present a hazard to building occupants, but there are some occupational exposure concerns, such as exposure to wood and cement dust during cutting. Both products are superior to formaldehyde-resin plywood from the perspective of carcinogenicity of the binder. The Homasote panels are superior from the perspective of irritant in binder, while the Viroc panels are similar to formaldehyde-resin plywood on this metric.
- **Environment.** Both products are superior to formaldehyde-resin plywood from the perspective of ecotoxicity and natural resource conservation. The Viroc product is inferior from an energy intensity life cycle perspective**.**
- **Technical criteria.** Technical and performance criteria of interest for these uses include strength, weight, response to moisture, storage, handling, fastening, finishing, fire resistance, thermal resistance, and mold, rot and insect resistance. Both alternatives present some advantages and some disadvantages on these metrics. For example, Homasote is superior to formaldehyde-resin panels on several measures including resistance to insects, rot, and mold, and is inferior on certain other measures, such as impact resistance and tensile strength. Viroc is superior on measures including resistance to insects, rot, and mold, fire resistance, and impact resistance, and inferior on parameters such as tensile strength. Both Viroc and Homosote panels must be thicker and heavier than formaldehyde-resin panels to withstand an equivalent load over the same span.
- **Cost.** Both alternatives are currently more expensive than traditional formaldehyde-containing plywood.

Emerging alternative

The JER Envirotech Company is in the process of developing an extruded building panel made of wood fiber and polypropylene thermoplastic. This is an "emerging technology" that may substitute for particleboard and structural uses. The Institute did not assess this alternative in detail, but encourages further study of this option.

Perchloroethylene

Perchloroethylene (PCE) is a synthetic chlorinated hydrocarbon. It is used primarily as a solvent in dry cleaning and industrial degreasing and as a chemical intermediate.

Short-term exposure to PCE can cause symptoms such as skin, eye, and respiratory irritation, headache, and nausea; very high exposure can be fatal. Long term exposure to PCE may cause liver, kidney or central nervous system damage. PCE may also affect the developing fetus. IARC lists PCE as a probable human carcinogen (Group 2A).

PCE most often enters the environment through fugitive emissions from dry cleaning and metal degreasing industries and by spills or accidental releases to air, soil or water. Exposure results from environmental contamination, presence in consumer products or occupational sources. PCE has been found in breast milk, one indication of its ubiquitous presence in the environment.

The Institute assessed alternatives to PCE in three categories of use: dry cleaning, vapor degreasing, and aerosol automotive cleaning.

Dry cleaning

The Institute analyzed five categories of PCE alternatives for dry cleaning: hydrocarbons (HC), volatile methyl siloxanes (VMS), substituted aliphatic glycol ethers (SGE), wet cleaning, and liquid carbon dioxide (CO_2). Like PCE, the first three of these categories are based on organic solvents. For each category except CO_2, the Institute selected an individual chemical or process as a representative of the broader category.

- **Health.** All the alternatives are superior to PCE from the perspective of carcinogenicity. VMS and CO_2 are superior from the perspective of irritation, while SGE and wet cleaning are roughly equivalent to PCE on this metric. HC, wet cleaning, and CO_2 are superior from the perspective of exposure limits. Recent research has raised concerns about adverse effects of decamethylcyclopentasiloxane (D5), the dry cleaning solvent used in the VMS system, in laboratory animals.
- **Other hazards.** Unlike PCE, HC and VMS are combustible.
- **Environment.** The alternatives are less persistent than PCE in water, soil, sediment, and air, with some exceptions: the hydrocarbon alternative is more persistent than PCE in soil. The CO_2 used in the process is captured from industrial processes and thus the garment cleaning adds no net CO_2 to the atmosphere.
- **Technical criteria.** The first four alternatives are commercially available in Massachusetts. No commercial CO_2 facilities were identified in Massachusetts, although there are facilities in other states. Thus, all of the alternatives are known to have commercial viability at this time. Technical criteria of interest for this application include time for washing; load capacity; the range of soils that can be removed effectively; the types of clothing that can be washed using a given system; and the efficiency of spot cleaning before washing.

- All the alternatives require more time for cleaning than PCE, except CO_2, which requires less time. This time differential is decreasing as operators gain more experience with the alternatives. The alternatives are variable on the metric of load capacity: VMS is superior on this metric and wet cleaning is superior in some cases, while carbon dioxide is similar to PCE and HC and SGE are inferior.
- The hydrocarbon and VMS alternatives are able to clean fewer types of soil compared with PCE. The SGE and carbon dioxide systems are similar to PCE on this metric. Wet cleaning can be either equivalent or inferior to PCE on this metric.
- HG and SGE are superior to PCE in the range of types of clothing that they can clean. VMS is similar to PCE on this metric, and wet cleaning and carbon dioxide are more limited in the range of clothing types they can clean.
- Carbon dioxide is superior on the spotting metric; hydrocarbon, VMS and wet cleaning are inferior; and SGE can be either similar or inferior to PCE on this metric.

- **Cost.** Cleaning system costs include equipment, solvent, labor, energy, and regulatory costs. The Institute gathered comparative cost information on these parameters from a number of Massachusetts cleaners. Hydrocarbon systems have higher equipment and labor costs, counterbalanced by lower solvent and regulatory costs. VMS systems have higher equipment cost; figures were unavailable for several other parameters. SGE systems have higher equipment and solvent costs, counterbalanced by lower regulatory costs. Wet cleaning has higher labor costs, counterbalanced by lower equipment, solvent, and regulatory costs. Carbon dioxide has higher equipment costs and lower regulatory costs.

Vapor degreasing

The Institute carried out alternatives assessments on one product based on n-propyl bromide (nPB), a product based on a volatile methyl siloxane (VMS), and two hydrochlorofluorocarbons (HCFCs). All of these are solvent-based vapor degreasing substitutes for PCE. The Institute did not conduct an alternatives assessment on aqueous cleaning systems as part of this project because the Institute's Surface Solutions Laboratory has already produced extensive resources in this area. As documented in other work by the Institute, approaches other than use of a drop-in solvent replacement are often superior from a health, environmental, technical and cost perspective.

- **Health.** All of the alternatives have potentially significant environmental and occupational health and safety impacts. The HCFC products have significant adverse environmental impacts, including persistence and global warming potential, but should be somewhat less toxic than PCE. There are significant concerns about the toxicity of nPB; it is a neurotoxin, and its carcinogenicity is now under study. Exposure to high levels of VMSs can cause dizziness, disorientation, and shortness of breath.

- **Other hazards.** All of the alternatives have higher vapor pressures than PCE, which will lead to greater evaporation and the potential for more vapors to escape from the degreaser; this will increase the potential for worker exposure, and may cause greater fugitive emissions than with PCE. A significant safety hazard is presented by the VMS product, which is highly flammable with a very low flash point. Its use as a vapor degreaser would present a significant fire and explosion hazard, and special handling would be required to use it safely, including the requirement for a closed system, spark-proof equipment, and worker training.

- **Environment.** nPB and VMS are superior to PCE on measures of persistence in water, soil, sediment, and air. The two HFCs are inferior on these measures. nPB is superior from the perspective of bioaccumulation, while the others are inferior on this measure. The two HFCs also have global warming potential.
- **Technical criteria.** Over all, the vapor degreasing alternatives have technical features comparable to those of PCE. The alternatives all have higher vapor pressures than PCE, which will contribute to product loss through evaporation. On the other hand, the alternatives all have lower surface tensions than PCE, which should enhance their ability to clean complex parts. Soil removal testing performed at the Institute's Surface Solutions Laboratory found that all four alternatives were as effective as PCE in removing oil-based soils.
- **Cost.** All the alternatives currently cost more to purchase than PCE, creating an initial barrier for companies interested in switching to an alternative vapor degreaser. Operating costs such as energy use, waste solvent handling costs, and solvent lifetime may help to offset this higher purchase price. For example, many of the alternatives can be used at lower operating temperatures than PCE to achieve the same level of cleaning performance. On the other hand, all of the alternative solvents are more volatile than PCE, which might increase costs due to greater evaporative losses.

When addressing a specific cleaning need it is important to consider all options, including process and product modifications. Therefore, other options to consider include alternative cleaning processes such as an aqueous or a semi-aqueous system, working within the supply chain to change the contaminant on the part that requires cleaning, or investigating a material change to prevent contamination and thereby making cleaning unnecessary. All of these options would be preferable to using PCE or any of the drop-in alternatives discussed here. The Institute has demonstrated the viability of this approach in projects to assist industry in replacing chlorinated solvents with safer alternatives.

Aerosol automotive cleaning

The Institute carried out alternatives assessments on four brake cleaning alternatives, seven external engine cleaning alternatives, three internal engine cleaning alternatives, and four tire cleaning alternatives.

- **Health.** With regard to human toxicity, products containing n-hexane, 2-butoxyethanol, DGME, toluene, and glycol ethers are of equal or more concern compared with products containing PCE. Aqueous-based products will have lower human health concerns than any of the solvent-based products.
- **Other hazards.** Most of the solvent-based cleaners are highly flammable, and great care must be taken in their use, especially around hot engines. PCE is nonflammable, as are the aqueous-based cleaners, so these alternatives are preferable with regard to fire potential.
- **Environment.** Many of the alternative cleaners have the potential for significant environmental impact upon release. The medium of most concern is air, since these products are used as aerosol sprays. Most of the alternative products have ingredients with atmospheric half-lives exceeding two days and thus, like PCE, are considered persistent.

- **Technical criteria.** It is difficult to assess the technical performance of the alternatives objectively, since test data are not available. Stakeholders indicated that the alternative solvent-based cleaners are likely to perform as well as PCE-based cleaners, while aqueous-based cleaners may require more mechanical agitation to achieve equivalent results.
- **Cost.** Cost information is also difficult to assess. Some alternative products were more expensive per ounce than the corresponding PCE product, and some were less expensive per ounce. The actual cost per use may be quite different, however, since more or less of the different products may be required to obtain equivalent levels of cleaning.

Hexavalent Chromium

Chromium is a metallic element found in nature in the form of chromite ore or the mineral crocoite. Chromium provides manufactured products with hardness, shininess, durability, color, corrosion resistance, heat resistance, and decay resistance. Important uses of chromium compounds include wood preservation, metal processing, leather tanning, and production of pigments. The major application of chromium is in the production of alloys, primarily stainless steel; historically, this has amounted to 50-60% of total chromium use.

There are several oxidation states of chromium, each with its own chemical characteristics. The most common forms are trivalent chromium and hexavalent chromium. Trivalent chromium compounds occur naturally, while the hexavalent compounds result primarily from industrial activity.

Hexavalent chromium poses far more health hazards than trivalent chromium. Short-term effects of hexavalent chromium exposure can include eye and respiratory irritation and sensitization. In large quantities, ingestion of hexavalent chromium compounds can result in acute gastroenteritis, vertigo, gastrointestinal hemorrhage, convulsions, ulcers, kidney damage or failure, and liver damage or failure. Acute skin exposure can cause burns, liver damage or failure, kidney damage or failure, and anemia. Effects of chronic skin exposure include dermatitis, hypersensitivity reactions, eczema, and kidney or liver damage. Hexavalent chromium is classified by IARC as a known human carcinogen (Group 1).

Workers have the highest risk of adverse health effects from hexavalent chromium exposure. The industries with the greatest risk of occupational exposure are chrome electroplating, stainless steel welding, metal coating and painting, printing, textiles, leather tanning, wood preservation, and cement or masonry work.

The Institute assessed three general categories of use: decorative chrome electroplating; hard chrome electroplating; and chromate conversion coatings. The category of chromate conversion coatings was narrowed further to focus only on passivation of zinc and zinc alloy plated parts and zinc galvanized steel.

Decorative chromium electroplating of consumer and automotive products

Decorative chrome plating is used for consumer applications such as appliances, metal furniture, plumbing fixtures, knobs and hand tools, and for automotive trim. It creates an attractive blue-white finish and helps to reduce tarnishing.

The major advantage of decorative hexavalent chromium is its appearance, especially its blue-white color. It also presents some processing difficulties. These include poor throwing power (a measure of coverage in recessed areas of a part being plated), low resistance to burning during plating,

difficulty in removing impurities from the plating bath, problems in rinsing the plating solution from the plated parts, and intolerance to interruptions or variations in the electrical current during plating.

The Institute assessed two alternatives to hexavalent chromium for decorative chrome electroplating: trivalent chromium plating baths, and low temperature arc vapor deposition of trivalent chromium.

- **Trivalent chromium plating baths** use a very similar process to that used in hexavalent plating.
- **Low Temperature Arc Vapor Deposition (LTAVD®)** is a proprietary process in which parts to be coated are exposed to a vaporized metal that condenses on the parts, depositing a thin, solid film.

The Institute assessed health, environmental, technical, and cost criteria for each of these alternatives.

- **Health.** Both options are superior to hexavalent chromium plating from the perspective of carcinogenicity and occupational exposure standards. LTAVD® is superior from the perspective of skin irritation/sensitization, and trivalent chromium baths are either similar or superior to hexavalent chromium baths on this metric.
- **Environment.** Both options are superior to hexavalent chromium plating from the perspective of waste generation. LTAVD® avoids the need for a lead anode; trivalent chromium baths may or may not use a lead anode.
- **Technical criteria.** Criteria of interest include uniformity of coating, adhesion to substrate, hardness, color, and resistance to corrosion and wear.
    - Decorative trivalent chromium plating has many processing advantages over hexavalent chromium plating. Examples of these advantages include superior throwing and covering power; tolerance of electrical current interruptions; low susceptibility to burning; and ease of rinsing and removing impurities. Trivalent chromium plating has a naturally micro-porous structure, which is advantageous for corrosion resistance. In the past, the color of trivalent chromium plating was a disadvantage, but recent developments now make it possible to produce a trivalent plate with an appearance equivalent to that produced using hexavalent chromium.
    - LTAVD® operates at room temperature, making it possible to use it on a substrate with a low melting point, such as plastic. By using different combinations of gases and metals, a variety of coatings can be formed. Metals with dissimilar characteristics, such as titanium and aluminum, can be alloyed using this process, creating unique coating materials. Most of the technical assessments of LTAVD® have been conducted by the company that holds the patent rights. Findings of these assessments indicate that LTAVD® produces a very uniform coating with good adhesion to the substrate, corrosion resistance similar to or better than that of hexavalent chromium, color similar to that produced with hexavalent chromium, and hardness superior to that produced with hexavalent chromium.
- **Cost.** Trivalent plating chemicals are more expensive than hexavalent plating chemicals, although economies of scale are likely to lead to falling prices as trivalent systems increase in popularity. The cost of chemicals, however, is offset by the greater efficiency of the trivalent

process and greatly reduced costs for exposure control and disposal. One study estimated that the volume of sludge generated by the hexavalent process is about 30 times that of the trivalent process. Another found that hexavalent treatment costs were nearly 10 times that of the trivalent process. While cost information for LTAVD® has not been published, the process is being used by several major manufacturers of consumer hardware, indicating that it is commercially viable. Since a wide variety of gases and metals are used, material costs also would vary accordingly. A major operating cost would be energy. Waste treatment costs are likely to be minimal.

Hard chromium electroplating of industrial components

Hard chrome plating, also known as functional or industrial chrome, typically is thicker than decorative chrome. It is used on industrial components that must perform under demanding conditions such as high temperatures, and repetitive grinding and impact forces (such as aircraft engines and landing gear, hydraulic cylinders, and drill bits). Unlike decorative chrome, appearance usually is not an important issue.

The two main reasons for using hard chrome are to provide wear and corrosion resistance, and to rebuild worn components to precise dimensions. It has a low coefficient of friction, is hard and heat-resistant, adheres well to substrates of various geometries, and provides corrosion resistance.

Hard chrome plating suffers from a number of technical limitations. The plating process involves numerous steps, which may need to be repeated in order to achieve an adequate coating. The coating can be brittle, leading to failure or reduced corrosion resistance. It can also be difficult to achieve even plating thickness.

The Institute assessed six processes that can serve as alternatives to hard chromium electroplating:

- **Thermal sprays** include high velocity oxy-fuel (HVOF) and plasma sprays. Thermal spray is a coating process in which wire or metallic powder is melted by a high temperature flame and sprayed as particles or droplets onto a substrate.
- **Weld facing** is a dry method of joining a hard coating, edge, or point to a metal or alloy substrate to improve its resistance to abrasion, corrosion, heat or impact. It also is used to restore worn surfaces.
- **Heat treatments and plasma nitriding** methods use heat to diffuse elements into the top surface of a substrate metal to form an alloy or layer with desired properties.
- **Nanocrystalline coatings** use electrodeposition, vapor deposition, or spray conversion processing to deposit very small grains of crystalline alloys on a metal substrate.
- **Vapor deposition:** In *physical vapor deposition (PVD)***,** parts to be coated are exposed to a vaporized metal that condenses on the parts, depositing a thin, solid film. Types of PVD processes include ion plating, vacuum evaporation, thermal evaporation, electron beam evaporation, and sputter deposition. *Chemical vapor deposition (CVD)* is similar to PVD, but uses gases that combine on a hot surface to form the hard coating.
- **Functional trivalent plating**: The Faraday Technologies' Faradaic™ process is similar to the wet hexavalent plating process, with the capability to plate a thick, functional chromium coating using a trivalent chromium plating bath. It is intended as a "drop-in" alternative to hexavalent baths.

Some of these categories include several related processes that differ in their functional details. In addition, the categories often overlap to a certain extent, so that a given process may be classified differently in different sources. Surface coatings of various materials, typically other metals, alloys, and metal carbides or nitrides, can be applied using these processes. Coatings that may be used to replace hard chrome include those based on titanium, tungsten, cobalt, aluminum and silicon.

For each of these alternatives, the Institute assessed human health, environmental, technical, and cost criteria.

- **Health.** All the alternatives are superior to hexavalent chromium from the perspective of carcinogenicity. However, there are health hazards associated with the alternatives as well. For example, thermal sprays may contain cobalt powder, which is classified as possibly carcinogenic to humans. This is an improvement over hexavalent chromium, which is classified as a known human carcinogen.
- **Environment.** All the alternatives are superior to hexavalent chromium from the perspective of waste generation.
- **Technical criteria.** All of the alternatives have the potential to offer equivalent or better performance compared to hard chrome plating, although several have some limitations in their application. However, given the range of alternative processes and coating materials, there is likely to be at least one alternative that can meet the technical requirements of every hard chrome plating application.
- **Cost.** Many of the alternatives require a significant capital investment. On the other hand, the manufacturers of these systems claim that operating costs are significantly reduced. In some cases, new equipment may pay for itself within a few years through reduced operating costs.

Passivation of zinc plated parts and zinc galvanized steel

Passivation is a surface treatment that provides resistance to corrosion. The protection is afforded by a film or thin coating that interacts with the underlying metal. Hexavalent chromium is a standard passivating chemical for zinc and zinc-alloy plated parts, and zinc galvanized steel.

In passivation with hexavalent chromium, zinc plated parts are dipped into an acidic solution containing a mix of chemicals. The solution reacts with the plating to form a film of zinc chromate and other chromate compounds in both the trivalent and hexavalent state. This is referred to as a "conversion coating" because the hexavalent chromium solution converts the surface to zinc chromate. The hexavalent chromium reacts with the metal, forming an inert trivalent chromium layer with "releasable" hexavalent chromium ions that inhibit corrosion. The residual hexavalent chromium in the film will repassivate any areas on the surface that become compromised due to chemical or mechanical damage to the area. This property is referred to as "self-healing."

The Institute selected three alternatives for study: molybdates, trivalent chromium compounds, and mineral tie-coat.

- **Molybdate-based coatings** inhibit corrosion by forming a protective oxide layer on metal.
- **Trivalent chromium passivates** exist in several types. They vary in appearance, performance characteristics, thickness of the coating, and other characteristics.

- **The mineral tie-coat** process is a patented method of applying a thin mineral film on the surface of metal parts. It involves cleaning and conditioning the surface to be plated, immersing it in a sodium silicate solution, and then electrodepositing a mineral coating. The reaction between the coating and the metal surface forms a new protective surface.

For each alternative, the Institute assessed health, environmental, technical, and cost criteria.

- **Health.** All the alternatives offer significant improvements over hexavalent chromium from the perspective of carcinogenicity and occupational exposure. Chemicals used in the trivalent chromium passivation process may pose skin irritation/sensitization hazards similar to those used in the hexavalent chromium process.
- **Environment.** All of the alternatives offer significant improvements in terms of their environmental impact, although chemicals used in some molybdate formulations are toxic to aquatic life.
- **Technical criteria.** Performance criteria of interest for passivation of zinc include corrosion resistance, heat resistance, torque/tension performance, and appearance.
    - Several technical evaluations have concluded that molybdates do protect against corrosion, but do not perform as well as hexavalent chromium passivation on this metric. Trivalent chromium may be inferior, equal, or superior to hexavalent chromium on this metric, depending on the thickness of the coating, the plating method, the additives, and whether a topcoat was used. According to the manufacturer, mineral tie-coat has superior corrosion resistance when used with a topcoat.
    - Trivalent chromium compounds do not have the "self-healing" properties of hexavalent chromium, and require a sealer/topcoat in order to offer the same level of corrosion resistance. The manufacturer of the mineral tie coat process claims that it is equal to or better than hexavalent chromium in corrosion resistance (with topcoat), heat resistance, and torque/tension performance.
    - Trivalent chromium coatings differ in appearance from hexavalent chromium films. For most applications, color is a matter of user preference rather than of performance. In cases where a specific color is required, topcoats or sealers can be used to achieve the desired effect.
    - The molybdates offer better heat resistance than hexavalent chromium.
- **Cost.** Little cost information is available for these alternatives. One analysis indicated that a molybdate-based process would be similar to a hexavalent chromium process in terms of labor and capital, more expensive for chemicals and energy, and less expensive for waste processing.

DEHP

Di (2-ethylhexyl) phthalate (DEHP) is a synthetic organic chemical that is used primarily as a plasticizer to impart flexibility to rigid plastics such as PVC. It belongs to the class of chemicals known as phthalates, which are used primarily as plasticizers in PVC plastics in a range of applications. DEHP is used in a wide variety of flexible plastic products.

DEHP is classified by the U.S. EPA as a probable human carcinogen (Class B2). In 2000, IARC changed its classification for DEHP from Group 2A ("possibly carcinogenic to humans") to Group 3 ("cannot be classified as to its carcinogenicity to humans"). Animal studies have found that DEHP is toxic to the male reproductive system. When DEHP is metabolized in the human body, it produces compounds that are likely to be reproductive toxicants.

DEHP can be released to the environment during its production, distribution and incorporation into PVC. DEHP is also released when PVC material is heated or comes into contact with certain media. DEHP is not chemically bound into the polymer matrix and therefore can migrate out of the polymer. It is especially likely to migrate out of the polymer in the presence of fatty solutions. Indoor releases of DEHP to the air from plastic materials, coatings, and flooring in home and work environments can lead to higher indoor levels than are found in the outdoor air.

Use of DEHP in flexible PVC medical devices is a significant source of exposure, especially in neonatal care. The National Toxicology Program (NTP) has expressed serious concern about reproductive toxicity in male infants who are exposed to DEHP in medical care. The Food and Drug Administration has recommended that health providers consider using alternatives to DEHP-containing medical devices when high-risk procedures are to be performed on male neonates, pregnant women who are carrying male fetuses, and peripubertal males.

The Institute assessed alternatives to DEHP in PVC in three categories: medical devices for neonatal care; resilient flooring; and wall coverings. Because DEHP is used primarily as a plasticizer in PVC plastics, two types of substitutions may be relevant: substitution of an alternative plasticizer for use with PVC, or use of a different material that does not require addition of a plasticizer. For each application, the Institute examined alternatives in both categories.

Resilient flooring

Resilient flooring is defined as tile and sheet materials that have the ability to return to their original form after compacting. The Institute assessed alternative plasticizers for use in PVC flooring, as well as alternative flooring materials.

Alternative plasticizers

The Institute assessed four alternative plasticizers for use in resilient flooring: di (2-ethylhexyl) terephthalate (DEHT), di isononyl phthalate (DINP), dipropylene glycol dibenzoate (DGD), and di (2-ethylhexyl) adipate (DEHA).

- **Health.** All the alternatives appear to be superior to DEHP from the perspective of reproductive toxicity, although some evidence exists that DEHA may be toxic to the developing fetus. None of the alternatives has been classified as to carcinogenicity in humans, but there is evidence that DINP is carcinogenic in rodents.
- **Environment.** All of the alternatives are less bioaccumulative than DEHP. DEHA is less persistent in sediment and less toxic to fish than DEHP; the other plasticizers are similar to DEHP for these parameters.
- **Technical criteria.** Technical parameters of interest for alternative plasticizers in resilient flooring include volatility, ease in compounding, tensile elongation, compatibility with PVC, and loss of plasticizer during manufacture and use. All the alternatives are comparable with DEHP from the perspective of volatility and tensile elongation. All except DEHT are comparable to DEHP with regard to compounding, and all except DEHA are comparable to

DEHP with regard to PVC compatibility. DINP has greater emissions during use, DEHA is inferior with regard to emissions during both manufacturing and use, and DGD has unknown properties on this metric.

- **Cost.** All the alternative plasticizers are comparable in cost to DEHP for resilient flooring applications on a functional equivalence basis.

Alternative materials

The Institute assessed three alternative flooring materials: natural linoleum, cork, and polyolefin.

- **Health.** Many studies have examined the human health and environmental implications of choice of flooring materials. Most of these studies examine the entire life-cycle of the product, from production to disposal. In general, these analyses favor the alternatives over DEHP/PVC flooring. Polyolefin flooring has the advantage of very low VOC emissions during use.
- **Environment.** Linoleum and cork are derived from sustainable materials and are biodegradable, making them superior to DEHP/PVC on these metrics. Cork offers the additional advantage that it can be installed without the use of adhesives. Linoleum has less impact on energy use from a life cycle perspective than DEHP/PVC flooring.
- **Technical criteria.** Technical criteria of interest for flooring applications include the availability of a range of colors and patterns; ease of maintenance; and recyclability. Linoleum and polyolefin flooring materials offer a range of colors and patterns that make them similar to DEHP/PVC in this regard, while cork is more limited in this respect. Ease of maintenance is generally similar across all the options. Polyolefin flooring is recyclable; linoleum and cork are not.
- **Cost.** The alternatives are generally similar to DEHP/PVC in purchase and installation cost, although costs vary depending on application. All the alternative materials have a longer expected life span than DEHP/PVC, further decreasing the overall cost.

Medical devices for neonatal care: sheet and tubing applications

Two distinct categories of medical devices used for infants in neonatal intensive care facilities were the focus of this study: bag/sheet devices, and tubing. The Institute investigated both alternative plasticizers and alternative materials for this application.

Alternative plasticizers

The Institute assessed five alternative plasticizers for use in medical devices.

- **Trioctyl trimellitate (TOTM)** is a clear, oily liquid that is a high production volume plasticizer in the US. In the medical device industry, TOTM is currently used primarily in blood and bag infusion sets.
- **Di (2-ethylhexyl) adipate (DEHA)** has properties that make it a useful plasticizer for materials used to store medical solutions that must be kept cold.
- **Butyryl trihexyl citrate (BTHC)** is a plasticizer specifically designed for use in medical articles, especially blood storage bags.

- **Di (isononyl) cyclohexane-1,2-dicarboxylate (DINCH)** is the hydrogenated product of the corresponding di C9 phthalate ester (DINP).
- **Di isononyl phthalate (DINP)** is currently used as a plasticizer in medical tubing devices.

TOTM, DEHA, BTHC, and DINCH are applicable for use in bag/sheet devices. Based on their elastic recovery properties, DEHA is also applicable for use in tubing, and DINP was assessed for use in tubing only. For each of these alternatives, the Institute assessed health, environmental, technical, and cost criteria.

- **Health.** All the alternatives are superior from the perspective of carcinogenicity and reproductive toxicity, although there are grounds for concern about DINP and DEHA, as noted above. The alternatives are generally superior with regard to skin, eye, and respiratory irritation, with some exceptions.

  A key issue associated with potential health effects is the ability of a plasticizer to exude from the polymer matrix as well as its potential to produce metabolites of concern. DEHP is lipid soluble and therefore is likely to exude out of the polymer when exposed to a lipid-soluble solution. TOTM, BTHC and DINCH appear to be less likely to migrate out of the polymer in the presence of lipid-soluble medical solutions. DINP appears to be similar to DEHP in this regard, and the potential for DEHA to migrate is not well defined.

  Little information is available on the health effects of metabolites associated with the alternatives assessed. The exception is BTHC, which can be metabolized to butyric acid, a chemical that is associated with negative impacts on the GI tract, liver and skin.

- **Environment.** All the alternatives are equally or less persistent in sediment compared to DEHP (DINCH persistence is unknown). The alternative plasticizers studied are all superior from the bioaccumulative and aquatic toxicity perspectives, with the exception of DINP, which has aquatic toxicity similar to that of DEHP. The aquatic toxicity of BTHC is not known.

- **Technical criteria.** Important criteria for both sheet/bag and tubing applications include flexibility when cold, clarity, compatibility with PVC, sterilizability, and plasticizer loss during manufacture and use. In addition, elastic recovery is an important parameter for tubing applications. Some important differences between DEHP and alternatives are noted below:
  - TOTM is inferior on measures of cold flexibility; DEHA is similar; and the other three alternatives are superior to DEHP on this measure.
  - DEHA is less compatible with PVC than DEHP.
  - BTHC is not steam sterilizable, while DINP tolerates steam sterilization better than DEHP. The sterilizability of DINCH is not known.
  - TOTM, BTHC, and DINCH are superior to DEHP on measures of plasticizer loss during use. DEHA and BTHC are inferior to DEHP on measure of plasticizer use during manufacture.

- **Cost.** Costs of DEHA and DINP are similar to those of DEHP, while the other alternatives are more expensive.

Alternative materials

The Institute evaluated five alternative materials for medical devices: ethyl vinyl acetate (EVA), polyolefins (polyethylene and polypropylene), glass, silicone, and polyurethane. Some of these could replace DEHP/PVC sheets, while others could replace DEHP/PVC tubing.

- **Ethyl vinyl acetate (EVA)** is a copolymer blend of vinyl acetate, ethylene, and ethyl acetate that has been used for many years in medical sheet applications. EVA bags are also used for custom mixing of drugs by pharmacies.
- The **polyolefins** polyethyelene (PE) and polypropylene (PP) are widely used compounds that are valued for their flexibility, transparency and toughness.
- **Glass** was commonly used to store medical solutions prior to the extensive use of plastics.
- **Silicone** is a synthetic rubber that can be used in medical tubing. Silicone tubing is translucent, biologically inert, and inherently flexible.
- **Thermoplastic polyurethane (TPU)** is used in tubing applications.

The Institute assessed health, environmental, technical and cost criteria for each alternative.

- **Health.** All the alternative materials are superior to DEHP/PVC from the perspective of leaching plasticizers with known health concerns, since none of the alternatives utilize plasticizers. While rigid and more difficult to handle due to the potential for breakage, glass is the most inert material available on the market today for health care.
- **Environment.** All the alternative materials are superior to DEHP/PVC materials plasticized with DEHP in the sense that they do not generate hazardous chlorinated organic compounds when incinerated. However, there is significant variation among the alternatives in level of toxicity over the life cycle of the product. Manufacture of TPU involves use of diisocyanates that are listed on the Massachusetts Science Advisory Board's list of more hazardous chemicals. Incineration of TPU also releases hazardous chemicals including isocyanates and hydrogen cyanide. On measures of recyclability, glass is far superior to PVC containing DEHP; other alternatives are equally or more difficult to recycle compared with DEHP/PVC.
- **Technical criteria.** Using materials that are inherently flexible eliminates one of the key problems with DEHP/PVC, the potential for the material to become brittle due to loss of plasticizer. Therefore, the alternatives may have longer shelf lives than their DEHP/PVC counterparts and the possibility of leached plasticizer entering the body is eliminated. Other performance criteria of interest for these uses include elastic recovery, cold flexibility, sterilizability, gas permeability, and manufacturability. Some key differences between the alternative materials and DEHP/PVC are noted below.
    - TPU exhibits inferior elastic recovery.
    - Only silicone is superior to DEHP/PVC from the perspective of cold flexibility. Glass is not flexible.
    - Neither EVA nor polyolefin is appropriate for steam sterilization.
    - Manufacturability (i.e., the ease with which the material can be transformed into the finished product) is superior for glass, and inferior for EVA, silicone and TPU.

- **Cost.** Currently raw material prices and relative use costs for the alternatives vary relative to DEHP/PVC. However, costs of the alternatives are changing in response to increasing demand for and supply of DEHP- and PVC-free medical devices. Technical differences among materials can also be a source of cost savings. For example, EVA film can be manufactured at a thinner gauge than similar PVC film, thus reducing the per-item cost. For tubing applications, silicone and TPU can be used for longer periods of time than PVC/DEHP, thereby reducing the cost differential. Large hospital chains are also driving market changes, and cost reductions, by specifying PVC- or DEHP-free materials in their purchasing contracts.

Wall coverings

DEHP/PVC (vinyl) wall coverings are used in both commercial and residential settings for decorative and protective purposes. Vinyl wall coverings are popular because they are available in a wide array of patterns and colors and are both durable and scrubbable.

It is worth noting that there are viable process alternatives to vinyl wall coverings, including painted wall surfaces or using different wall materials (such as wood paneling). They differ significantly from wall coverings in terms of aesthetics, but can be functionally equivalent. These process alternatives were not included in the assessment.

Alternative plasticizers

The Institute assessed two plasticizer alternatives for use in wall coverings: DEHA and DINP.

- **Health.** As previously discussed, DEHA is potentially toxic to the developing fetus and DINP has been found to cause cancer in laboratory animals. The potential for exposure to DEHA is greater than for DEHP.
- **Environment.** DEHA is less persistent in sediment than DEHP, and DINP is similar to DEHP on this parameter. Both are less bioaccumulative than DEHP. DEHA is less toxic to fish than either DEHP or DINP.
- **Technical criteria.** Criteria of interest for wall coverings include volatility, compounding, tensile elongation (life of product), compatibility with PVC, and emissions (during manufacture and use). DINP is similar to DEHP on all measures. DEHA is inferior on measures of volatility, PVC compatibility, and emissions during manufacture and use. Compared with DEHP, DINP has better high temperature performance and extraction resistance, which improves is processability.
- **Cost.** Both plasticizers are similar to DEHP in cost per pound applied. Compared with DEHP, DINP processing emits lower levels of plasticizer mist from process equipment. As a result, less plasticizer is lost to the air and more retained in the product, yielding overall cost savings.

Alternative materials

The Institute assessed five categories of alternative materials: glass woven textiles, cellulose/polyester blends, wood fiber/polyester blends, biofibers, and polyolefins.

The Institute evaluated health, environmental, technical, and cost criteria for each of these alternative materials.

- **Health.** The primary concern with DEHP in wall coverings is exposure during manufacture and use. No plasticizer is emitted during manufacture or use of the alternative materials, but there may be other volatile organic emissions. In particular, the glass textile and polyolefin alternatives have similar potential VOC exposures compared to DEHP/PVC. Little information on exposure associated with the other materials was available.
- **Environment.** All the alternative materials except the polyolefins are derived from more sustainable materials than DEHP/PVC. Some offer the advantage of being recyclable and one alternative material (wood pulp/recycled paper) is compostable. Two of the alternative materials (BioFibers and polyolefins) are routinely coated with Teflon® finish, which may pose occupational and other hazards.
- **Technical criteria.** All the alternatives are similar to DEHP/PVC in ease of maintenance. Wood fiber/polyester and cellulose/polyester alternatives offer a range of colors and patterns similar to those available with DEHP/PVC.
- **Cost.** Most of the alternatives are comparable in price to high-end DEHP/PVC wall covering products, but are much more expensive than low-end vinyl.

Economic Assessment

Financial considerations are discussed within each alternatives assessment. The information presented for each case varies according to context. For example, the price of materials is an important parameter for some cases, while operation, maintenance, or disposal costs may be salient for others.

Specific lessons that can be drawn from the alternatives assessments conducted here include the following.

- Some alternatives can be adopted without any adverse effect on Massachusetts employment or competitiveness. The formaldehyde alternatives assessment, for example, shows that elimination of formaldehyde dry sterilant from use in Massachusetts hair salons would produce savings and make sanitation standards at Massachusetts hair salons consistent with those in the rest of the country. Similarly, Massachusetts schools could adopt alternatives to formaldehyde-fixed dissection specimens without increasing costs.
- Massachusetts manufacturers could gain market share through adoption of some alternatives. For example, some Massachusetts firms are working to produce DEHP-free medical devices. With growing demand for such devices, firms may have opportunities for growth in this area.
- Some alternatives require capital investment at the outset. For some technologies, this investment will pay for itself over time in reduced operating costs.
- In some cases, alternatives are more costly at this time (*e.g.*, PCE vapor degreasing solvent alternatives) and for many no firm cost conclusions can be reached without more information.

In addition, the Institute convened a group of economic experts to assess potential state-wide implications of adopting alternatives for employment in the Commonwealth and competitiveness of Massachusetts firms. The panel of experts worked with TURI to develop a framework for analysis of the economic implications within Massachusetts of alternatives adoption. This framework will

assist users in analyzing likely economic impacts by clarifying the situational characteristics and factors that determine the outcome. Characteristics that may help to determine the economic implications of alternatives adoption include the size of the Massachusetts market in comparison with other markets, price sensitivity of consumers, nature of barriers to adoption, capacity of the workforce, and availability of useful and timely information.

Broader conclusions that emerged from the Institute's literature review and consultation with experts include the following.

- First, there is strong evidence that adoption of safer alternatives can produce economic benefits. This is a lesson from the experience of the TURA program, the literature on this topic, and some of the sectors considered in this report.
- There are some cases in which substituting chemicals or processes may have negative effects on some firms, even if there is a positive effect on the state economy more generally.
- There are many opportunities for government to support a positive economic outcome and to mitigate any negative effects for individual firms. In some instances, targeted assistance to industry can facilitate adoption of safer alternatives that will yield employment and competitiveness benefits over time.

Conclusions

The detailed information provided in this report should serve as a valuable resource for anyone interested in understanding the alternatives to the five chemicals that were examined in this study. The report is designed to be useful to policy makers, industry, public health and environmental professionals and advocates, and other stakeholders. In every case, at least one alternative was identified that was commercially available, was likely to meet the technical requirements of many users, and was likely to have reduced environmental and occupational health and safety impacts compared with the base chemical.

The active involvement of all stakeholders was key to the success of this project. Their expertise, willingness to collaborate and share perspectives, and review of the report were invaluable. The involvement of a wide range of stakeholders throughout the project resulted in a more accurate assessment, more valuable results, and increased understanding of the issues, challenges and perspectives among stakeholders. Stakeholder contributions to this project also revealed in detail the substantial investment firms have made in developing safer products. For example, efforts to reduce the negative impacts of formaldehyde in wood products have succeeded in producing formulations with greatly reduced off-gassing. Similarly, years of effort have been devoted to developing reliable lead-free electronics.

Many promising alternatives were identified during this study. Some of these will require further work to determine their practicality and applicability for specific applications. Such work will speed up the adoption of these alternatives, and could include detailed discussions with vendors and users, independent laboratory testing of technologies, pilot-scale industrial installations, supply chain workgroups and demonstration sites. The Institute has had success using these approaches for industrial toxics use reduction, and believes that there are many parallels for small businesses and consumer products.

The Institute's experience with this study has also yielded important lessons about the methodology of alternatives assessment. The experience of the Institute and the information contained in this report indicate that alternatives assessment is a useful approach to organizing information about chemicals and alternatives. The Institute encourages readers to build on the work that has been done

in this study, both by conducting alternatives analyses on other chemical uses, and by working to refine and streamline this methodology.

Finally, this study will have been a success if it spurs discussion and debate. It is the Institute's hope that the information in this report will serve as valuable source material for those discussions.

TURI Five Chemicals Alternatives Assessment Study

Chapter 2. Approach and Methodology

2.1 Approach

This chapter presents the approach taken by the Institute to perform the study and describes the methodology used to assess alternatives. The Institute's approach was designed to achieve the goals stated in Section 1.2, while recognizing the constraints of time and resources. As a "pilot project" the approach had to be flexible, allowing for changes in the methodology as it was implemented. As a result the project outcomes are both a more robust assessment methodology and a series of informative alternatives assessments for the five chemicals.

A consistent process for setting priorities and evaluating the alternatives for the five chemicals was first established. The methodology for this study is outlined in a companion document entitled "Five Chemicals Study Methodology - Alternatives Assessment Process Guidance" (see Appendix A). That document reflects the original methodology developed, and provides guidance to those conducting assessments. The guidance document was especially important because, due to the short timeline and broad scope of the project, different Institute staff members and their technical experts conducted the alternatives assessments simultaneously.

It is important to note that this study was not conducted in a manner designed to assess the relative safety of one alternative over the other. Rather, alternatives were compared to the study chemical as a baseline. The following graphic illustrates the phased approach that was used in this study.

Figure 2.1 Project Approach

Phase I focused on characterizing the potential environmental health and safety impacts of each chemical and identifying the priority uses in Massachusetts. In Phase II the Institute identified alternative chemicals and/or technologies for those priority uses and utilized a set of environmental, health and safety screening criteria to determine those alternatives that warranted assessment. In addition, where there were more potentially feasible alternatives than could be assessed in this study, additional criteria were used to determine those alternatives that were a high priority for assessment.

Each of these two initial phases was performed under an aggressive schedule so as to allow as much time as possible for completion of the assessments. Phase III represented the bulk of the assessment work, involving evaluation of the technical financial, and environmental and human health and safety parameters of the identified alternatives.

2.2 Stakeholder Involvement

To produce useful results in the time available it was necessary to narrow the scope of the project to areas that would have the greatest positive impact on Massachusetts. The Institute evaluated existing alternatives assessments would provide the most valuable and useful information for them. Representatives of Massachusetts companies, government, non-government environmental, health and labor organizations, and industry associations participated in a series of stakeholder meetings to assist the Institute in identifying significant uses, both in manufacturing and in products, and in prioritizing the uses and alternatives to be assessed.

Organizations participating at stakeholder meetings represented a wide range of Massachusetts interests, including but not limited to:

- Alliance for a Healthy Tomorrow
- Associated Industries of Massachusetts
- Astro Chemical
- Boston Scientific Corporation, Inc.
- Children's Hospital of Boston
- Clean Water Action
- Greater Boston Physicians for Social Responsibility
- Haemonetics Inc.
- Korean Dry Cleaners Association
- M/A-COM, a subsidiary of Tyco Electronics
- Massachusetts Public Interest Research Group
- Massachusetts Chemistry and Technology Alliance
- Massachusetts Coalition for Occupational Safety and Health
- Massachusetts Department of Environmental Protection
- Massachusetts Office of Technical Assistance
- Massachusetts State Legislature
- New England Fabric Care Association
- New England Korean Dry Cleaners Association
- North Shore Labor Council
- Rohm and Haas Electronic Materials
- Saint-Gobain
- Solutia
- Teknor Apex
- We Care Cleaners
- Western Massachusetts Coalition of Occupational Safety and Health

Stakeholder participants provided valuable contributions in three areas. First, they helped to refine the methodology and project plan. Second, they helped to narrow the scope of the project to areas that would have the greatest positive impact on Massachusetts. Third, stakeholders provided their own experience, expertise, and contacts to supplement the Institute's science and technical research. Comments were solicited at meetings, through email and telephone conversations, and through a draft report review process.

Four structured process meetings were held, as well as several less formal topic-specific meetings that addressed a specific method, chemical, or economic topic. The structured process meetings were held in Lowell and each were attended by close to forty participants:

1. September 26, 2005 - Methodology and Project Plan
2. October 21, 2005 - Use Prioritization
3. November 9, 2005 - Alternatives Prioritization

4. April 11, 2006 - General Project Update

While, in general, the input from stakeholders varied depending on their perspective, concerns and interests, during the use prioritization phase there were some common themes that emerged, including:

- A high priority should be placed on uses that are associated with higher potential exposure to the public and/or workers in small businesses.
- A low priority should be placed on uses where alternatives are already being readily adopted, or where significant research on alternatives is being carried out by others.

Stakeholders assisted in the identification of experts in academia, industry, national trade associations, labor, and environmental and health groups. Institute staff conducted on-site visits with specific industries to identify pertinent manufacturing and product performance criteria, as well as to obtain industry-specific financial information. For example, project staff visited several drycleaners using perchloroethylene and alternatives, and a resilient flooring manufacturer using DEHP and alternative plasticizers and materials. Certain industry experts met with Institute staff to address such topics as formaldehyde chemistry in adhesives, technical criteria for shooting range ammunition, and the toxicology of certain plasticizers. The stakeholder meetings and follow-up communications were very helpful in identifying highpriority uses and alternatives for assessment, as well as in ensuring the technical accuracy of Institute findings. Broad and detailed information collected at each stage was shared and posted on the project website at www.turi.org. At meetings focused on prioritization, each chemical was discussed separately, reviewing its hazards, uses and potential alternatives. Specific input from stakeholders on each chemical and use is included in the chemical chapters of this document.

2.3 Phase I: Chemical Impacts and Uses

2.3.1 Potential Impacts of Chemicals (Phase Ia)

Potential human health and environmental impacts associated with the use of the five chemicals were summarized as part of the prioritization process. This information was obtained primarily from public databases and published reference sources. In addition, peer-reviewed scientific journals, other published reference materials, industry trade group resources (publications and web sites) and advocacy group resources (publications and web sites) were used to provide more depth or to identify newer, emerging information. The Institute did not conduct a comprehensive review of toxicological studies.

The objective of this summary was to provide background information on the chemical, highlight environmental, health and safety issues, and provide a baseline against which the alternatives could be compared.

2.3.2 Identify Uses (Phase Ib)

Uses of chemicals in Massachusetts range from manufacturing processes to services to consumer products. For each of the five chemicals considered in this study, the majority of the major uses of the chemical were identified. This information is included in Appendix B. The range of uses identified for each chemical was so wide and varied that the Institute was not be able to evaluate all of them in the short time span allowed for this project. It was therefore necessary to narrow the scope to evaluate uses that were considered a high priority for Massachusetts (Phase I.c). In order to prioritize uses for further study, information was gathered from the literature and experts to determine the following:

- Major suppliers of the chemical

- Major derivatives, components and/or end products that incorporate the chemical or use the chemical as a feedstock, and their manufacturers - this considered the Massachusetts, domestic, and international markets
- Major distributors, retailers, or customers of end product, focused on Massachusetts customers
- Functionality requirements of chemical or component or end-product - for example, why is the chemical used and what is it used for?
- Relevant stakeholders, including businesses, industry associations, environmental, public health, and labor organizations.

2.3.3 Prioritize Uses (Phase I.c)

Meetings with Massachusetts stakeholders, as described in Section 2.2, were organized to provide information to stakeholders on the chemical use prioritization criteria, review the list of uses researched by the Institute, and solicit input from stakeholders on priority uses for further investigation. The Institute's final selections of high priority uses for study are listed in Table 2.3 A. The final selections were made based on the following criteria:

- Importance to the Commonwealth of Massachusetts:
  - Use in manufacturing: Total quantity of chemical used in manufacturing operations in Massachusetts
  - Use in consumer products: Total quantity of chemical used in products sold in Massachusetts.
  - Potential availability of alternatives.
- Exposure potential (environmental, occupational, and public health).
- Potential value to Massachusetts businesses and citizens of the alternatives assessment results. Specifically, the preferences of the pertinent stakeholders for each chemical were given priority.

In addition, for each chemical the Institute attempted to select at least one use that was applicable to each of three end users, i.e., Massachusetts manufacturers, small businesses and consumers, when making the final selection of priority uses to study. A detailed discussion of the prioritization process for each chemical is included in the relevant chemical chapter.

Table 2.3.3 : High Priority Uses

2.4 Phase II: Alternatives

2.4.1 Identify Alternatives (Phase II.a)

Alternatives to toxic chemicals may include drop-in chemical substitutes, material substitutes, changes to manufacturing operations, changes to component/product design, and other technological solutions. Existing and emerging alternatives were identified for each of the high priority uses of the chemicals. In addition, industry specific performance requirements were identified.

Sources of information on available and emergent alternatives included trade associations, manufacturers, U.S. Environmental Protection Agency (EPA) documents and programs, municipal, state and federal pollution prevention research centers, literature and internet searches, and other technical experts. In addition to experts at the Institute, experts from the University of Massachusetts Lowell, other universities, industry, medicine and many other organizations were consulted. As a result, more than 200 potential alternatives were identified for the 16 different use categories of the 5 chemicals. Each alternative typically consisted of several different chemical constituents.

2.4.2 Screen Alternatives

To eliminate from further study any chemical alternatives that would pose a high risk to the environment or human health, alternatives were subjected to an initial environmental, health and safety (EH&S) screen. If a specific alternative was determined to be persistent, bioaccumulative and toxic ("PBT"), a known or probable human carcinogen, or on the TURA Science Advisory Board's (SAB) 1999 More Hazardous Chemicals list, it was eliminated from further consideration. In order to be screened out as a "PBT" a substance needed to exceed the EPA criteria for two of the three PBT indicators (very persistent, very bioaccumulative, and high concern for toxicity). The PBT screening process utilized the EPA's PBT Profiler, a predictive modeling tool. Chemicals that are listed in either the EPA Group A or B, or the International Agency on Research of Cancer (IARC) Group 1 or 2A (carcinogenic or probably carcinogenic to humans) were also eliminated from further study. In the SAB list, "hazard" includes inherent toxicity, potential for exposure through dispersal in the work place (based on the physico-chemical properties of the chemicals such as vapor pressure) and indicators of safety of use (e.g., flammability).

The initial EH&S screen was only applied to the substances present in the alternative formulation or product, not to feedstock materials upstream, or breakdown products downstream. For example, if an alternative material is a polymer made from a carcinogenic monomer, it would not be screened out during this initial phase. A detailed discussion of the screening criteria is included in Appendix A.

2.4.3 Prioritize Alternatives for Study

At this stage, all available alternatives that had passed the EH&S screening were evaluated to determine which alternatives would be assessed fully. The objective of this step was to select for full assessment a small number of alternatives (typically 6 or fewer) that appeared most likely to be feasible and safer. The following criteria were considered in prioritizing the alternatives to be assessed:

1. Performance: Known performance of the alternative, which could include maintenance and durability as well as specific performance requirements and potential for future performance enhancements.
2. Availability: Number of suppliers or manufacturers and volume produced.
3. Manufacturing Location: Products or materials manufactured in Massachusetts were considered a higher priority.
4. Environmental and human health and safety issues: Concerns identified during the initial EH&S screening.
5. Global Market Effect: Pending or existing global restrictions
6. Classes of Similar Alternatives: Where several similar alternatives were identified, one representative of that type was chosen for further study.
7. Cost: Compared to the existing chemical and considering the potential for future cost reductions associated with increased production volume. Includes consideration of raw material costs, storage and handling costs, disposal costs, etc.
8. Value to Massachusetts Stakeholders: If an alternative was of particular interest to one or more stakeholder, or there appeared to be a high value to Massachusetts for the alternative to be included in the assessment, it was given a higher priority.

Meetings with stakeholders, as described in Section 2.2, were organized to provide information on the alternatives prioritization criteria, review the list of alternatives researched by the Institute, and solicit input

from stakeholders on alternatives for the assessment phase of this study. The final list of alternatives for full assessment is listed in Table 2.4.3.

Table 2.4.3 : High Priority Alternatives

Some alternatives, particularly those comprised of single chemicals, were assessed as generic alternatives (e.g., TOTM plasticizer or steel fishing sinkers). Other alternatives vary considerably depending on the precise formulation or manufacturer. In these cases a representative product was assessed (e.g., products for aerosol brake cleaning and educational specimens for dissection). The choice of a particular manufacturer's product as representative does not constitute an endorsement of that product, or indicate that other similar products are not worthy of further consideration by users.

2.5 Phase III: Alternatives Assessment

Information for each aspect of the assessment - technical, environmental, human health and safety, and financial - was collected and reviewed. The specific types of information and procedures for evaluating them are described in the following sections. When all available data had been collected for each alternative, the information was reviewed and summarized in a qualitative summary table for that particular use.

For each critical parameter in the summary table, a qualitative assessment of "better than" (+), "similar/equivalent" (=), or "worse than" (-) the chemical being studied was indicated. Where insufficient information was available to make a determination, a "?" was indicated. It should be noted that these are approximate indicators only, and that all parameters should not be considered equal (for example, most users would not consider "carcinogen" with equal weight as "irritant." For these reasons, it is not appropriate to simply add up the total number of +, - , and = in order to determine the "best" alternative. Users should look to the summary tables, and the supporting assessment text and tables, for guidance in conducting their own assessment of feasibility and preferred alternatives. Their own assessments will include personal or corporate values, priorities, levels of concern/acceptability and situation-specific modifications and additions to the assessments included in this report.

2.5.1 Technical Feasibility

The study identified application-specific performance requirements that were required for each use - including longevity, key performance requirements, key physical characteristics and key quality parameters. One primary source of this information was industry/user experience with the chemicals and their substitutes. User comments and review were sought from manufacturers, trade associations and customers who use the chemical or its derivatives.

The quality of performance information that the Institute was able to obtain on the alternatives varied considerably among uses. For some uses information was obtained from published robust studies or directly from several users of the alternatives or technical experts. For other uses assessments relied on information provided by product manufacturers. This directly impacts the degree and nature of follow-up that would be required for a user to make a determination of technical feasibility for their unique application. Where appropriate, the study also included readily available information on life cycle considerations, such as maintenance requirements, although it is important to note that this study did not include a comprehensive life cycle assessment.

The summary tables include a relative assessment of key performance parameters as appropriate for each use, compared with the reference chemical or product, using the symbols discussed above.

2.5.2 Financial Feasibility

Financial information was sought for each alternative (see Appendix A for table of financial assessment parameters). Data sources included manufacturers, stakeholders, the Chemical Economics Handbook and other publicly available reference sources. The amount of financial information available for each use and alternative varied widely. In many cases, particularly for emerging alternatives with few or no current instances of actual use, no hard cost information was available; if so, this is indicated in the discussion of those particular alternatives. In other cases, sufficient cost information exists to conclude that the alternative is either more or less costly than the current chemical use; again, this is noted in the discussion where appropriate.

Other significant barriers to determining financial feasibility of alternatives include: manufacturers' reluctance to share cost information, facility or application-specific nature of many costs, and the fact that cost comparisons today may not be the final answer tomorrow for technologies not yet widely adopted, since economy of scale and market size will often reduce costs. This issue is discussed more thoroughly in Chapter 8.

For these reasons, the financial assessments should be viewed as a preliminary look at potential impacts as a result of adopting an alternative. Those wishing to conduct a more thorough financial analysis will need to include application- and facility-specific impacts, including the cost of raw material, capital improvements and new equipment, processing changes, waste disposal, energy, worker health and safety protection, permitting, and other life cycle costs, such as end-of-life product management. Tools and information for "total cost assessment" and other financial assessment approaches may be found in many existing publications (contact the Institute for more information).

2.5.3 Environmental and Human Health Assessment

The Institute assessed each alternative for its impact on human and environmental health relative to the chemical of concern. A set of pertinent environment, health and safety (EH&S) parameters was evaluated. The list of the parameters and their associated metrics, concern levels and primary data sources is presented in Appendix A. The Institute did not perform a detailed toxicological review for each alternative. Rather, the study relied on information obtained from authoritative bodies1, with the most recent validated data presented first or data that has been referenced by a US governmental agency such as the Environmental Protection Agency (EPA), the Centers for Disease Control (CDC) and the Occupational Safety and Health Administration (OSHA). The primary sources were those available from the National Library of Medicine's Toxicology Data Network (ToxNet)2. Where this type of information was not available, or where more recent studies called into question the results previously published by authoritative bodies, supplementary information was noted.

Differences of opinion among experts and variations in test results were also noted where applicable. Table 2.5.3 lists the environmental, health and safety parameters that were researched and evaluated. Specific sources of information for individual parameters are provided in the complete EH&S assessment tables in Appendix D. These sources also contain detailed background information about the parameters. Unless otherwise noted in the tables in Appendix D, the assessments used the US EPA PBT Profiler3 software to determine environmental persistence, bioaccumulation potential and toxicity for organic chemicals. The summary table for each use found within the individual chemical sections of this report includes the EH&S parameters judged to be most critical to the particular use and set of alternatives.

In many instances key parameter data were not available for all alternatives. In this case a "?" was inserted into the summary table. It is important for users of this report to consider the implication of data gaps for their particular situation. In some cases users may have access to data that the Institute did not, thereby

allowing them to make a fuller comparison of the alternative to the reference chemical. In others, users can assume that a question mark is indicative of a need for additional research or testing.

Where appropriate the study also included readily available information on key life cycle considerations, such as waste disposal limitations, energy usage required during manufacture, impact on product recyclability or reuse potential, etc. This was typically included where complex materials or products were being assessed, rather than individual chemicals or formulations because the life cycle issues become more important in those types of comparisons. It is important to note that this study did not include comprehensive life cycle assessments of each alternative, but rather provides qualitative discussions of life cycle considerations where appropriate.

Table 2.5.3: EH&S Parameters Considered in Assessing Alternatives

2.5.4 Procedures Followed for Evaluating Mixtures, Material Alternatives, and Process Alternatives

For the purposes of this study, a chemical is considered to be any element, chemical compound or mixture of elements and/or compounds. Chemicals are the constituents of materials. A chemical "mixture," also known as a chemical "preparation," includes multiple chemicals. A one-for-one chemical substitution represents the simplest type of alternative, where the chemical being evaluated can be directly substituted with another chemical that satisfies the functional requirements for the particular use. In this instance, the alternatives assessment was relatively straightforward; information associated with the parameters in Appendix A were obtained, verified and presented in a way that allows a direct comparison of the two chemicals.

Evaluating Mixtures

Often the chemicals being evaluated are used in formulations of multiple chemicals. In this case, each of the chemical constituents of the mixture was considered in the assessment in a manner similar to that used for individual chemicals (as above). The Institute obtained environmental and human health information about each of the chemical constituents of a mixture, and performance and cost information for the overall formulation when doing the assessment. The primary source of information on the constituents of a mixture was the product Material Safety Data Sheet (MSDS). For the purposes of this study, the Institute focused on the primary constituents of each formulation being evaluated. Specifically, constituents present in amounts exceeding 1% by mass were included in the assessment. Although no quantitative indicators were calculated for mixtures during the evaluation process, the general approach was to consider the weight percents of constituent chemicals in determining overall EH&S impacts. When formulation breakdowns were presented on associated MSDSs as a range, the Institute assumed the average weight percentage of the range presented.

As the EH&S factors associated with the constituents of a mixture were determined, their relative significance to the overall EH&S characteristic of the mixture was evaluated based on the weight percent within the mixture. The actual approach to evaluating the EH&S impact of a mixture differed depending on whether the chemicals in the mixture cause similar or different health effects. If the health effects are similar (e.g., two constituents are central nervous system (CNS) depressants), their weight percentages were added and the overall impacts of the combined chemicals assessed. If the health effects are different (e.g., one chemical is a CNS depressant, while another is a respiratory irritant), the effects were evaluated separately based on the weight percentages of each constituent.4 When alternative mixtures were evaluated in summary tables, an attempt was made to apply the weighting criteria described above, although the

resulting indicator typically reflected the most problematic constituent for that mixture. Evaluating Material AlternativesA material is defined as the basic matter (e.g., metal, wood, plastic, fiber) from which the whole or the greater part of something physical (e.g., a machine, tool, building, fabric) is made. In some cases the chemical being studied is used to impart particular qualities in a material. For instance, DEHP is used in poly vinyl chloride (PVC) to make this otherwise rigid plastic flexible. Rather than find other ways to make the material (PVC) less rigid, there may be opportunities to find alternative materials (e.g., other plastics) that are inherently more flexible, therefore bypassing the need for this particular chemical additive.

When evaluating material alternatives, performance and cost considerations may be readily compared. However the impact of a material on environmental or human health may not be as readily assessed as it can be for chemical substitutes. For materials, life cycle considerations may become more important. For this study the Institute looked both at EH&S impacts when appropriate and at life cycle issues that, based on the research, appear to be of most significance relative to the material being replaced. The inclusion of life cycle considerations only occurred when a preponderance of literature indicated that life cycle issues exist that should be accounted for. It is important to note that comprehensive life cycle assessments were not performed as part of this study. Rather, when the research indicated that at a particular point in a material's life cycle there are important positive or negative impacts, these were noted qualitatively relative to the material being substituted.

Evaluating Process Alternatives

For the purposes of this study, process alternatives are those that employ a different technology, process or approach to achieve the objective or function of the original product or process associated with the chemical. For example, when considering alternatives to perchloroethylene in vapor degreasing, one approach might be to change the upstream process to use lubricants that either do not require cleaning, or are easier to remove using water-based surfactants. The feasibility of this type of alternative can be assessed, but it is very difficult to compare the EH&S impacts quantitatively. These types of alternatives are included in the study where appropriate, and their feasibility assessed qualitatively. Where our research indicates that there are important positive or negative attributes or impacts relative to the substance being substituted, these are mentioned.

2.6 Economic Impact Study

As part of the study, the Commonwealth requested an analysis of potential impacts on employment level and economic competitiveness of the Commonwealth from adopting any alternative chemical or technology. Dependable economic and employment predictions are lengthy and expensive to prepare, and require a great deal of information about both broad economic conditions and material and industry-specific costs. In addition, the impacts cannot be generalized across products and industry sectors. Rather, the impacts depend on the many different situations that exist for the five chemicals, their uses and alternatives.

Therefore, the approach taken in this study was to develop guidance to those seeking to quantify economic impacts from substitution by identifying the principal factors that influence the result for a given situation. Case material was used to create a useful list of economic factors present in particular situations. Further development by experts of the influences, duration, dynamics, interactions, sector specificity or other characteristic of these economic factors led to useful guidance regarding economic impacts for specific alternatives. This evaluation was completed using the following process:

1. The Institute briefly reviewed existing literature on the economic impact of environmental regulations, alternatives assessment and the TURA program.

2. Case materials were created for the following sectors: formaldehyde in building materials, lead in electronics, and perchloroethylene in dry cleaning. This material was used to focus the discussion by experts. (See Appendix E)
3. Ten experts in the economics of technology change and innovation were gathered for a facilitated discussion. They included representatives from Associated Industries of Massachusetts, the Small Business Association, the Massachusetts Manufacturing Partnership, Tufts University, Northeastern University, the University of Massachusetts, the Economic Development Research Group, Tellus Institute, and the Environmental Management Accounting Research and Information Center. Using the case materials, a list of economic factors and their influences was developed.

Chapter 8 presents a summary of this analysis and a framework outlining the factors that may influence the economic impact of adopting an alternative chemical or technology. Due to the limitations discussed above, this chapter does not present specific quantitative information.

2.7 Quality Assurance / Quality Control (QA / QC)

All EH&S data were initially collected by one Institute staff member and independently verified by a second staff member. The initial data were entered into a spreadsheet; this included the chemical name and CAS number, the actual data, and the sources of the data. The second staff member independently checked the accuracy of the CAS number and consulted the original data source and, where available, a secondary source. If data sources were inconsistent, the information was further evaluated and either a determination was reached or the differences noted. Each Institute researcher leading the individual chemical assessment section also reviewed the data provided, and augmented the EH&S data using current peer-reviewed scientific research obtained during the course of the assessment.

In addition to general input on the methodology for this study that was received from stakeholders and experts, the Massachusetts Toxics Use Reduction Act Science Advisory Board (SAB) was asked to review the screening criteria and environmental, health and safety parameter list. The SAB was created by the Toxics Use Reduction Act (TURA) of 1989 specifically to advise the Institute on scientific matters, and consists of experts in health and environmental issues, as well as technical chemical experts. They commented on the draft methodology and concurred with the final methodology.

Each assessment was sent out to the appropriate stakeholders and experts for general technical review. Reviewers provided a great deal of valuable technical feedback that improved the accuracy of the study, but were not asked to verify all information and data in the report.

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Figure 2.1: Project Approach

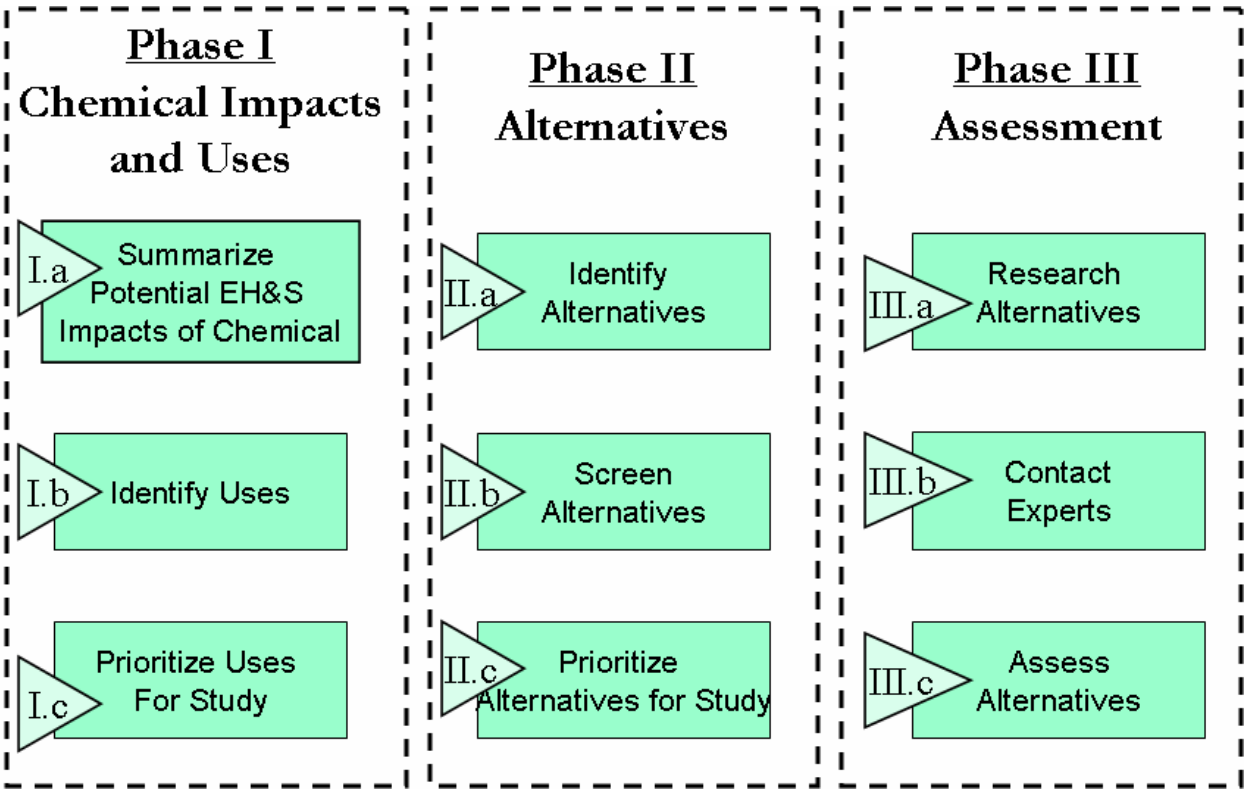

Table 2.3.3 : High Priority Uses

Chemical	Final High Priority Uses for Study
Lead	• Ammunition for shooting ranges • Wheel weights • Fishing sinkers • Heat stabilizers for PVC wire and cable coatings
Formaldehyde	• Sanitary storage in barbering and cosmetology • Preserved educational specimens for dissection • Building panels
Perchloroethylene	• Dry cleaning • Vapor degreasing • Automotive aerosols (brake, external and internal engine, and tire cleaners)
Hexavalent Chromium	• Decorative chrome electroplating • Hard chrome electroplating • Passivation of zinc
DEHP	• Resilient flooring • Medical devices for neonatal care (sheet and tubing applications) • Wall coverings

Table 2.4.3 : High Priority Alternatives

Chemical	High Priority Use	High Priority Alternatives to be Assessed
Lead	Ammunition for Shooting Ranges	1. Bismuth 2. Copper 3. Iron 4. Tungsten 5. Zinc
	Wheel Weights	1. Copper 2. Steel 3. Tin 4. Zinc and zinc/copper/aluminum alloy (ZAMA)
	Fishing Sinkers	1. Bismuth 2. Steel 3. Tin 4. Tungsten 5. Ceramic
	Heat Stabilizers for PVC Wire and Cable Coatings	1. Calcium zinc 2. Barium zinc 3. Magnesium zinc 4. Magnesium aluminum hydroxide carbonate hydrate 5. Magnesium zinc aluminum hydroxide carbonate
Formaldehyde	Sanitary Storage in Barbering and Cosmetology	1. Process change to eliminate use of paraformaldehyde "Steri-dri" sterilants 2. UV sterilization chamber
	Preserved Educational Specimens for Dissection	1. Specimens in Formalternate (propylene glycol-based) 2. Specimens in Wardsafe (gluteraldehyde-based) Specimens in STF Preservative (diazolidinyl urea-based) 3. Virtual/Video dissection
	Building Panels	1. Wood plywood panels (Purebond) made by Columbia Forest Products (soy adhesive binder) 2. Recycled paper-based panels made by Homasote (paraffin wax binder) 3. Wood fiber-Portland Cement panels made by Viroc 4. Plastic-wood composite panels by JER Envirotech
Perchloro-ethylene	Dry cleaning	1. Hydrocarbon (Exxon Mobil DF-2000) 2. Substituted aliphatic glycol ethers (Rynex) 3. Volatile Methyl Siloxane (GreenEarth) 4. Wet cleaning – traditional (PowerBrite detergent) 5. Wet cleaning - Icy Water (DWX 44 detergent) 6. Wet cleaning - Green Jet (DWX 44 detergent) 7. Liquid CO_2
	Vapor Degreasing	1. N-propyl bromide (Ensolv) 2. Volatile methyl siloxane (Dow OS 10) 3. HFC (Micro Care Flux Remover C) 4. HFC (Dupont Vertrel MCA) 5. Aqueous cleaning

Table 2.4.3 : High Priority Alternatives

Chemical	High Priority Use	High Priority Alternatives to be Assessed
	Automotive Aerosols (brake, external and internal engine, and tire cleaners)	18 different commercial products, based on: 1. Aqueous (water and detergent) 2. Silicone 3. Glycol ethers 4. Hydrocarbons, petroleum distillates 5. Toluene 6. Xylene 7. Heptane 8. Citrus based terpene (d-limonene)
Hexavalent Chromium	Decorative Chromium Electroplating	1. Trivalent chromium plating baths 2. Low temperature arc vapor deposition of trivalent chromium
	Hard Chromium Electroplating	1. Thermal sprays: high velocity oxy-fuel and plasma sprays 2. Weld facing methods and micro-arc welding 3. Heat treatments and plasma nitriding 4. Vapor deposition 5. Nanocrystalline coatings 6. Trivalent chromium plating baths
	Zinc galvanized steel passivation	1. Molybdates 2. Trivalent chromium compounds 3. Mineral tie-coat
DEHP	Resilient Flooring	1. DEHT, di 2-ethylhexyl terephthalate 2. DINP, di (isononyl) phthalate 3. DGD, dipropylene glycol dibenzoate 4. DEHA, di 2-ethylhexyl adipate 5. Natural linoleum 6. Cork 7. Polyolefin
	Medical Devices for Neonatal Care: Sheet Applications	1. TOTM, tri-2-ethylhexyl trimellitate 2. DEHA, di (ethylhexyl) adipate 3. BTHC, butyryl trihexyl citrate 4. DINCH, di (isononyl) cyclohexane-1,2-dicarboxylate 5. EVA 6. Polyolefins 7. Glass
	Medical Devices for Neonatal Care: Tubing Applications	1. DINP, di (isononyl) phthalate 2. DEHA, di (ethylhexyl) adipate 3. Silicone 4. Thermoplastic polyurethane (TPU)
	Wall Coverings	1. DEHA, di (ethylhexyl) adipate 2. DINP, di (isononyl) phthalate 3. Glass woven textiles 4. Wood fiber/Polyester 5. Cellulose/polyester blends

Table 2.5.3: EH&S Parameters Considered in Assessing Alternatives

Environmental Effects	Other Environmental Hazards	Acute Human Health Effects	Chronic Human Health Effects	Other Hazards
Hazardous Air Pollutant Water Solubility Density Specific Gravity Vapor Pressure Henry's Law Coefficient Kd (soil sorption coefficient) Koc (adsorption coefficient) Log Kow (octanol-water partition coefficient) Persistence: Water, Soil, Sediment, Air Bioaccumulation Aquatic Toxicity Drinking Water Quality	Degradation Products Ozone Depleting (ODC) Greenhouse Gas	Metabolites Dermal Absorption Lethal Dose concentration: Inhalation LC 50, Oral LD50, Dermal LD50 Occupational Exposure Limits: IDLH, PEL, REL, TLV, Ceiling/ST Irritation: Dermal, Ocular, Respiratory	Reference Dose Mutagenicity Carcinogenicity Skin Sensitization Reproductive & Developmental Toxicity Target Organ	Flammability Reactivity Corrosivity Flash Point

Appendix A. Alternatives Assessment Process Guidance

Five Chemicals Alternatives Assessment Study

Five Chemicals Study:
Alternatives Assessment Process Guidance

Toxics Use Reduction Institute

March 2006

Chemicals Being Studied:

Lead
Formaldehyde
Perchloroethylene
Chromium (Hexavalent)
Di (2-Ethylhexyl) Phthalate

This guidance document was prepared by
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Alternatives Assessment Process Guidance

Five Chemicals Alternatives Assessment Study

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Objective of the Five Chemicals Study

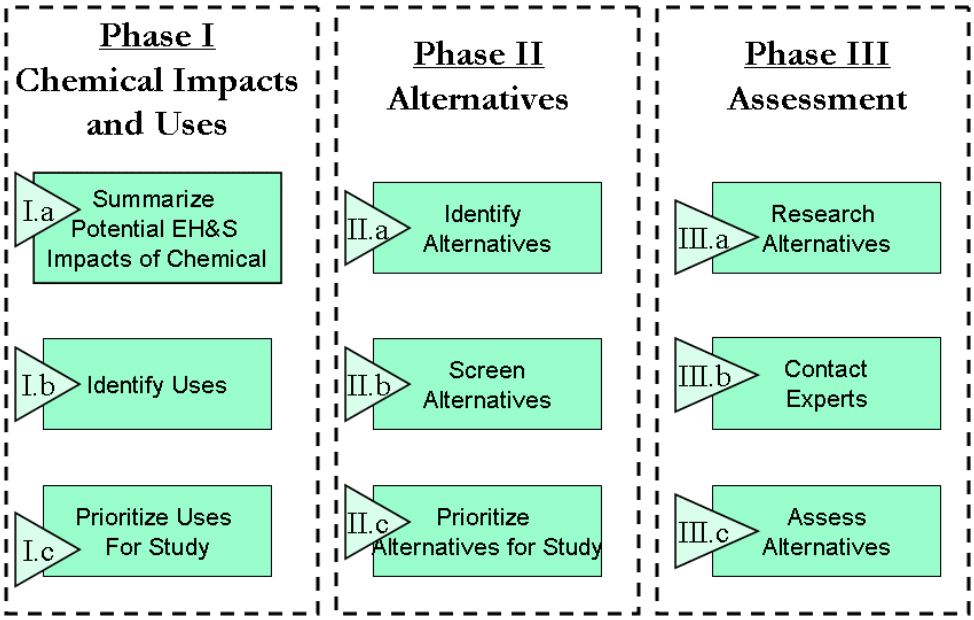
The Commonwealth of Massachusetts has requested that the Toxics Use Reduction Institute (the Institute) conduct an assessment of the feasibility of adopting alternatives for five toxic or hazardous chemicals (lead, formaldehyde, perchloroethylene, hexavalent chromium and di (2-ethylhexyl) phthalate (DEHP)). The text of the Legislative budget item is found in Attachment A.

The goal of this study is to identify alternatives to these five chemicals in a use-specific manner, and compare environmental, performance, economic and human health and safety aspects to determine the feasibility of adopting chemical or technological alternatives. It is important to note that this study is not being conducted in a manner designed to assess the relative safety of one alternative

over the other. However, the Institute intends to prioritize and focus its efforts on those alternatives that are expected to be safer.

The objective of this guidance document is to define a consistent process for setting priorities for study and evaluating the alternatives for the five chemicals. The proposed methodology for the five chemicals is outlined in this document. Preferred information sources include Institute publications and research, government documents and databases, and other publicly available, peer reviewed resources. This document also includes suggestions for specific types of resources for certain phases of the study. Each chemical lead will be responsible for implementing the methodology for their respective chemical

The following graphic illustrates the phased approach that is being used in this study.



Phase I will focus on identifying and prioritizing the uses in Massachusetts of the five chemicals. During this phase of the study the Institute will also summarize potential human health and environmental impacts associated with the use of the five chemicals as a baseline against which alternatives may be compared. In Phase II the Institute will identify alternative chemicals, materials and/or technologies for those priority uses and will utilize a set of screening criteria to determine those alternatives that warrant assessment. Each of these two initial phases will be performed under an aggressive schedule so as to allow as much time as possible for completion of the assessments. Phase III represents the bulk of the assessment work, wherein the Institute will evaluate the technical, financial, and environmental and human health and safety parameters of the identified alternatives.

Stakeholder Involvement

To produce useful results in the time available, and to provide the greatest positive impact on Massachusetts, the Institute will seek input from Massachusetts stakeholders. Stakeholders include representatives of Massachusetts companies, government, non-government environmental, health and labor organization, and industry associations. A series of three formal meetings will be held. In addition, the Institute will be conducting on site visits at Massachusetts operations as appropriate, and will host informal meetings with stakeholders as requested and time permitting.

Formal Stakeholder Meetings

Stakeholder Meeting 1 – Project Overview

Involvement of stakeholders will begin with an initial meeting with identified Massachusetts stakeholders. The purpose of this meeting will be to review the objectives of the project, share information about the proposed methodology and receive feedback from stakeholders. At that time the Institute will also give the stakeholders information about the timing of the project and an opportunity to attend subsequent more specific meetings.

Stakeholder Meeting 2 – Priority Uses Discussion

Once the Institute has researched and determined a list of uses associated with the five chemicals, it will conduct one day-long series of successive chemical-focused stakeholder meetings. It is important to note that the Institute will strive for a balance between the various stakeholders so that each chemical's interests are well represented. The stakeholder meeting will be organized to allow those stakeholders or experts in attendance who are interested in all chemicals to attend the entire day, and those who have only an interest in one or more specific chemical to attend only for those sections of the meeting.

The purpose of this second meeting will be to accomplish the following:

- Provide information on the chemical use prioritization criteria;
- Review the list of uses researched by the Institute; and
- Solicit input from stakeholders on priority uses for further investigation.

Stakeholder Meeting 3 – Priority Alternatives Discussion

The Institute will conduct a third one day-long series of successive chemical-focused stakeholder meetings with stakeholders after it has researched and developed a list of potential alternatives associated with the priority uses determined in part with stakeholder input. This meeting will also be organized to allow those stakeholders or experts in attendance who are interested in all chemicals to attend the entire day, and those who have only an interest in one or more specific chemicals to attend only for those sections of the meeting.

The purpose of this third meeting will be to accomplish the following:

- Provide information on the prioritization criteria developed for alternatives for chemicals;
- Review the list of alternatives developed by the Institute and our suggestions on alternatives warranting further study;
- Review uses and alternatives – depending on the number of likely feasible alternatives identified, the Institute may reduce the number of uses being evaluated; and
- Solicit input from stakeholders for each of the above topics.

Based in part on stakeholder feedback from this third meeting, the Institute will develop a list of priority uses and alternatives for further study. The Institute recognizes that each chemical may have a different balance of uses to be studied and alternatives per use to be studied. The decision of how many uses and alternatives to study will be informed by our discussions with stakeholders as well as our ability to address options in a consistent, thorough and scientific manner in the time allowed. The list of uses and alternatives to be included in the alternatives assessment will be finalized and communicated to the stakeholders.

Phase I – Chemical Impacts and Uses

During this phase of the project the Institute will be investigating the various uses of the five chemicals and prioritizing those uses that warrant further study. This phase will include meetings with stakeholders to inform them of our methods and findings relative to uses of the chemicals. Our goal is to use the stakeholder process to solicit input on priorities for study.

Phase I.a – Potential Impacts of Chemicals

As stated in Attachment A, this study includes not only an identification of the uses of the five chemicals, but also the potential human health and environmental impacts associated with the use of the five chemicals. This will not be a detailed toxicological review; rather it will summarize the current state of knowledge of these impacts. Differences of opinion among experts and variations in test results will be noted where they exist.

Information about potential human health and environmental impacts associated with the use or exposure to the five chemicals can be found in a number of sources: public databases, peer-reviewed scientific journals, reference materials, industry trade group resources (publications and web sites) and advocacy group resources (publications and web sites). The Institute will review various sources of information, and will provide a synopsis of the most current information from publicly available sources about potential human health and environmental impacts associated with use and exposure to each of the five chemicals.

Human health and environmental impacts that will be evaluated include, but may not be limited to those parameters itemized in Attachment B.

The objective of this summary will be to provide background information on each chemical, highlight environmental, health and safety issues, and provide a baseline against which the alternatives can be compared.

Phase I.b - Identify Chemical Uses

Uses of chemicals in Massachusetts range from manufacturing processes to services to consumer products. The Institute's first task will be to identify the uses for each of the five chemicals. Uses may include use in manufacturing operations, use in non-manufacturing operations (e.g. services such as dry-cleaning), as well as use in consumer and industrial products.

The following information will be gathered when identifying the various uses of the specific chemical.

- Major suppliers of the chemical;
- Major derivatives, components and/or end products that incorporate the chemical or use the chemical as a feedstock, and their manufacturers (Massachusetts, domestic, international);
- Major distributors, retailers, or customers of end product (focus on Massachusetts customers);
- Functionality requirements of chemical or component or end-product (i.e., why is it used and what is it used for?); and
- Concerns of relevant stakeholders, including businesses, industry associations, environmental, public health and labor organizations.

Information will be gathered from the literature (both published and on-line sources), experts and other data sources. As part of the use identification process, Institute staff may contact and interview representatives from manufacturers, trade associations and customers who use the chemical or its derivatives. However it is more likely that this level of work will be done as part of the alternatives assessment phase (Phase III of this project).

Possible Sources of Information: Chemical Economics Handbook, Kirk-Othmer, TURA data, U.S. EPA Toxics Release Inventory data, U.S. Geological Survey, trade/industry associations.

Phase I.c - Prioritize Chemical Uses for Evaluation

Develop a preliminary prioritization of chemical uses for further evaluation

Each of the five chemicals has a variety of uses associated with it. These uses range from manufacturing process chemical usages to services to consumer product uses. For each of the chemicals, the range of associated uses is so wide and varied that the Institute will not be able to fully evaluate them all in the short time span allowed for this project. Therefore it is necessary to narrow the scope to evaluate uses that are a priority for Massachusetts. Chemical uses will be prioritized using the following criteria:

1. Importance to the Commonwealth of Massachusetts:
   - Use in manufacturing and businesses: Total quantity of chemical used in manufacturing and business operations in Massachusetts (*Possible sources: TURA data, national TRI data, USGS chemical experts*)
   - Use in consumer products: Total quantity of chemical used in products sold in Massachusetts. (*Possible source: Chemical and Economics Handbook, national TRI data, government and trade association data*)
2. Potential availability of alternatives (conduct a quick scan of available alternatives – are they still in the developmental stage or readily available commercially?)
3. Exposure potential (environmental, occupational, and public health). For example, what is the mobility of the chemical for a particular use? If the chemical is used in a product, is the user likely to be exposed to it?
4. Potential value to Massachusetts businesses and citizens of the alternatives assessment results. Specifically, the preferences of the pertinent stakeholders for each chemical will be given priority.
5. Other criteria as appropriate

Conduct an internal review of chemical use prioritization

The Institute will hold an internal meeting to review information collected for criteria 1-3 (above) for each of the chemicals. During this meeting we will discuss the following:

- Sources of information used for prioritization efforts
- Determine the appropriateness of criteria used
- Identify other information that would be helpful to provide to stakeholders

Summarize chemical use information

Based on the results of the internal review, the Institute will update the information for prioritization of chemical uses. An overview document and information matrix will be prepared for use in the Use Prioritization Stakeholder Meeting.

Phase II – Alternatives Identification and Prioritization

Phase II.a – Identify Alternatives

The Institute will identify existing and emerging alternatives for each of the high priority uses of the chemicals. The alternatives may include drop-in chemical substitutes, material substitutes, changes to manufacturing operations, changes to component/product design, or other technological solutions. Appropriate industry specific performance requirements for each use will be necessary criteria in determining if an alternative is technically feasible. The Institute will roughly determine each alternative's characteristics relative to those technological criteria to assess feasibility. However, in the case of emerging technologies, further investigation may be warranted without proof of adherence to any applicable performance criteria.

Possible Sources of Information: Trade associations, manufacturers, EPA documents and programs, municipal, state and federal pollution prevention research centers, literature/internet search, and experts.

Phase II.b – Screen Alternative

Expert Review of Screening Criteria

The Toxics Use Reduction Act's Science Advisory Board (SAB) consists of experts in health and environmental issues, as well as technical chemical experts. The Toxics Use Reduction Act (TURA) of 1989 created the SAB to work with the Institute as described in Massachusetts General Laws, Chapter 21I, Section 6. The Institute may call on the SAB for scientific advice concerning TURA-related issues. For this project, the Institute will request that the SAB review the proposed screening criteria and provide comment and recommendations.

Initial Alternatives Screening

The purpose of the initial screening effort is to eliminate from further study any chemical alternatives that would pose a high risk to the environment or human health. All identified chemical alternatives will be screened based on the following criteria. If an alternative meets any of the following criteria, then it will be eliminated from further consideration as an appropriate alternative. It is important to note that, if no data associated with one or more of the screening parameters are available this chemical will not be screened out based on that parameter.

Persistence, Bioaccumulation and Toxicity

The US EPA in its Pollution Prevention Framework[1] references it's PBT Profiler software for levels of concern for chemicals that are persistent, bioaccumulative or toxic (PBT). The highest level of concern expressed in the PBT profiler has been chosen for the ultimate screening of chemicals based on PBT. The PBT Profiler will be first run with the CAS number of each ingredient for each alternative. If a CAS number is not found by the PBT profiler, the chemical will be checked to see if

[1] Go to www.epa.gov/opptintr/p2framework. Criteria can be found at http://www.pbtprofiler.net/criteria.asp.

it is inorganic or a mixture (PBT Profiler does not handle those substances); in some instances the chemical structure will be drawn and input into the software. If a chemical alternative exceeds the criteria for any **two** of the PBT categories it will be screened out from further assessment.

a. Persistence: The US EPA PBT Profiler defines very persistent chemicals in terms of their half life[2] in specific media, as follows:

Environmental Medium	Half-Life
Water	> 180 days
Soil	> 180 days
Air	> 2 days[3]
Sediment	> 180 days

If any **one** of the environmental media half lives is exceeded, the chemical is considered to be persistent for this study. We have included the "persistent" classification for half life in air since no "very persistent" criteria is established within the PBT Profiler.

b. Bioaccumulation: As defined in the PBT Profiler, the US EPA considers a chemical very bioaccumulative if it has a bioconcentration factor (BCF[4]) greater than 5,000 (or log K_{ow} greater than 5) [5].

c. Aquatic Toxicity: According to the PBT Profiler, chronic aquatic toxicity values less than 0.1 mg/L indicate that a chemical is of high concern. The parameter used to evaluate for freshwater fish species toxicity is based on 30-day exposure duration, with the endpoint for evaluation expressed in ChV[6] (mg/l). Toxicity data for other aquatic species are not included in this initial screening criterion. In many cases data for aquatic toxicity is not available. In this case the chemical will not be screened out based on toxicity, and can only be screened out as a PBT if the criteria for P and B are exceeded.

Carcinogenicity

For the purposes of this study, a chemical will be screened out if it is classified under one of the following classifications:

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[2] Half-life is the length of time it takes for the concentration of a substance to be reduced by one-half relative to its initial level, assuming first-order decay kinetics.

[3] Note that this value is classified as "persistent" rather than "very persistent" by the PBT Profiler

[4] The bioconcentration factor (BCF) is a measure of the ability for a water-borne chemical substance to concentrate in fatty tissue of fish and aquatic organisms relative to its surroundings. EPA defines bioconcentration as the net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water through gill membranes or other external body surfaces (60 FR 15366). In general, chemicals that have the potential to bioconcentrate also have the potential to bioaccumulate. Because BCF values are much easier to measure (and estimate), the BCF is frequently used to determine the potential for a chemical to bioaccumulate.

[5] This value (either the BCF or the equivalent log K_{ow}) is associated with highly bioaccumulative chemicals and is used as an initial screening value for this study.

[6] ChV is the chronic (long-term) toxicity value to fish over the timeframe specified. This is the same as a chronic no-effect-concentration (NEC) and the geometric mean of the maximum allowable toxicant concentration (MATC). The MATC is the range of concentrations between the lowest-observed-effect concentration (LOEC) and the no-observed-effect concentration (NOEC).

US EPA Classifications[7]:

Group A: Known Human Carcinogen
Group B1: Probable Human Carcinogen (Limited human evidence)
Group B2: Probable Human Carcinogen (Sufficient evidence in animals)

IARC Classifications[8]:

Group 1: Known Human Carcinogen
Group 2A: Probable Human Carcinogen

Sources of information: IUPUI (Indiana University - Purdue University - Indianapolis) EH&S Program web site, which lists carcinogen status by CAS number (http://www.ehs.iupui.edu/ehs/prog_carcinogen.asp)

More Hazardous Chemicals

If a chemical is listed on the Massachusetts Toxics Use Reduction (TUR) Science Advisory Board's list of More Hazardous Chemicals it shall be eliminated from consideration as a viable chemical alternative. The TUR program list of more hazardous chemicals[9] has been developed by the TUR Program Science Advisory Board. In this list, "hazard" includes inherent toxicity, potential for exposure through dispersal in the work place (based on the physico-chemical properties of the chemicals, e.g., vapor pressure) and indicators of safety of use (e.g., flammability). Potential for exposure and indicators of safety do not include site-specific conditions.

The following table provides the list of TUR more hazardous chemicals and their associated CAS numbers:

[7] Guidelines for Carcinogen Risk Assessment, September 24, 1986, Federal Register 51(185):33992-34003 or go to http://www.epa.gov/ncea/raf/car2sab/guidelines_1986.pdf

[8] Go to http://www-cie.iarc.fr/monoeval/grlist.html for more information on the International Agency for Research on Cancer (IARC) classification system for carcinogens

[9] Massachusetts Toxics Use Reduction Institute "Categorization of the Toxics Use Reduction List of Toxic and Hazardous Substances" (1999), Methods and Policy Report No. 18.

Chemical Name	CAS #
Acrylamide	79-06-1
Acrylonitrile	107-13-1
Arsenic compounds	NA
Arsenic	7440-38-2
Cadmium compounds	NA
Cadmium	7440-43-9
Carbon tetrachloride	56-23-5
Chlorine	7782-50-5
Chloroform	67-66-3
Chromic acid	1333-82-0
Chromium compounds (+6)	NA
Cyanide compounds	NA
Dibromochloropropane	96-12-8
Dichloroethane	107-06-2
Diethylsulfate	64-67-5
Dimethyl formamide	68-12-2
Dioxane	123-91-1
Epichlorohydrin	106-89-8
Ethylene oxide	75-21-8
Formaldehyde	50-00-0
Hydrazine	302-01-2
Hydrogen cyanide	74-90-8
Hydrogen fluoride	7664-39-3
Lead	7439-92-1
Lead compounds	NA
Methylene bisphenyl isocyanate	101-68-8
Nitrobenzene	98-95-3
Nickel compounds	NA
Phosgene	75-44-5
Propyleneimine	75-55-8
Propylene oxide	75-56-9
Selenium and selenium compounds	7782-49-2 (elemental)
Silver chromate	7784-01-2
Sulfuric acid	7664-93-9
Sulfuric acid (fuming)	7664-93-9
Tetrachloroethylene	127-18-4
Toluene diisocyanate (mixed isomers)	26471-62-5
Trichloroethylene	79-01-6

Phase II.c - Prioritize Alternatives for Further Evaluation

The purpose of the prioritization effort is to focus assessments on the most feasible alternatives for a particular use. Our intention at this stage is to do a high level evaluation of the potential alternatives to identify any factors leading to immediate screening out of the chemical or informing the prioritization of the alternative as a potentially feasible alternative to one of the five chemicals. The Institute will consider the following:

1. ***Performance***: Known performance of alternative. Performance criteria should be specific to the use of the chemical/material, and may include items such as maintenance and durability as well as specific performance requirements. Consider the potential for future performance enhancements.
2. ***Availability***: Number of suppliers/manufacturers that commercially provide the alternative. In addition, information about the volume of the alternative produced may be important (i.e., is the alternative available only in very small quantities).
3. ***Manufacturing Location***: Is the product manufactured in Massachusetts or outside of Massachusetts? Products or materials manufactured in Massachusetts would receive a higher prioritization for evaluation as this may have a greater impact on the Massachusetts economy.
4. ***Cost***: Current costs associated with the alternative compared to that of the hazardous chemical. Consider the potential for future cost reductions (e.g., economies of scale due to higher volume production). If available, consider other significant costs such as raw material costs, storage and handling costs, disposal costs, etc.
5. ***Environmental, Health, and Safety***: Known environmental, health and safety risks or benefits compared to that of the hazardous chemical.
6. ***Global Market Effect***: Information about pending or existing global restrictions that might materially affect the ability of an industry to market its products internationally. Since our world has become an increasingly global marketplace, taking into account the impact of international marketability on a product is essential for sustained economic viability for most industry sectors.
7. ***Other:*** Other use specific criteria as appropriate. For example, in some instances multiple similar alternatives exist for a particular use. In this case one alternative that is representative of that type will be chosen for further study.

Additionally, if the initial alternatives screening identifies a substance that exceeds the "median" level of concern for PBT as defined by the PBT Profiler, this will be noted and considered along with the above criteria. The Institute's goal is to identify a list of alternatives for further evaluation that is achievable in the timeframe allotted.

Conduct an internal review of alternatives information and screening

The Institute will hold an internal meeting to review the information on alternatives and the screening out of unacceptable alternatives for each of the chemical's uses. The following will be discussed:

- Sources of information used for the screening and prioritization efforts;
- The appropriateness for criteria used; and
- Other information that would be helpful for screening and prioritization.

Summarize screening and prioritization information of alternatives

Based on the result of the internal review, the Institute will update the screening and prioritization information of alternatives for use by external stakeholders and experts.

Phase III – Alternatives Assessment

Phase III.a – Research Alternatives

For each of the high priority uses of the chemical and for each identified priority alternative, the Institute will compile and assess data for the following four assessment categories. Attachment B provides detailed lists of the parameters to be studied.

- Technical/Performance (including longevity, key performance requirements, key physical characteristics and key quality parameters);
- Financial (including purchase price, availability of alternative and associated capital costs);
- Environmental (including PBT, environmental mobility and other environmental hazards); and
- Human Health/Safety (including acute and chronic human effects, other hazards such as flammability and corrosivity and exposure potential).

The Institute will use the following protocol when evaluating environmental and human health data:

- All data must represent current science and be derived from peer reviewed and publicly available (i.e., published) sources. Our primary source of this data will be the sources available from the National Library of Medicine's Toxicology Data Network (ToxNet)[10].
- For human health, data based on human epidemiological studies will be used preferentially. Data based on tests of non-human sources will be used if human epidemiological data is not available. If neither human epidemiological data nor data based on non-human sources is available, data derived from models will be used; and
- If modeled data is to be used, the Institute will use models approved by the US EPA.

When presenting data for any of these categories, the Institute will rely on information obtained from authoritative bodies[11], with the most recent validated data presented first. When faced with multiple or conflicting data, the Institute will preferentially use data that has been referenced by a US governmental agency such as EPA, CDC and OSHA. Specific sources of information for individual parameters are provided in Attachment B.

Not all data listed in Attachment B will be available for all chemicals being evaluated. However some of the data are more important for the purposes of this assessment and every effort will be made to obtain these data. These priority data are indicated in Attachment B by an asterisk (*).

Some of the assessment data will be specific for each use of the chemical and its alternatives, and some assessment data will be the same for various uses of the chemical and its alternatives. The Institute will devise a way of indicating which data are use-specific in its final reporting format.

Developing data on persistence, bioaccumulation potential and toxicity are deemed to be especially important from an environmental assessment standpoint. In order to present more comprehensive data, we will utilize the US EPA PBT Profiler[12] software for those chemicals for which there is no currently available persistence, bioaccumulation or toxicity data. The PBT Profiler evaluation will be

[10] Go to http://toxnet.nlm.nih.gov/ for more information

[11] Authoritative bodies include the US Environmental Protection Agency, the Occupational Safety and Health Administration, the National Toxicology Program, the International Agency on Research of Cancer, National Institute of Health, and the Center for Disease Control, etc.

[12] Go to http://www.pbtprofiler.net/ for more information

conducted by a subset of the Assessment Team, consisting of chemists and chemical engineers who can appropriately interpret the data, in order to assure consistent use and interpretation of the results of this tool. Other publicly available scientific-based and peer-reviewed estimation tools that are identified and tested over the course of this study may also be used to augment the available information about each of the chemical substitutes evaluated.

Phase III.b - Develop user experience data associated with alternatives

While conducting the technical/performance assessment, the Institute will identify any industry-specific performance requirements that must be met for each feasible alternative. One primary source of this information will be industry/user experience with the chemicals and their substitutes. Institute staff may contact and interview representatives from manufacturers, trade associations and customers who use the chemical or its derivatives.

Additionally, the Institute will look for readily available information on key life cycle considerations that may affect the feasibility of the alternative. This is not intended to be a comprehensive life cycle assessment. Rather, key life cycle considerations would include such issues as waste disposal limitations, energy usage required during manufacture, impact on product recyclability or reuse potential, etc. This information will be presented in the final report only when more than one source corroborates the data, and when it may materially impact the overall assessment of one alternative's feasibility.

Phase III.c – Assessing Alternatives

The environmental, technical, financial and human health data obtained for each alternative will then be organized and evaluated to assess its feasibility as a substitute for the chemical and use. User experience and pertinent and reliable life cycle considerations will be included in this evaluation. The Institute will dedicate a subset of the overall project team to conducting this evaluation in order to assure consistency and quality of data and presentation.

It is important to recognize that the Institute will not be assigning a judgment of the preference of alternatives relative to each other or to the chemical and use they are replacing. No weighting factors will be provided when or if data are aggregated. Rather, all collected data will be presented along with guidance for interpretation (an Institute project to be completed subsequent to the completion of this study). This will allow the readers of our final report to determine for themselves, based on their specific requirements, which alternative (if any) is preferable.

Evaluating chemical alternatives

For purposes of this study, a chemical is any element, chemical compound or mixture of elements and/or compounds. Chemicals are the constituents of materials. A chemical "mixture," also known as a chemical "preparation," includes multiple chemicals.

A chemical alternative represents the simplest case, where the chemical being studied can be directly substituted with another chemical that satisfies the functional requirements for the particular use. In this instance, the evaluation will be relatively straightforward, where information associated with the parameters in Attachment B are obtained, verified and presented in a way that maximizes usefulness to those looking for tools to help in designing products using alternative chemicals. This will be done primarily in a tabular or matrix format.

Evaluating mixtures

Often the chemicals being evaluated are used in formulations of multiple chemicals. In this case, each of the chemical constituents of the mixture needs to be considered in the assessment in a manner similar to that used for individual chemicals (as above). The Institute will obtain environmental and human health information about each of the chemical constituents, and performance and cost information for the overall formulation when doing the assessment. If information on the mixture is available from a manufacturer's MSDS, then that information will be used for available parameters.

For the purposes of this study, the Institute will focus on the primary constituents of each formulation being evaluated. Specifically, constituents present in amounts exceeding 1% will be included in the review. When formulation breakdowns are presented on associated MSDSs with ranges, the Institute will assume the average weight percentage of the range presented. This is the only time that a weighting factor will be included in our assessment of alternatives. As the EH&S factors associated with the constituents of a mixture are determined, their relative significance to the overall EH&S characteristic of the mixture will be determined based on the weight percent within the mixture.

The actual approach to evaluating the EH&S impact of a mixture will differ depending on whether the chemicals in the mixture cause similar or different health effects. If the health effects are similar (e.g., two constituents are CNS depressants), their weight percentages will be added and the overall impacts of the combined chemicals will be assessed. If the health effects are different (e.g., one chemical is a CNS depressant, while another is a respiratory irritant), the effects will be evaluated separately based on the weight percentages of each constituent.[13]

Evaluating material alternatives

A material is defined as the basic matter (as metal, wood, plastic, fiber) from which the whole or the greater part of something physical (as a machine, tool, building, fabric) is made. Human-made materials like petroleum-based plastics are synthesized from chemicals.

In some cases the chemical being studied is used to impart particular qualities in a material. For instance, DEHP is used in PVC to make this otherwise rigid plastic flexible. Rather than find other ways to make the material (PVC) less rigid, there may be opportunities to find alternative materials that are inherently more flexible, therefore bypassing the need for this particular chemical additive.

When evaluating material alternatives performance and cost considerations are still important. However the impact of a material on environmental or human health may not be as readily assessed as it can be for chemical substitutes. For materials, life cycle considerations may become more important. For this study the Institute will look both at EH&S impacts when appropriate and at life cycle issues that based on our research appear to be of most significance relative to the material being replaced. It is important to note that this will not be a comprehensive life cycle assessment. Rather, when our research indicates that at a particular point in a material's life cycle there are important positive or negative impacts these will be mentioned qualitatively relative to the material being substituted. In this way, the reader can determine which materials satisfy their own particular needs.

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[13] This approach to mixtures is widely used in occupational and environmental health. See e.g. Craig, et al., "Recommended Default Methodology for Analysis of Airborne Exposures to Mixtures of Chemicals in Emergencies," Ann Occ Env Hyg 14 (9): 609-17, 1999.

Evaluating process alternatives

For the purposes of this study, process alternatives are those that employ a different technology, process or approach to achieve the objective or function of the original product or process. For example, when considering alternatives to perchloroethylene in vapor degreasing, one approach might be to change the upstream process to use lubricants that either don't require cleaning, or are easier to remove using water-based surfactants. The feasibility of this type of alternative can be assessed, but it is very difficult to compare the EH&S impacts quantitatively. These types of alternatives will be included in the study where appropriate, and their feasibility assessed qualitatively. When our research indicates that there are important positive or negative attributes or impacts relative to the substance being substituted, these will be mentioned.

Quality Assurance/Quality Control (QA/QC)

All EH&S data will be collected by one TURI staff member and independently evaluated by a second staff member. The initial data will be entered into a spreadsheet; this will include the chemical name and CAS number, the actual data, and the sources of the data. The second staff member will independently check the accuracy of the CAS number and consult the original data source. Whenever an inconsistency is encountered, the reviewer will consult with the collector of the original data and a consensus will be reached. Any unresolved conflicts will be brought to the Principal Investigator for final resolution.

Phase IV – Study Report

Statewide Economic Impact of Switching to Alternatives

An important component of the overall study funded by the Massachusetts Legislature is an analysis of potential impacts on employment level and economic competitiveness of the Commonwealth from adopting any alternative chemical or technology. Dependable economic predictions are lengthy and expensive to prepare, and specific economic data for the five targeted chemical alternatives and Massachusetts industry will not be available until late in the study. For this reason case material will be used to create a useful list of economic factors probably present. Further development of the influences, duration, dynamics, interactions, sector specificity or other characteristic of these economic factors will lead to useful tools for decisions about alternatives.

This evaluation will be completed using the following process:

1. Case materials will be created for the following sectors: formaldehyde in building materials, lead in electronics, and perchloroethylene in dry cleaning.
2. Ten experts in the economics of technology change from Associated Industries of Massachusetts, the Small Business Association, the Massachusetts Manufacturing Partnership, Tufts University, Northeastern University, the University of Massachusetts, the Economic Development Research Group, Tellus Institute, and the Environmental Management Accounting Research & Information Center will be gathered for a facilitated discussion. Using the case materials, a list of economic factors and their influences will be developed.
3. A discussion summary and report draft will be shared with the group of experts for further comment and validation.

4. The final report will include a summary of the discussion, including viewpoints, limitations of this approach, and any useful frameworks or tables that can be offered.

Assessment Report

The report will be structured in a way that the reader can focus on specific chemicals if desired, or can use the entire document (see report content guidelines in Attachment C). The report structure will begin with an overall introduction to the study objectives and methods, then focus on the individual five chemicals for details about the assessment of the chemicals and their studied alternatives, and finally will provide a summary of the economic evaluation of the impact of the use of alternatives on the Massachusetts economy. The report will be synthesized into an executive summary that will be available individually or as part of the overall report.

In general, the Institute will make use of tables and graphs as much as possible to facilitate quick access and understanding of information used in this study. Appendices will be used for larger data sets that do not materially affect the reader's ability to understand our logic, but that may provide additional information for greater understanding. All relevant information will be provided, aggregated only as is appropriate for that particular section. However, significant data for one chemical's application may be quite different from that of another application or chemical

Conduct internal review of draft report

The draft report will be reviewed by internal reviewers for accuracy, completeness, adherence to the alternative assessment methodology outlined in this document, and consistency of language and presentation. The Institute will then update the draft report based upon the feedback provided by the internal reviewers.

Conduct external review of draft report

The Institute will establish a list of experts to conduct an external review of the updated draft report. Relevant sections of the draft report will be sent to selected experts and stakeholders for review. At least two weeks will be allowed for review and feedback from external parties.

The Institute will conduct the following steps to develop the final version of the report:

- Review feedback provided by external parties.
- Conduct follow-up with external parties as necessary to fully understand the feedback provided.
- Determine whether or not the draft report should be updated for each point provided by external reviewers.
- Update the draft version of the report as necessary.

Publish final report

The Institute will publish the final report in the following formats:

- Electronically, available on our website (www.turi.org)
- Hard copy bound reports. A limited number of printed reports will be created for dissemination to stakeholders, experts and key members of the Massachusetts Legislature, including all members of the Joint Committee on Environment, Natural Resources and Agriculture.

- Hard copy bound executive summary reports. This summation of the findings of our work will be provided to each member of the Massachusetts Legislature.

Report Out to Legislature

The Institute will present the results of this work to the Massachusetts Legislative body in the following ways:

1. Submission of the full written report
2. Submission of an executive summary
3. In person briefings

Phase V – Project Wrap Up and Outreach

Subsequent to presentation of our results to the Massachusetts Legislature the Institute will focus on filing and record keeping responsibilities associated with the study, including cataloging of documents and resources used to complete this study, publication and archiving of the report, etc.

Outreach activities will comprise an important part of the follow-up activities of this study. The Institute plans to prepare a case study that will summarize the methodology, the resources required, and the effectiveness of the approach for use by other government agencies interested in doing this type of work. In addition, the Institute intends to create a guidance document to assist users of the report in interpreting and utilizing the information provided therein.

ATTACHMENT A: Massachusetts Legislative Budget Item for Five Chemicals Study

FY06 Budget Item, from FY06 Budget Conference Report (House and Senate overrode Governor's veto of budget item 14 July 2005)

7100-0350
For an assessment at the Toxics Use Reduction Institute on the feasibility of adopting chemical or technological alternatives for the following toxic or hazardous substances:

Lead,
Formaldehyde,
Perchloroethylene,
Hexavalent chromium, and
Di-(2 ethylhexyl) phthalate (DEHP);

provided, that the assessment shall, for each named toxic or hazardous substance, identify:

(1) **Significant uses** of the toxic substance in manufacturing, consumer products and any other applications;

(2) **Potential human health and environmental impacts**;

(3) Any **alternative chemicals or technologies**, both proven and emergent, and an analysis of their potential to serve as substitutes for any of the toxic or hazardous substances listed above, which shall include an assessment of:

(a) **Specific applications** of any alternative chemical or technology;

(b) **Potential impacts on the environment, human health, workers, employment level and economic competitiveness** of the commonwealth from adopting and implementing any alternative chemical or technology as substitutes;

(c) The **economic opportunities or feasibility of adopting** and implementing any alternative chemical or technology as a substitute including, but not limited to, consideration of the potential effects on capital, operating and production unit costs, and product price, to result from the substitution;

and provided further, that the Institute shall report its findings to the joint committee on environment, natural resources and agriculture by July 1, 2006

Note: **emphasis** *added*

ATTACHMENT B – Five Chemical Study Assessment Criteria/Sources of Information

Technical/Performance Assessment for Component/End-product

	Technical/Performance Parameter	Measure/Metric	Sources of Information
		Component/End-product	
	Longevity/Life in Service	• Useful life of component/end-product • Shelf/storage life of component/end-product	Manufacturer specifications
	Key standards for component/end-product: safety, flammability, others (determined by chemical application)	Examples include: • UL 910 • DIN 4102 • ASTM E662 • ISO 6940 • IEC 332-3C • Others	Industry associations, manufacturer specifications
*	Key physical characteristics (determined by chemical application)	Examples include: • Size • Weight • Density • Color • Other	Manufacturer specifications
*	Key performance requirements (determined by chemical application)	Examples include: • Tensile strength • Tear strength • Compressibility • Flame retardant • Power requirements • Accuracy • Resistance to shock/vibration • Noise level • Operating temperature • Other	Manufacturer specifications
*	Key quality/reliability parameters (determined by chemical application)	Examples include: • Mean time between failure (MTBF) • Mean time to repair (MTTR) • Mean cycles between failure (MCBF) • Other	Manufacturer specifications

	Technical/Performance Parameter	Measure/Metric	Source of Information
		Manufacturing processes	
	Key performance characteristics for chemicals used in manufacturing processes	Examples include: • Energy consumption • Equipment requirements • Process change requirements	Industry/manufacturing expertise

Financial Assessment

	Financial Parameter	Measure/Metric	Sources of Information
		Primary Data	
*	Initial purchase price for chemical/alternative	Retail price	Price catalogues or websites of manufacturers, distributors, retailers, etc.
	Initial purchase cost for end-product/component	Retail price	Price catalogues or websites of manufacturers, distributors, retailers, etc.
*	Availability of chemical/alternative	Number of chemical suppliers	Chemical Economics Handbook[14] Special Chem[15]
	Availability of component/end-product	Number of component manufacturers	Industry associations
	Capital costs	Cost for additional equipment required for switch to alternative	Industry experts, Industry trade associations
		Additional Data if Available	
	Key manufacturing costs for component/end-product	Energy consumption, maintenance costs	U.S. Department of Energy (Energy Information Administration) [16]
	Key operating costs during use of end-product	Energy consumption, maintenance costs	Energy Information Administration
	Replacement rate	Product life, shelf/storage life	Product data sheets
	Key end-of-product life costs	Disposal fee	Massachusetts DEP[17] Wastecap[18]
	Other intangible costs	Employee and consumer training costs	Industry trade associations, if available
		Regulatory compliance costs	TURA EPA
		Safety costs (e.g., PPE, control devices, special storage measures)	OSHA MSDS

[14] SRI Consulting, Menlo Park, CA
[15] http://www.specialchem.com/
[16] http://www.eia.doe.gov/
[17] http://www.mass.gov/dep/toxics/toxicsus.htm
[18] http://www.wastecap.org/

	Financial Parameter	Measure/Metric	Sources of Information
		Insurance costs	Industry trade associations, if available
		Taxes, fees	Industry trade associations, if available
		Other key costs	Industry trade associations, if available
	Financial evaluation	Return on investment, internal rate of return, payback period, net present value	Manufacturer, customer, or industry financial requirements

Environmental Assessment

	Environmental Parameter	Measure/ Metric	Concern Level	Sources of Information
	Persistence, Bioaccumulative, Toxicity (PBT)			
*	Persistence/ Biological Degradability	Half-life (days): soil, marine, freshwater, air, sediments	**High**: Half-life in water, soil, sediment > 180 days **Medium**: between 60 and 180 days **Low**: < 60 days	HSDB[19] PBT Profiler[20]
*	Bioaccumulation	• Log K_{ow} • Bioconcentration Factor (BCF)	**High**: BCF > 5,000 **Medium**: BCF between 1,000 and 5,000 **Low**: BCF < 1,000	HSDB PBT Profiler
*	Aquatic Toxicity - Acute	• Fish 96 hour LC_{50}, Daphnid 48 hour LC_{50}, • Algae 72 or 96 hour EC_{50}	**High**: Value is < 1 mg/L **Medium**: Value is between 1 and 100 mg/L **Low**: Value is > 100 mg/L	HSDB
*	Aquatic Toxicity - Chronic	• Fish 30 day ChV, • Daphnid ChV or 16 day EC_{50}, • Algae ChV	**High**: Value is < 0.1 mg/L **Medium**: Value is between 0.1 and 10 mg/L **Low**: Value is > 10 mg/L	HSDB PBT Profiler
	Water Quality	µg/l	Depends on the chemical and the water source (e.g., drinking water, ground water, surface water)	HSDB U.S. EPA Water Quality Criteria[21]

[19] Hazardous Substances Data Bank, National Library of Medicine [http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB]
[20] US EPA PBT Profiler [http://www.pbtprofiler.net]
[21] US EPA [http://oaspub.epa.gov/wqsdatabase/wqsi_epa_criteria.rep_parameter]

	Environmental Parameter	Measure/ Metric	Concern Level	Sources of Information
	Hazardous Air Pollutants	Yes or No	Depends on the chemical	National Emission Standards for Hazardous Air Pollutants[22]
	Environmental Mobility			
	Affinity for Water	Water solubility (mg/l)	NA - Provides indication of ability of chemical to migrate into water	HSDB PBT Profiler[23] MSDS
	Affinity for Soil	K_d (soil sorption coefficient)	NA - Provides indication of ability of chemical to become bound into the soil matrix	HSDB PBT Profiler MSDS
	Affinity for Sediments	K_{oc} (organic carbon partition coefficient)	NA - Provides indication of ability of chemical to become bound into sediments	HSDB PBT Profiler MSDS
	Affinity for Lipids	K_{ow} (octanol-water partition coefficient)	NA - Provides indication of ability of chemical to become adsorbed into fatty portions	HSDB MSDS
	Other Environmental Hazards			
	Degradation Products	Degradation products of concern	Literature indicates potential env. or human health effect due to exposure to degradation products	Peer-reviewed scientific literature
	Biodiversity	Endangered species affected	Literature indicates potential harm to regionally susceptible species	Peer-reviewed scientific literature
	Ozone Depleting Chemicals (ODC)	CFC, HCFC, halons, carbon tetrachloride, methyl bromide and bromochloromethane	Listed as a Class 1 or Class 2 ODC	World Meteorological Association[24]
	Greenhouse Gases	Global warming potential (GWP) of the chemical compared to that of CO_2	GWP > 1	Third Assessment Report values, Intergovernmental Panel on Climate Change (IPCC)[25]

[22] US EPA [http://www.epa.gov/ttn/atw/188polls.html]
[23] experimental data included with PBT Profiler (not modeling results)
[24] *The Scientific Assessment of Ozone Depletion, 2002*, A report of the World Meteorological Association's Global Ozone Research and Monitoring Project, accessed via EPA's web site at http://www.epa.gov/ozone/ods.html and www.epa.gov/ozone/ods2.html
[25] Table 4, Greenhouse Gases and Global Warming Potential Values: Excerpt from the Inventory of US Greenhouse Emissions and Sinks: 1990-2000, USEPA, April 2002. (accessed via www.epa.gov/ozone/ods.html)

Human Health and Safety Assessment

	Human Health and Safety Parameter	Measure/Metric	Concern Level	Sources of Information
		Acute Human Effects		
*	Lethal Dose/ Concentration	Inhalation LC50 (ppm) Oral LD50 (mg/kg) Dermal LD50 (mg/kg)	Lower than chemical of concern	HSDB RTECS
*	Immediately Dangerous to Life or Health (IDLH)	ppm (gas or vapor) mg/m^3 (particle)	Lower than chemical of concern	NIOSH
*	Worker Exposure Limit	• Permissible exposure limit (PEL) (ppm, gas or vapor) (mg/m^3, particle) • Recommended exposure limit (REL) (ppm or mg/m^3) • Threshold limit value (TLV) (ppm or mg/m^3)	[Use the **lowest** of the three]	NIOSH American Conference of Govt. Industrial Hygienists (ACGIH)[26]
	Irritation	Dermal Ocular Respiratory	Positive evidence	HSDB NIOSH MSDS
		Chronic Human Effects		
	Metabolites	Metabolites of concern	Literature indicates potential env. or human health effect due to exposure to metabolite	Peer-reviewed scientific literature
	Reference Dose (RfD)	mg/kg/day	Lower than chemical of concern	HSDB IRIS
*	Carcinogenicity	• U.S. EPA Group A, B1, B2, C, D, E, • IARC Group 1, 2A, 2B, 3, 4	**High**: Known or Probable – EPA: A, B1, B2 IARC: 1, 2A **Medium**: Possible – EPA: C, IARC: 2B **Low**: Unclassifiable or Not Likely – EPA: D, E, IARC: 3, 4	EPA[27], International Agency for Research on Cancer (IARC)[28]
	Skin Sensitization	Yes/No	Positive evidence	Sax[29] HSDB MSDS

[26] ACGIH (2005): TLVs and BEIs Based on the documentation of the threshold limit values for chemical substances and physical agents & biological exposure indices.
[27] U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program List of known (http://ntp.niehs.nih.gov/ntp/roc/eleventh/known.pdf) and reasonably suspected (http://ntp.niehs.nih.gov/ntp/roc/eleventh/reason.pdf) carcinogens
[28] http://www-cie.iarc.fr/monoeval/crthall.html
[29] Sax, N. I. and Lewis, R. J., Sr., *Rapid Guide to Hazardous Chemicals in the Workplace*, Van Nostrand Co., Inc., 1986.

	Human Health and Safety Parameter	Measure/Metric	Concern Level	Sources of Information
	Mutagenicity	Yes/No	Listed with an R46 or R68 EU risk phrase	ESIS[30] CA Proposition 65 RTECS[31]
	Endocrine Disruption	any indication	Positive evidence in the peer-reviewed literature	Peer reviewed scientific literature
	Reproductive or Developmental Toxicity	Yes/No	Listed as an R60 or R61 EU risk phrase	ESIS, California Proposition 65[32] RTECS[33]
	Target Organs	• Identification of target organs	Positive evidence	HSDB NIOSH MSDS
	Other Physical Characteristics			
*	Corrosivity	pH scale	pH < 2 pH > 12	NFPA[34] HMIS[35] MSDS
*	Reactivity	0, 1, 2, 3, 4	2, 3 or 4	NFPA HMIS MSDS
*	Flash Point	Degrees Celsius	<38°C	MSDS
	Flammability			NIOSH
*	Vapor Pressure	mm Hg at 25°C	Higher than chemical of concern	HSDB NIOSH PBT Profiler MSDS
	Exposure Potential			
	Dermal Absorption	Yes/No		HSDB; NIOSH; MSDS

[30] European Chemical Substances information System - Annex I to Directive 67/548/EEC on Classification and Labeling of Dangerous Substances http://ecb.jrc.it/esis/esis.php?PGM=hpv
[31] RTECS will be used only if information is not available from other sources and is critical to assessment
[32] www.oehha.ca.gov/ prop65/prop65_list/Newlist.html
[33] RTECS will be used only if information is not available from other sources and is critical to assessment
[34] http://safety.science.tamu.edu/nfpa.html
[35] http://www.paint.org/hmis/index.cfm

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- Economic Assessment for all alternatives
- Environmental Assessment for all alternatives
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- Summary of Alternatives for Use 1

3.4.2 Use 2 Report

- Technical Assessment for all alternatives
- Economic Assessment for all alternatives
- Environmental Assessment for all alternatives
- Human Health Assessment for all alternatives
- Summary of Alternatives for Use 2

3.4.3 Use 3 Report

- Technical Assessment for all alternatives
- Economic Assessment for all alternatives
- Environmental Assessment for all alternatives
- Human Health Assessment for all alternatives
- Summary of Alternatives for Use 3

3.5 Lead Assessment Summary

8. Statewide Impact on Massachusetts Economy

Chapter 8. Statewide Economic Impact

Five Chemical Alternatives Assessment Study

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8.1 Overview

Part of the Institute's mandate was to assess potential effects on the employment level and the economic competitiveness of the Commonwealth associated with adopting alternative chemicals or technologies. Cost considerations specific to individual chemicals and alternatives are discussed in the earlier chapters of this report, but this information is not evenly available and the cost for a material or chemical may depend on variable energy costs or material availability. Assessing economic effects also requires information on materials, labor, production, market and other data that may change over time. In addition, the employment and competitiveness implications of adopting an alternative are tied to the policy environment in which the alternatives adoption occurs. Voluntary adoption of alternatives, technical assistance programs, mandatory chemical phase-outs, or grant or loan programs designed to ease the transition to safer alternatives may all produce different market outcomes.

In order to make the best possible use of limited time and resources, the Institute did not attempt to draw firm conclusions about the employment and competitiveness implications of adopting the

alternatives that are explored in this report. Instead, the Institute sought to identify major factors that influence the economic outcomes of adopting safer alternatives. The Institute briefly reviewed the experiences of the TURA program and the literature on the economics of environmental regulation and alternatives assessment, and held a day-long discussion session with selected economists and other experts in innovation and technology diffusion. A brief look at the five chemical assessments yielded additional insights. In this section the Institute offers a framework as guidance for users of this report on critical factors to consider when assessing the economic impacts of alternatives adoption. Appendix E contains more detailed discussion topics from the day-long session, as well as case materials, which serve to ground this topic with specific examples.

Introduction

The charge for this section of the alternatives assessment study was to:

> "Conduct an analysis of potential impacts on employment level and economic competitiveness of the Commonwealth from adopting and implementing any alternative chemical or technology as substitutes."

TURA Experience

The economic impacts of toxics use reduction in Massachusetts are explored in the 1997 program evaluation report of the Toxics Use Reduction Act (TURA) (Toxics Use Reduction Institute (TURI) 1997). This benefit-cost analysis found that economic benefits outweighed costs, even without accounting for increased revenue from capital investments in improved processes, benefits to non-TURA firms in Massachusetts from TURA program resources, or human health and ecological benefits. For the period from 1990 through 1997, the direct monetized benefits were found to be $90.5 million in 1995 dollars. The costs were found to be $76.6 million ($49.4 million in compliance costs, and $27.1 million for capital investments), so the net benefit was $13.9 million. Specific examples of cost savings are discussed in case studies that have been developed by the Institute and the Office of Technical Assistance for a number of companies, detailing the types of production changes that were undertaken and the yearly savings that were achieved as a result.[1] Some of these companies achieved toxics use reduction by improving efficiency of chemical use, while others adopted alternative chemicals or processes.

The TURA program requires large quantity toxics users to make a toxics use reduction plan that documents a mass balance of materials, considers safer options, and includes total cost accounting methods. Implementation of these plans is voluntary. The program evaluation found that TURA regulated firms have discovered opportunities that were both financially and environmentally beneficial and that might not have been discovered without the requirement to look for such opportunities. In addition, industry made use of and valued the training, informational support and technical assistance provided by government entities under the TURA program. Finally, TURA regulated firms have become leaders in efficient production, corporate environmental reporting, and management systems methods that make them more competitive.

[1] Case studies are available on the website of the Massachusetts Office of Technical Assistance for Toxics Use Reduction, at http://www.mass.gov/envir/ota/publications/case_studies1.htm.

Literature Review

There is a substantial literature on the economic implications of pollution prevention, including many case studies of specific firms' experiences in adopting safer substitutes. This literature has been summarized elsewhere and is not reviewed here. As a context for the experts' discussion of the economic implications of alternatives adoption, the Institute briefly reviewed the literature on economic implications of environmental regulation.

Economist Michael Porter developed the hypothesis that strict government environmental regulation can promote efficiency and catalyze innovation, thus improving industrial competitiveness. This idea has been extensively debated since its publication in the 1990s (Ashford, 1999, Porter, van der Linde, Claas 1995). Many questions remain about the relationship between environmental regulations and economic competitiveness, as well as between the environment and economy more generally. This section summarizes some of the key parameters of the issue as developed by others.

The literature generally shows that costs for environmental performance improvement are overestimated, although there is some disagreement (Harrington, Morgenstern & et al. 2000, Hodges 1997, McGarity, Ruttenberg 2002, Office of Technology Assessment (OTA) 1995). Reasons for overestimation include lack of information, reliance on estimates from the affected industries, and a static approach to analysis that ignores learning effects and economies of scale (Ackerman 2006), as well as the potential for innovation. The process of estimating costs of any change in a facility is difficult and there are many unknowns. Also, there is no guarantee that innovation efforts will be successful (Lazonick). Many argue that the design of a particular regulation is an important determinant of its economic impact and/or effectiveness, and argue for technical flexibility regardless of whether strict or loose regulations are advocated (Ashford 2002, Majumdar 2000, Porter, van der Linde, Claas 1995).

Many studies have found that the overall state or national economic effect of environmental regulations is neutral (Ackerman 2006, Goodstein 1999, Meyer 1995). Among the reasons cited are (1) "regulation does not remove money from the economy, so much as cause it to be spent in different sectors,"(2) environmental regulatory costs are comparatively small in the context of other business cost factors, and (3) macroeconomic drivers such as Federal Reserve policy have an overriding impact. In addition, little evidence has been found to support the "pollution haven" hypothesis that firms move to areas of lesser environmental regulations (Ackerman 2006, Goodstein 1999). Factors such as wage rates, market access, and availability of skills and natural resources appear to dominate location decisions. However, even if neutral overall, there may very well be transitional difficulties caused by regulatory action, and impacts on individual firms may differ substantially from overall economic impact.

With environmental efforts, as in all other aspects of the economy, there will be gains and losses. Some companies will face reduced costs through environmentally beneficial process changes such as waste prevention and increased efficiency of chemical use, (Lenox, King 2002) and may gain competitive advantage through innovative and proactive responses to regulation or environmental issues (Clarkson, Li & Richardson 2004, Porter, van de Linde, Claas 1995). Other companies may be hampered by regulatory costs and become less competitive under changing regulatory and market environments (Clarkson, Li & Richardson 2004, Joshi, Krishnan & Lave 2001). Some regulations may have a disproportionate effect on small businesses (Crain, Hopkins 2000, Dean 2000). Radical innovation may benefit the economy as a whole, but put existing dominant industries at a competitive disadvantage (Ashford 1999).

Another important area of literature deals with the economic costs associated with preventable illnesses that result from toxic exposures. Although these are very difficult to quantify, studies at the national and the state level have estimated the costs of environmentally attributable illnesses. In addition to the direct costs of treating preventable illnesses, these figures include the costs to employers of workers' compensation and work days missed, the costs to families of institutional or home care for individuals who are ill or disabled, the costs to state and local budgets of special education services, and the costs of productivity losses over the lifetime of affected individuals (Davies 2005, Fahs, Markowitz 1989, Landrigan, Schechter 2000, Massey, Ackerman 2003, Salkever , Trasande, Landrigan 2005, Waitzman et al. 1995, Waitzman, Romano & et al. 1994).

Expert Discussion Group

The Institute convened a group of experts to discuss the economic factors involved in determining the possible economic impacts of adoption of safer alternatives and the variety and scope of possible impacts. Participants were chosen for their economic and development expertise relating to industry, labor, innovation, and environmental economics, and included:

- Stephen J. Adams, Small Business Administration
- James Goldstein, Tellus Institute
- William Lazonick, University of Massachusetts Lowell
- Teresa Lynch, Economic Development Research Group
- Edward March, University of Massachusetts Lowell
- Andre Mayer, Associated Industries of Massachusetts
- Deborah Savage, Environmental Management Accounting Research & Information Center

Three others were not able to attend the meeting but were asked for their perspectives, and their comments were incorporated into this report. These were:

- Frank Ackerman, Global Development and Environment Institute, Tufts University
- Michael Goodman, Donahue Institute, University of Massachusetts Boston
- Christopher Tilly, University of Massachusetts Lowell

Case material (Appendix F) helped to ground the discussion with examples for the following sectors: formaldehyde in building materials, lead in electronics, and perchloroethylene in dry cleaning. These sectors were selected as useful, representative, and well-documented examples that represent three different scenarios for Massachusetts; *i.e.,* a product that is manufactured elsewhere and imported into the state (building materials), a product that is manufactured in the state and exported elsewhere (electronics), and a local business conducted entirely within the state (dry cleaning). These were characterized as import, export, or local industries to describe the supply chain perspective and other market dynamics.

Table 8.1 describes the three cases in terms of the significant factors identified by the panel.

Table 8.1. Panel observations on case study characteristics

Industry	PCE in Dry Cleaning (local)	Lead in Electronics (export)	Formaldehyde in Building Materials (import)
Supply chain	• Local service • Machine and chemicals imported into MA. • 5-6 PCE manufacturers (all outside MA).	• Imports: finished products and components • Exports: high-end. • Complex international supply chain.	• Primarily import products • Limited export and local manufacture
Availability and cost of alternatives	• Many alternatives • Alternatives more and less costly than existing	• Alternatives agreed on • Long-term performance and environmental issues not well understood	• Some products have readily available alternatives, others do not. • Alternatives not widely used or available
Chemical use trends	• National decline of use • Adoption of PCE-free alternatives slow	• Decreased use of lead in electronics applications	• Green building movement expanding rapidly • Low off-gas formulations increasing
Existing drivers	• California regulations and incentives • Consumer demand	• Regulations in European Union (RoHS), California, and China • Customer requirements	• Concerned consumers • Green Building, increasing interest in LEED Certification.
Industry	• >90% Small family businesses, immigrant • Few suppliers of machines and chemicals	• Many companies of all sizes • Many specialty niches	• Numerous contractors and manufacturers of all sizes • Many products regionally distributed
Financial	• High-cost long-life machines • Financing often assisted by trade associations	• Higher energy costs • Capital cost for new processing equipment and product redesign	• Consumer construction loan financing (banks) • Durability and resale value important.
Market and competition	• Majority of consumers price sensitive • 10% high-end customers • Not a Massachusetts competitiveness issue.	• Significant international competition on the basis of price or technology • Massachusetts cannot compete on price, must compete on technology	• Market segments: residential, commercial, institutional • Residential more difficult to affect • Competition highly product or application dependent

8.2. Economic Impact Assessment Framework

The economic experts' discussion yielded a broad framework for conducting an economic analysis of alternatives adoption. Future projects could be designed to provide much of the specific information needed for an analysis of this kind. This framework is presented in Figure 8.2.

Figure 8.2. Economic Impact Assessment Framework

This framework outlines the ways in which alternatives adoption may affect jobs, industry, and other aspects of the economy.

Scoping

Scope of the Proposed Substitution

Technology and Industry
Economic impact will depend on readiness of alternatives and agility of industry

Alternatives Readiness

- What are chemical use trends?
- What is driving these trends?
- Are there feasible alternatives?
  - Technical risk and reliability
  - Financial viability
  - EH&S impact
  - Market demand and acceptance
  - Availability from suppliers

Industry Agility

- What are characteristics of the industry sector?
- What are characteristics of the supply chain?
- What are characteristics of the market and the competition?

Existing economic conditions for alternatives adoption

Existing Conditions

- Substitution is rewarding, cost effective, market driven or
- Barriers exist to implementing substitutions.

Barriers and Policy Instruments
Economic Impact will also depend on the nature of existing barriers to alternatives adoption and the policy context

Possible Barriers

- **Technical:** Alternatives not readily available
- **Informational:** Inadequate information flows between consumers, industry, researchers
- **Market:** Uncertainty about demand or lack of demand for alternatives
- **Industry:** Aspects of industry or supply chain hinder change
- **Financial:** Inadequate financial structure for financing alternatives
- **Regulatory:** Conflicting requirements or regulatory uncertainty

Policy Instruments

- Technical assistance
- Information (on issues, alternatives, advanced companies, products)
- Incentives or financial assistance (for R&D, equipment purchase, etc.)
- Market support (Environmentally Preferred Purchasing, ad campaigns, volume purchasing commitments)
- Tax policy
- Restrictions or requirements (material, waste, or product)
- Coordinated actions with other States

The following sections provide more detail about the major headings found in Figure 8.3.

Scope of the Proposed Substitution

Alternatives Readiness

What are chemical use trends?

Chemical use trends can be described and listed as uses, geographic locations, and impacts and quantified as volumes and substitution rates.

What is driving these trends?

There may be a number of existing drivers for substitution, including better quality or less expensive alternatives and changes in regulation or consumer preference. Detailed information may include

- Costs – *e.g.*, the cost of disposal of toxic waste, chemical prices or use taxes
- Market changes -- *e.g.*, export market requirements, local consumer demand, company brand image protection, or customer programs in Environmentally Preferable Purchasing
- Innovation – *e.g.,* the obsolescence of existing equipment
- Regulation – *e.g.,* the European Union WEEE and RoHS Directives
- Financing/Insurance – *e.g.,* service providers requiring risk reduction

Are there feasible alternatives?

Technical, financial, and EH&S considerations for each alternative must be researched, including market and supply.

Industry Agility

What are characteristics of the industry sector?

Characteristics to consider include size (number of employees or annual sales), ownership, the education and skill levels of workers as well as their salary ranges, some measure of innovativeness, profit margins and investment practices.

Availability of capital is part of a broader picture of facility investment in an alternative, including the timing of such a transition, the value and remaining lifetime of any existing investments, and the hurdle rate used to make investment decisions.

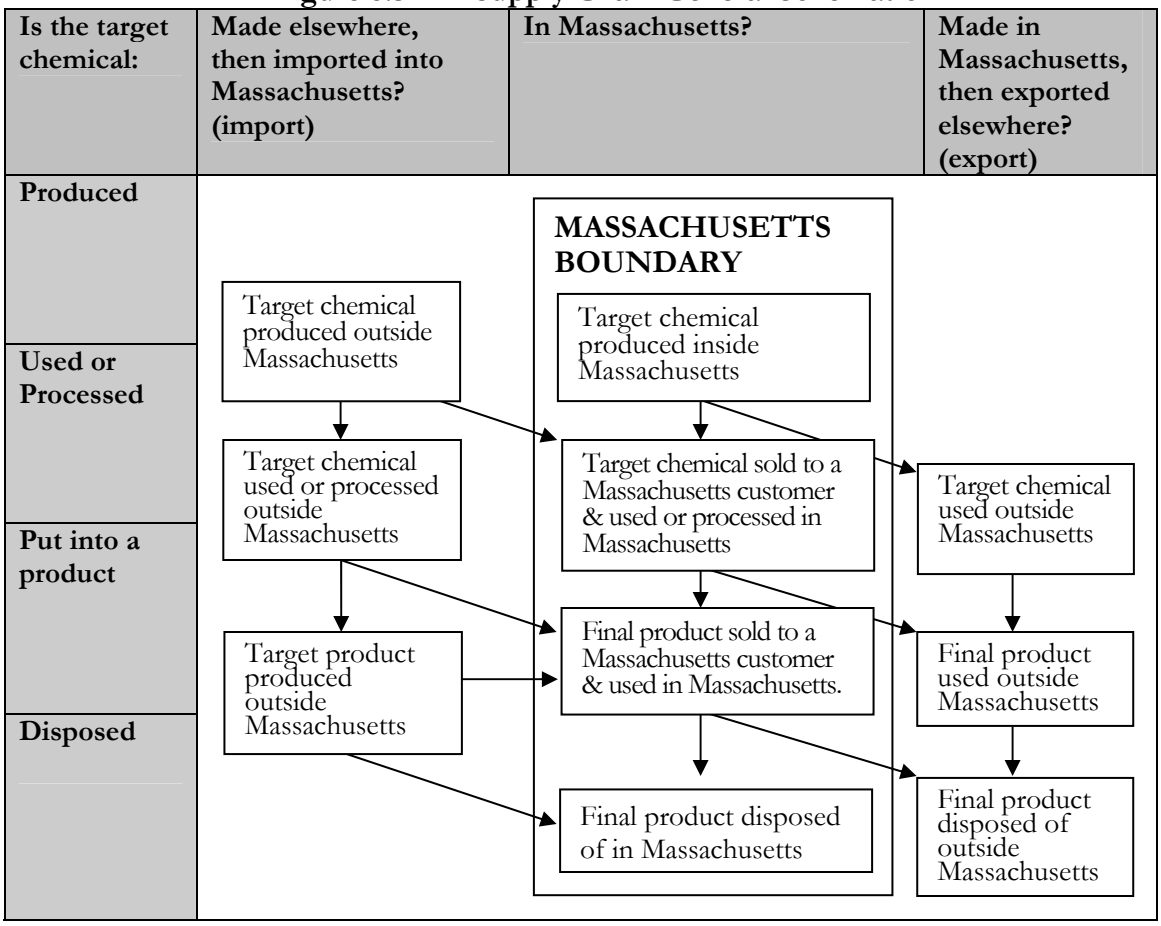
What are characteristics of the supply chain?

Are products containing substances of concern imported or exported, or are the products primarily local to Massachusetts? Who are suppliers and customers, and where and how large are they? Are trading partners large enough to influence the industry sector?

The location of Massachusetts in the supply chain will affect the degree and nature of Massachusetts influence on the market in a given chemical or alternative. It is also important to identify the actors that have most influence on the industry. These may include suppliers that provide information, banks that provide financing, or customers who demand a product change.

The charts below illustrate supply chain characteristics for two of the case studies as developed by one of the expert reviewers. The first chart, Figure 8.3A**,** provides a general schematic to help in visualizing supply chain dynamics, and the subsequent figures provide examples.

Figure 8.3 A -- Supply Chain General Schematic



In the case of PCE use for dry cleaning services, Figure 8.3B, Massachusetts is an importer of dry cleaning machines, but dry cleaning is a local process. As an importer, Massachusetts may not have sufficient market size to drive development of non-PCE machines on its own. However, given that California regulation and technical assistance programs are already driving commercialization of alternatives, Massachusetts action could speed the process of adopting these alternatives.

In the electronics sector, Figure 8.3C, Massachusetts manufactures components, assembles high-tech equipment, and consumes components and equipment. In the first two cases Massachusetts is an exporter, and must respond to international market drivers in order to remain competitive. Component manufacturers must be aware of demand for lead-free components, as well as supply costs, the extent of EU demand, and location decisions.

Figure 8.3. B -- Massachusetts Perchloroethylene Drycleaners – "Local" Supply Chain Example

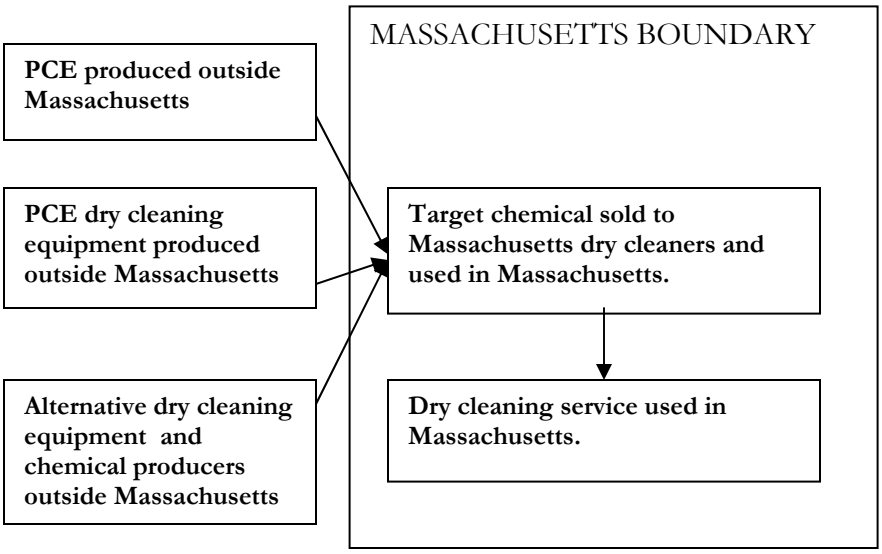
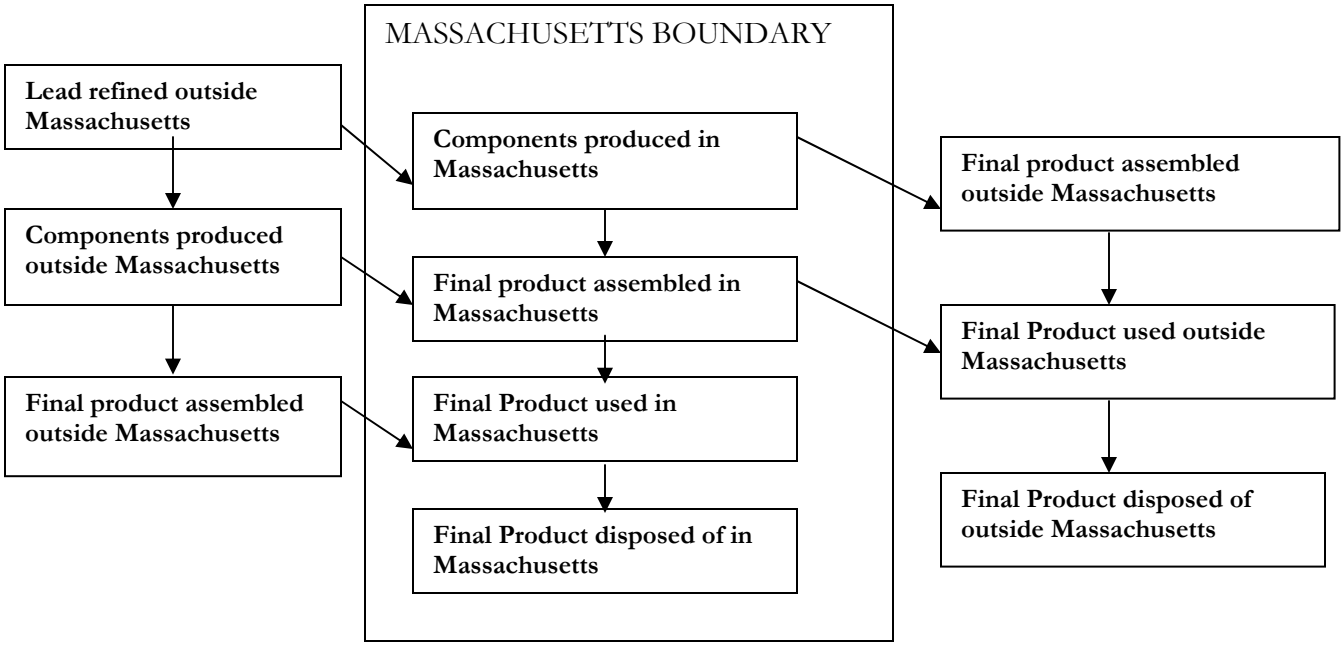


Figure 8.3 C -- Massachusetts Lead-Free Electronics – "Export" Supply Chain Example



What are characteristics of the market and the competition?

A shift to alternatives may raise or lower costs of producing a product or providing a service. Market characteristics will determine the extent and form of resulting economic impacts. Factors to consider in assessing the influence of competition and markets include the following:

- Is the market local, regional, national or international?

- What is the size of the Massachusetts market vs. other locations?
- Does Massachusetts compete based on location, price, and product quality?
- How much does a change in price affect demand?
- How important are non-price characteristics, such as brand image and quality?
- Are there market niches that would respond differently to changes?
- What existing regulations influence the industry?
- How frequently does the market require a new or improved product?

In some cases there may be product niches that can be capitalized for developing greener alternatives, while in other cases the market structure may prevent charging a premium for green innovations. Market divisions may respond differently to changes. For the building materials case (formaldehyde), experts suggest that residential, commercial, restorative, and institutional building markets have different characteristics. Green building practices are being adopted more quickly in institutional and commercial buildings. These customers have better access to information about alternatives than residential customers. Markets with rapid product turnover are more likely to be able to respond quickly to changing requirements.

Factors important to a firm's ability to adapt to changes are summarized in Table 8.3.

Table 8.3: Industry Status and Trends Summary Table

Industry	Supply chain	Competition & Market
• Size • Ownership • Workforce • Profit margin • Innovation • Investment Practices	• Import/export/local • Suppliers & customers • Partner influence	• Competitive basis • Price elasticity • Market influence • Market divisions • Regulatory environment • Speed of market change

Existing Conditions

Understanding the availability of alternatives and the agility of industry gives an indication of the existing economic conditions for alternatives adoption. In some situations substitution may already be rewarding, cost effective, market driven, and proceeding on its own. In other situations, barriers exist to implementing substitutions, and use of old alternatives continues.

Possible Barriers

The third phase of this economic assessment involves consideration of existing barriers, as well as the policies which can address these barriers and facilitate adoption of alternatives.

Technical Barriers: Alternatives not readily available

As this study demonstrates, for some chemicals and some uses alternatives are well understood and readily available. In other cases, fully-developed alternatives may be unavailable at the outset. In other instances, alternatives may be well developed from the perspective of researchers and a few leading companies, but there remain technical, reliability, cost, and risk concerns for most companies.

In cases in which alternatives are not well developed it is helpful to understand (a) the relevant time-frame for transforming costs into benefits, (b) whose interests will be served by a focus on

innovation in this area, and (c) if public funds are used for research, the institutional mechanisms for ensuring that public investment results in public benefits when the innovation is successful.[2]

Information Barriers: Inadequate information flows among consumers, industry, and researchers

Lack of information can be a barrier to change. The TURA Program has demonstrated the effectiveness of providing training and information on alternatives to businesses. Information can also be provided to consumers through labeling, product guides, advertising, and certification for contractors and products.

Market Barriers:

Uncertainty about demand or a lack of demand for alternatives can hinder a firm from moving forward into new technologies. Other industry characteristics that can hinder alternatives adoption include low profit margins or a volatile price environment, lack of necessary expertise among workers, or an industry culture resistant to change.

Financial Barriers: Inadequate financing structure

In cases in which alternatives adoption requires a significant capital investment, lack of adequate financing can be a barrier. Studies suggest that environment-related investment costs and savings are not often considered adequately in firms' investment analyses. Some approaches to book-keeping may hide the costs of using toxic chemicals, or may consider these costs in a separate department. Mayers (2005) suggests that more time be "spent re-engineering business accounting systems to accurately track environment-related costs (and returns) and determine where substantial cost-savings can truly be found." Other potential financial barriers may include lack of familiarity with alternative technologies among finance providers.

Regulatory Barriers: Conflicting requirements, regulatory uncertainty, unregulated competitors

Sometimes adoption of alternatives is delayed because it is unclear whether a regulation will hold. Some companies will delay action if they view pending future regulation as changing the playing field in an unpredictable way. Conflicting regulatory requirements may hinder industry action. For example, the use of drawer sanitizers in salons is required by regulation in Massachusetts.

Policy Instruments

The interactions among policies may be mutually reinforcing, redundant, or conflicting. Policies that influence economic impact can include:

- Technical assistance and training
- Information provided on technology and methods issues, alternatives, leading companies, products, tools, and legislation for Massachusetts companies and for consumers. Particularly helpful is advance information about trends and pending science and policy.[3]
- Incentives or financial assistance for research and development, equipment purchase, *etc.*

[2] The Sixth EU Framework Programme for Research and Technological Development (FP6) has explicit language requiring proposals include a "plan for use and dissemination' to show that knowledge generated will be successfully exploited and there is an 'obligation to use and disseminate the results of the project' within a set time. (European Union, 2006).

[3] The state offers an array of informational tools as part of the Commonwealth of Massachusetts Environmentally Preferable Products Procurement Program.

- Market support through Environmentally Preferred Purchasing programs in government, advertising campaigns, and volume purchasing commitments
- Tax policies
- Restrictions or requirements for use of targeted materials or products
- Coordinated actions with other states

There is a substantial body of literature about environmental policy options, including writings about market-based vs. traditional regulatory approaches. The policy options included here are ones that were discussed by the panel and described in the text where appropriate; it is not a comprehensive listing.

8.3 Economic Themes

The TURA experience, research and the panel discussion yielded important themes that are relevant to the Legislature's charge.

- **Protecting human health:** Economic benefits of public health improvement resulting from safer alternatives may be overlooked because they are difficult to quantify, but they are very significant. The impact of a reduction in these costs was not extensively discussed by the panel, though many stated that they wanted to see this addressed.
- **Identifying economic opportunities:** There may be economic opportunities in environmental improvement.
- **The Commonwealth as convener:** The Commonwealth can play a useful role in facilitating industry problem-solving. There is substantial evidence supporting strategies that bring industry and universities and trade associations together, and help industry problem-solvers make the case for change.
- **Economic outcomes are uneven:** Not all companies benefit from business opportunities created by new technology, regulations, incentives, or other conditions. Regardless of whether the overall state-level impact of a change is found to be positive, negative, or neutral, there will be economic winners and losers. For example, a trend toward capital-intensive CO_2 dry cleaning would favor larger dry cleaners, whereas a trend toward labor-intensive wet-cleaning would favor small businesses, regardless of whether the shift from perchloroethylene dry cleaning was regulatory or market driven.
- **Supporting small businesses:** Small businesses were recognized as important to innovation, employment and entry into business ownership . They also may be disproportionately affected by environmental regulation (as well as other factors for which economies of scale are important). At the same time, if small businesses are not ready for upcoming transitions (such as international regulations like the European Union Restriction on certain Hazardous Substances Directive, "RoHS") they may lose business. If businesses in the state are ahead of these transitions and able to meet requirements or new market demands more quickly or cheaply, companies may gain business.
- **Maintaining a range of job types:** Research and development spending, manufacturing facilities, and regulation may or may not create and maintain good jobs in the state. Research support may not directly address employment for less educated workers, although through a

multiplier effect it can lead to greater demand for less skill-demanding jobs such as waitstaff or other support to professional and technical workers.

Manufacturing facilities that currently provide middle-class wages for lower-education jobs in Massachusetts today are vulnerable, and workers may benefit from advanced training to earn middle-class wages in manufacturing in Massachusetts. Business consolidation (e.g. larger dry cleaners) may cause the loss of small immigrant-owned entrepreneurial businesses.

- **Flexible options:** Technical assistance programs are helpful in supporting positive economic outcomes from substitution, as are preferred purchasing programs, information dissemination, capital financing assistance, government assisted research, and labeling programs like Energy Star. However, voluntary options may leave behind more marginal companies and concentrate negative impacts on the economically disadvantaged.
- **Influence of Regulatory Policy:** Regulatory action may influence the economic impact of alternatives adoption under different circumstances. Many areas of disagreement remained among panel members concerning the significance of these circumstances, which can be organized as follows from the perspective of supply chain and availability of alternatives.

  - ***Imports***

  In cases where Massachusetts is an importer of goods, the issue is the extent to which companies will need to cater to unique demands from the relatively small Massachusetts market in the following situations:

    - If alternatives exist but are not available, the Massachusetts market alone **is likely** to be large enough to provide a market incentive for companies to improve distribution of these alternatives
    - If no alternatives exist and Massachusetts is an importer of goods, the Massachusetts market alone **is unlikely** to be large enough to provide a strong market incentive for companies to develop new alternatives. There was discussion about whether California was large enough, and agreement that the European Union definitely was, as evidenced by the Restrictions on certain Hazardous Substances Directive "RoHS" and the Waste Electrical and Electronic Equipment Directive "WEEE". It was agreed that states working together, *e.g.,* New England and New York, could make a bigger market that could influence alternatives. The possibility was discussed of creating a market niche that ultimately substitutes a locally developed product for what was previously an import product, thus creating a new export industry.

  - ***Exports***

  In cases where Massachusetts is an exporter of goods, the issue is the competitive position of Massachusetts manufacturers in national or global markets. There is significant disagreement over whether unique Massachusetts requirements for manufacturing processes and products put Massachusetts companies at a competitive advantage or disadvantage. The different viewpoints include:

Disadvantage

- Massachusetts-specific requirements where there are existing global requirements could add expense rather than help companies meet challenges.
- Added costs for reducing or eliminating certain toxics that the global market does not require could reduce competitiveness.
- Whether Massachusetts policy appears to industry to be relatively restrictive or inviting might influence company location, expansion, or investment decisions.

Advantage

- Massachusetts requirements could help Massachusetts companies meet global challenges such as RoHS and forthcoming requirements elsewhere.
- Costs of regulations are often less than anticipated, and thus do not, in actuality, reduce competitiveness.
- There is no or little evidence to support the claim that regulatory climate is a key determinant of companies' decision-making around locating and/or investing in facilities.

- ***Local***

In service-industry cases, for example dry cleaning, auto-body, or hair salons, and certain other industries, such as cement, the market is local. Out of state purchases of the service or product are rare other than in border towns.

While there is agreement that larger markets have more influence than smaller ones, there are some disagreements on the implications of that fact for Massachusetts. Many of the reviewers agreed that an approach of collaboration with other states, such as in past efforts to reduce mercury, or ongoing efforts to reduce greenhouse gases, would help reduce costs. However there were disagreements over effects where Massachusetts sets policy ahead of other state and national initiatives, and there was some concern whether other states and countries would follow such initiatives. Whether or not other states would follow a leading state-level policy is an area of analysis for which there is extensive literature and debate but no consensus.

- **The role of innovation is an issue**. Massachusetts currently has an innovation advantage driven by major private research universities and high technology industries such as biotech, polymers, defense, and electronics. However, the degree to which the Commonwealth has a significant influential role in developing or maintaining industrial competitive advantage is less clear.

  There is evidence that Massachusetts companies could be helped to be innovative environmental leaders that use advanced technology to increase competitiveness while simultaneously meeting more stringent environmental standards. There is capacity here: the Commonwealth's existing knowledge base in both universities and companies offers unique high-tech capabilities with which to take advantage of emerging market opportunities for safer technologies. Public policy

is needed to help build and maintain an advantage as, according to one expert, "…state subsidy is in virtually all places and at virtually all times integral to the innovation process." (Lazonick) However, it is possible that responding to market conditions rather than to government mandates is more economically attractive. State funded studies to identify emerging opportunities and ensure the high quality of the regional educational system in environmental technologies may have the best chance to increase competitiveness.

Research on the innovative process is discussed further in Appendix E.

8.4 Lessons from the Five Chemical Assessments

Financial considerations and available information have been presented earlier in the course of each chemical-specific alternatives assessment. The information presented for each case varies according to context. For example, the price of materials is an important parameter for some cases, while operation, maintenance, or disposal costs may be salient for other cases. The Institute intentionally selected chemical uses for which some viable alternatives were expected to be available, and for which a detailed assessment of the technical, financial, and environmental health and safety characteristics of those alternatives was expected to be useful. In every case, the assessment showed that at least one alternative was commercially available, was likely to meet the technical requirements of many users, and was likely to be preferable from a human health and environmental perspective. Based on the Institute's experience with the uses discussed in this report, some broad patterns can be identified.

1. Some alternatives can be adopted without any adverse effect on Massachusetts employment or competitiveness. The formaldehyde alternatives assessment, for example, shows that elimination of formaldehyde dry sterilant from use in Massachusetts hair salons would produce savings and still achieve the desired level of sanitation. Similarly, Massachusetts schools could adopt alternatives to formaldehyde-fixed dissection specimens without increasing costs. The DEHP alternatives assessment notes that nearly all vinyl wall covering sold in the US today is manufactured in China and Southeast Asia. Many of the alternative wall covering materials are produced in the U.S.; thus, increasing demand for these alternatives could benefit domestic producers. Where Massachusetts firms have capacity for innovation, this is an opportunity.
2. Massachusetts manufacturers could gain market share through adoption of some alternatives. For example, some Massachusetts firms are working to produce DEHP-free medical devices. With growing demand for such devices, Massachusetts firms have the opportunity to develop this market niche. Another example is the potential competitive advantage of those wire and cable firms that have eliminated lead in their products, and now stand ready for markets in Europe and Japan that restrict this chemical.
3. Some alternatives require capital investment at the outset. For some technologies, this investment will pay for itself over time in reduced operating costs. For example, many of the alternatives to chromium plating offer technical production advantages that can yield significant savings for firms in the medium term. Many existing case studies of pollution prevention efforts by firms in Massachusetts and elsewhere document the savings that can be achieved through adoption of safer technologies. In contrast, some investments in safer alternatives may not be feasible for small businesses in the absence of targeted grant or loan programs. For example, a small dry cleaner that has recently purchased equipment for cleaning with PCE may not be able to convert to a safer alternative without assistance.

8.5 Conclusions

This chapter supplements the specific cost discussions in previous chapters with a broader consideration of economic patterns. It was not possible for the Institute to draw conclusions about the general employment or competitiveness impacts of alternatives adoption, but several broad lessons emerge.

First, there is strong evidence that adoption of safer alternatives can produce economic benefits, especially for those supported by the current market. This is a lesson from the experience of the TURA program, the literature on this topic, and some of the sectors considered in this report.

Second, there are some cases in which substituting chemicals or processes may have negative effects on some firms, even if there is a positive or neutral effect on the state economy more generally.

Third, there are many opportunities for government to support a positive economic outcome and to mitigate any negative effects for individual firms. In some instances, targeted assistance to industry can facilitate adoption of safer alternatives that will yield employment and competitiveness benefits over time. Government can have a role to play in facilitating adoption of alternatives that require an initial capital investment. Loan or grant programs may be particularly useful for small and medium sized enterprises. For example, California has demonstrated the viability of grant programs in facilitating the transition to safer alternatives for small dry cleaning facilities. Partnerships in research and skills development can also enhance knowledge of emerging safer technologies.

Finally, the framework presented in this chapter can be used to analyze likely economic impacts from alternatives adoption by clarifying the situational characteristics and factors that determine the outcome.

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Chapter 4. Formaldehyde

Five Chemical Alternatives Assessment Study

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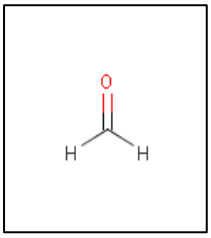
4.1 Overview



The metal catalyst oxidation process to create formaldehyde from methanol was discovered in 1868 by A. W. Hofmann. Formaldehyde's use grew rapidly throughout the 19th and 20th centuries, and formaldehyde (CH_2O, CAS#50-0-0) remains a common and important industrial chemical. Profoundly simple, inexpensive and useful, many products are made from or contain formaldehyde, including resins, permanent press fabric treatments, tissue preservatives, lawn fertilizers, cosmetics and disinfectants. Combustion of fuels and biomass is a significant source of formaldehyde in the environment. Formaldehyde is produced in animals and plants as a result of natural metabolic processes, but is rapidly metabolized through a dedicated metabolic pathway (formaldehyde dehydrogenase) (Agency for Toxic Substances and Disease Registry (ATSDR) 1999b; Liteplo et al. 2002).

Wood adhesives used to make plywood, particleboard and other manufactured wood products are the dominant end use for this chemical, accounting for 64% of the total 24 million metric tons consumed worldwide each year (Bizzari 2004). The plastics industry also uses formaldehyde-based resins extensively, especially for car parts. Because the polymerization of these resins can partially incomplete or can reverse under certain circumstances, construction materials, furniture and consumer products have been identified as sources of formaldehyde in indoor air at levels consistently higher than outdoor air, and at levels with the potential to cause health effects, such as respiratory irritation. In the early 1980's attention to high average levels in mobile homes helped bring about emission standards for formaldehyde-resin building materials that have decreased product "off-gassing." While humans have evolved to metabolize the very low levels of formaldehyde that are endogenous to human cells, at higher levels these metabolic processes are overwhelmed (Agency for Toxic Substances and Disease Registry (ATSDR) 1999b). Thus, formaldehyde can be highly toxic to humans. It has strong odor, is highly irritating, is a potent sensitizer, and has been determined by IARC, EPA, OSHA and NIOSH to be a carcinogen.

4.1.1 Characteristics of the Chemical

Formaldehyde is a gas at room temperature and is soluble in polar solvents, including water. It is easily synthesized from methanol. It has a strong irritating odor and a low odor threshold. It is colorless and flammable (Agency for Toxic Substances and Disease Registry (ATSDR) 1999a). Formaldehyde polymerizes readily with heat which makes it especially useful in resin production, and especially expensive and challenging to transport. Because of these limitations, it is usually made close to where it is used and there is very little trade in pure formaldehyde. Formaldehyde is most often produced, transported and used as a 37% solution in water known as formalin. These solutions also contain a stabilizer, typically methanol (at 12%), to prevent polymerization. In the presence of air and moisture at room temperature, formaldehyde readily polymerizes to paraformaldehyde, a solid form that is also a commercial product.

Table 4.1.1 A: Chemical/Physical Characteristics of Formaldehyde
(Agency for Toxic Substances and Disease Registry (ATSDR) 1999b; Environmental Science Center 2004; Hazardous Substances Data Bank)

Characteristic	Description
Melting/Boiling Point	-92° C /-21° C
Vapor Pressure	Gas
Octanol/Water Partition Coefficient	Log Kow = 0.350
Density	0.815 g/mL at -20° C; Gas: 1.067 (Air = 1)
Solubility	Very soluble in water and polar solvents; up to 55% (freshwater at 20 °C). Soluble in alcohol, ether, acetone, benzene
Soil Sorption Coefficient	Log Koc = 1.567; very high mobility in soil
Bioconcentration Factor	3.2 (estimated based on the chemical's octanol/water partition coefficient); formaldehyde is not expected to bioaccumulate
Henry's Law Coefficient	3.27×10^{-7} atm-m^3/mol @ 25 °C
Biodegradation	Half-Life (in sunlight) 1.6-19 hours producing H_2 and CO or H^+ and HCO^-

4.1.2 Health and Environmental Impacts

Exposure and Effects on Human Health

Because formaldehyde is highly reactive, water soluble and rapidly metabolized, people may experience its toxic, irritating and sensitizing effects at the site of contact, such as the upper respiratory tract, the eyes and the skin (Liteplo et al. 2002). Such symptoms may be experienced by those exposed at their jobs, but also have been reported among students in gross anatomy labs who are exposed to formaldehyde used to preserve human and animal specimens (Kriebel et al. 2001) and occupants of mobile homes constructed largely of particleboard. (Liu et al. 1991) Inhaled formaldehyde is readily absorbed by the upper respiratory tract and can be rapidly metabolized and detoxified into formate by almost every cell in the body (Agency for Toxic Substances and Disease Registry (ATSDR) 1999b). Skin contact results in severe irritation and burns and some formaldehyde may pass through the skin, though it is unlikely to cause systemic effects due to rapid metabolism. Repeated prolonged exposures may result in sensitization of the individual to formaldehyde. Sensitized individuals are more likely to experience contact dermatitis and asthma attacks than the non-sensitized. Formaldehyde exposure may also trigger asthma attacks in individuals with underlying asthma. Headaches, chest pains, and other symptoms may also be linked to exposure to low levels of formaldehyde in indoor air. While unlikely occurrences, ingestion of formaldehyde or very high air concentrations can quickly cause death due to burning of the lungs and subsequent edema ("flooding" of the lungs).

In 2004 IARC moved formaldehyde from the 2A – probable human carcinogen group, to Group 1: sufficient evidence that it is a human and animal carcinogen (International Agency for Research on Cancer (IARC) 2004). This determination was based on several epidemiological studies. Occupationally exposed industrial workers and those handling embalming fluids or preserved tissues were found to have elevated risks of nasopharyngeal cancer. Six of seven studies of embalmers and pathologists and two of three studies of industrial workers also found excess risk of leukemia. It has been hypothesized that because formaldehyde is a natural part of the environment and humans have evolved to cope with such low level exposures, high levels of exposure are required to induce carcinogenesis (Natz 2006). ATSDR and WHO reviewed toxicology and epidemiological studies and did not conclude that formaldehyde causes adverse reproductive and related outcomes, although

some animal and human studies have found reproductive or developmental effects (Taskinen et al. 1999; Zeljenkova, Szabova 2004). Formaldehyde has been found to be toxic to cells and genes (ATSDR 1999b). Human health effects are summarized in Table 4.1.2 A

Table 4.1.2 A: Human Health Effects

Acute	• Irritation of the eyes, nose, throat, and skin. • Burns. • Narrowing of the bronchi and an accumulation of fluid in the lungs. • Risk of death from severe inhalation exposure: throat swelling, chemical burns to the lungs. • Drinking as little as 30 mL (about 2 tablespoons) of formalin can cause death.
Cancer	• Nasopharyngeal cancer. Possibly leukemia and cancer of the sinuses.
Other chronic	• Sensitization: contact dermatitis and possibly asthma (case reports only) • Central nervous system depression: headache, depression, mood changes, insomnia, irritability, attention deficit, and impairment of dexterity, memory, and equilibrium. • Genotoxic: sister chromatid exchange and chromosomal aberrations. • Cytotoxic

People – workers, children, community members, building occupants – are exposed to formaldehyde through natural sources, and those that are human-made, in many contexts. The main human-made sources of exposure are summarized in Table 4.1.2 B, along with some measured exposure levels in Table 4.1.2 C. Note that many of the values reported in this table of historical exposures come from exposure studies conducted in the 1970's and 1980's; exposure levels today are expected to be lower as a result of the reduction in free formaldehyde in building products and compliance with the 1992 OSHA formaldehyde standard, which lowered permissible exposure levels in workplaces.

Table 4.1.2 B: Sources of formaldehyde exposure

Occupational	• Industrial production (resins, molding compounds, fertilizer, paper, wood products, furniture, laminates, plastics, pesticides, chemical manufacture, rubber, leather tanning, iron foundries, photographic film, textiles, scientific supply, and cosmetics) • Agriculture (sugar production, grain and seed preservative) • Oil extraction (well-drilling fluids) • Funerary work (embalming fluid) • Hospitals, laboratories and schools (preserved tissue and specimens) • Construction (manufactured wood products) • Transportation and energy (combustion) • Beauty salons (sanitizer, cosmetics)
Environmental	• Smog in the lower atmosphere • Mobile sources (exhaust from cars, trucks) • Stationary combustion sources (power plants) • Cigarettes and other tobacco products • Gas cookers and open fireplaces • Consumer products (antiseptics, medicines, cosmetics, dish-washing liquids, fabric softeners, shoe-care agents, carpet cleaners, glues and adhesives, lacquers, paper, plastics) • Indoor air in buildings made with or containing furniture made with plywood, particleboard, medium density fiberboard, oriented strand board; insulation; carpets and other flooring; adhesives • Industrial emissions and waste • Fertilizer • Foods (cheese, fumigated grains, naturally occurs in plants and animals)

Table 4.1.2 C: Historical Exposure Levels in Air
(Hazardous Substances Data Bank ; Hiipakka et al. 2001; Hodgson et al. 2002; Kriebel et al. 2001; Olcerst 1999)

Outdoor	• Rural areas 0.2 ppb; suburban areas 2–6 ppb; heavily populated area or near some industries 10–20 ppb
Non-industrial indoor	• Averages: Mobile homes: ~37 ppb; conventional homes ~14 ppb, classrooms~18 ppb; offices ~13 ppb • Funeral Homes: averages between 0.25 ppm and 1.4 ppm; occupational exposure avg 4.8 ppm • Cosmetology classroom (paraformaldehyde sterilent): 0.08 ppm
Industrial	• Permanent-press fabric plants: 0.3 ppm to 2.7 ppm • Resin manufacturing plants: 0.08-12 ppm • Plywood mills, particle-board mills, furniture factories, other wood product and paper mills: 0.07-6 ppm • Textile mills and garment factories: 0.08 to 1.6 ppm • Foundries and other industrial facilities: 0.03 to 31 • Mortuaries, hospitals, and laboratories: 0.04 to 3.4 ppm
Laboratory	• 0.70 ppm average exposure and 11 ppm highest short-term exposure for gross anatomy laboratory students

Formaldehyde has been identified as an important indoor air contaminant (Spengler et al. 2001). As part of their efforts to reduce sources of formaldehyde in indoor air, the California Air Resources Board commissioned a study of the emission rates of products and materials that contain or generate formaldehyde. At the end of the 20-hour test period, investigators measured the emission

rates of products placed in special chambers where temperatures and air flows approximated "typical" indoor air conditions. The following table shows that wood floor finish can contribute significant amounts of formaldehyde to indoor air as can many common products and building materials. Materials such as particleboard that are coated or covered with an impermeable surface emit far less formaldehyde than materials without such a barrier.

Table 4.1.2 D: Formaldehyde Emission Rates from Selected Indoor Sources
(Kelly 1997)

	Typical Conditions (µg/m²/h)
wood floor finish	11,000
fingernail hardener	300
latex paint	9
Cabinet door with acid-cured finish	460
medium-density fiberboard cabinet door	360
Particle board	240
Particle board with vinyl laminate	16
softwood plywood	4
new permanent-press shirts	110
washed permanent-press shirts	42
fiberglass insulation	32

Environmental Effects

Formaldehyde is a natural component of the environment and of the human body. The main effects of formaldehyde in the environment are discussed above as human health effects from exposures that exceed "normal" levels. In outdoor or indoor air, as a combustion product, an industrial pollutant, "off-gassed" from consumer products or building materials, or in smog, formaldehyde can cause acute and chronic health problems for exposed humans. Formaldehyde biodegrades readily in air, water and soil under both aerobic and anaerobic conditions (Hazardous Substances Data Bank). It is not commonly found in drinking water and only in limited quantities in food, such as in cheeses and grains where it occurs naturally and is added to kill pathogens. Formaldehyde in the air breaks down in sunlight during the day into carbon monoxide and formic acid, a component of acid rain. In animals, formaldehyde breaks down into formate and carbon dioxide. Formaldehyde is not bioaccumulative (does not build up in plants and animals).

Occupational and Environmental Standards and Guidelines

Formaldehyde is regulated as a human carcinogen, and classified as either a probable, potential or likely human carcinogen by IARC, OSHA, NIOSH, and EPA's NTP. OSHA's 1992 comprehensive standard requires employers to limit 8-hour exposures to less than 0.75 ppm, but they must take certain protective actions if exposures reach 0.5 ppm. Exposure monitoring, medical surveillance, and medical removal, engineering controls and respiratory protection, training and labeling are some of the extensive requirements of the standard. Formaldehyde is identified as a hazardous and toxic chemical in all media by the EPA and subject to Clean Air Act MACT standards, emissions permits and special disposal requirements.

Many manufacturers of consumer and building products have been reformulating to remove formaldehyde, or improving their products and processes to inhibit the release of formaldehyde. Urea-formaldehyde foam insulation, installed in the early 1970's across North America to conserve energy, and later found to contribute to high indoor formaldehyde levels, is restricted in many states, including Massachusetts, and manufacturers have stopped producing it. Beginning in 1985, the Federal Department of Housing and Urban Development restricted the use of wood products made with formaldehyde-based resins in mobile and prefabricated homes to those that met low emission limits as determined in standardized large chamber tests. Industry groups working with government and others have developed emission standards for particleboard and plywood and codified these in several ANSI standards. These standards are similar to HUD's. As a result of these standards and voluntary efforts by industry "manufacturers have reduced formaldehyde emissions from pressed wood products by 80-90% from the levels of the 1980's," according to the U.S. Consumer Product Safety Commission (CPSC 1997). However, over 50% of particleboard products destined for the US market (*e.g.,* furniture) are made in China; it is not known if these imported materials meet emission standards.

European and California restrictions on carcinogens in cosmetics have stimulated many makers to reformulate without formaldehyde (http://www.safecosmetics.org/newsroom/press.cfm?pressReleaseID=15). Because of concerns about formaldehyde's role in indoor air pollution and its impact on Californians' health and the economy, the California Air Resources Board is considering regulations to reduce formaldehyde emissions from consumer products and building materials. In its recent report on indoor air quality, CARB's highest priority recommendation to improve indoor air quality was to replace formaldehyde-emitting wood products with lower emitting ones (California Air Resources Board 2004).

Table 4.1.2 E: Exposure/Environmental Standards and Guidelines

(California Air Resources Board 2004)

OSHA (legal limits)	PEL: 0.75 ppm (averaged over an 8-hour workshift, 40-hour workweek) STEL: 2 ppm (15 minute) Comprehensive standard: requires workplace monitoring, labeling, and training and medical monitoring and engineering controls if employees are exposed above the action level of 0.5 ppm
NIOSH (recommended limits)	REL: 0.016 ppm (10-hr TWA) Ceiling: 0.1 ppm (15-minute) IDLH: 20 ppm Potential occupational carcinogen
ACGIH (recommended limits)	TLV®: Ceiling limit 0.3 ppm A2: Suspected human carcinogen
AIHA ERPG-2 (emergency response planning guideline)	10 ppm (1 hour)
EPA	Hazardous Air Pollutant under CAAA; hazardous waste under CERCLA, RCRA; hazardous substance under CWA; Federal drinking water guidelines: 1000 ug/l; Classification B1 probable human carcinogen
FDA	Food additive permitted in feed and drinking water of animals.
NFPA	(As 37% formalin liquid, no methanol): Health = 3; Flammability = 2; Reactivity = 0
HUD	Particleboard materials shall not emit in excess of 0.3 ppm; plywood 0.2 ppm measured in ASTM large chamber test

Table 4.1.2 E: Exposure/Environmental Standards and Guidelines
(California Air Resources Board 2004)

OEHHA* Chronic Reference Exposure Limit (based on irritant level)	27 ppb in indoor air over 8 hours
ANSI/Industry voluntary standards	Particleboard flooring: 0.2 ppm limit; other wood products 0.3 ppm
Carpet and Rug Institute (voluntary standard)	Carpets 0.04 ppm

4.1.3 Use and Functionality

Formaldehyde is a basic building block chemical and it finds its way, either directly or in derivative chemicals, into almost all sectors of the economy and thousands of products (Bizzari 2004). Over 24 million metric tons (26 million US tons) of formaldehyde were consumed in the US in 2003. Wood adhesives take the greatest share of production. Overall, US formaldehyde production has remained mostly flat as growth in formaldehyde-based products moves overseas, principally to China. Certain uses, such as in textile coatings and alkyd paints, are declining due to environmental concerns or increasing imports of pre-coated fabric. Major US uses of formaldehyde are summarized in Table 4.1.3.

Formaldehyde's readiness to polymerize makes it ideal for the production of resins that are durable, even in wet environments. The wood adhesives industry has made the greatest use of formaldehyde, accounting for 64% of formaldehyde consumed in the US. Plywood and other products that are "exterior-grade" or need to withstand wet conditions are usually made with the dark red phenol-formaldehyde resin. Hardwood plywood, particleboard and medium density fiberboard, often used for making furniture and cabinetry, are made with less expensive and higher-emitting urea-formaldehyde resins. Melamine-formaldehyde resins are also used in wood products and laminates and also molded plastic parts as are polyacetal resins. These resins are also formulated for giving specialty coatings to paper and fabrics.

Another important use for formaldehyde, (although not a large share of formaldehyde consumption), is as a sterilant and tissue preservative. Animal specimens used in high school and college biology classes traditionally have been fixed and preserved in formalin. In addition to its use in educational specimens, formaldehyde is the tissue preservative of choice for human and animal tissue preservation in medical and scientific laboratory settings. Formaldehyde is used by embalmers, and other funerary workers, who preserve human remains for burial. Formaldehyde is also used in small amounts as a pesticide in products such as latex paint and cosmetics. Its excellent disinfection properties are also made use of in paraformaldehyde salon disinfectants and in fumigants for grain and seeds.

Several commercially important chemicals are derived from formaldehyde including 1,4-butanediol (used to make polyurethane and spandex fibers), MDI, aminopolycarboxylic acids (*e.g.*, EDTA) used in cosmetics and as chelating agents, pesticides and lawn fertilizer; and "permanent-press" and flame retardant textile coatings. Interestingly, the leading substitute for formaldehyde in wood adhesives is methylene diisocyanate (MDI), which is made from formaldehyde. Additionally, 1,4-butanediol, 70% of which is made from formaldehyde, is the feedstock for the making of n-methyl pyrrolidone (nMP), a common chlorinated solvent substitute.

Many consumer products and cosmetics have added formaldehyde as resins and to kill microbes. Cosmetics that may include formaldehyde include: nail polish and hardeners (used as a film-forming resin), cuticle softener, shampoos and other hair preparations, suntan and dry skin lotions, makeup,

mouthwashes, bath products, deodorants, and shaving cream. Household cleaning products that may include formaldehyde include: cleaners, dishwashing liquids, fabric softeners, shoe care agents, car shampoos and waxes, and carpet cleaning agents. Latex paint may also contain formaldehyde or formaldehyde precursors (ATSDR 1999b). Many "green" building products are made with formaldehyde resins including bamboo and cork flooring and particleboard substitutes made with agricultural waste (Greenseal).

Table 4.1.3 A: Formaldehyde Uses in the US

Major Use Category	Product Category	Uses/Applications
Resins	Urea-formaldehyde resin (23% of US consumption of 37% formaldehyde)	Wood Adhesive (particleboard, medium-density fiberboard, hardwood plywood and waferboard: Internal, non-structural applications)
		Glass fiber roofing mats
		Molding compounds: Ball milling
		Molding compounds: electrical switches, circuit breakers and other
		Cross-linking agent for surface coating including flame retardants
		Other: Low-pressure laminates, wet strength additives and coatings for paper products, textile treating, cross-linking agents for surface coating
	Phenol-Formaldehyde resin (17%)	Wood adhesives (plywood, oriented strand board (OSB), hardboard, molded wood, particleboard); Structural applications; wet strength
		Insulation (phenolic foam insulation, binders for insulation)
		Decorative and Industrial (circuit board and personal computers) laminates
		Foundry mold binders
		Molding compounds
		Other: clutch facings, disk brake pads, automatic transmission components and brake linings, protective coatings (food containers), rubber processing additives, and abrasives for metal finishings
	Polyacetal resin (13%)	High performance plastic parts for automobiles, industrial machinery, plumbing, appliances, tools, and consumer goods such as ski bindings, knife handles
	Melamine-formaldehyde resin (3%)	Adhesive in decorative laminates, OSB, plywood, mdf, particleboard
		Thermoset surface coatings
		Molding compounds such as dinnerware (medical products, household fixtures), tire cord and ceiling tiles
		Paper and textile treating (wallpaper, wrinkle resistant clothing)
		Used as cross-linking agent for flame retardant
	Coating resins (7%)	Pentaerythritol (5%) is used to make alkyd resins in solvent-based paints and finishes; Trimethylolpropane and trimethylolethane impart UV and chemical resistance to coating resins; Polyhydric Alcohols (Polyols) are alkyd resins for use in automobile paint, house paints, artists' oil paints and synthetic lubricant markets

Table 4.1.3 A: Formaldehyde Uses in the US

Major Use Category	Product Category	Uses/Applications
Disinfectant/ Sterilant/ Preservative	Paraformaldehyde	EPA registered disinfectant, "Steri-dri"sanitizer and fungicide for barber and beauty and for households, ships, bedding, clothing, nonfood/non/feed transporting trucks
	Formalin	Microbiologically active against bacteria, fungi, bacterial spores, many viruses: 8% solution with isopropanol: bacteriacidal, tuberculocidal and sporicidal 6-8% solution: sterilant 1-8%: low to high level disinfectant
		Embalming fluid
		Tissue fixation/Pathology
		Antimicrobial used in cosmetics, metal working fluids, latex paint and low VOC paint; secondary oil recovery
Derivative Chemicals	1,4-Butanediol (10%)	Used to make tetrahydrofuran (THF); urethane elastomers (spandex); gamma-butyrolactone which is used to make n-methyl pyrrolidone
	Methylene diisocyanate (MDI) (9%)	Rigid and flexible urethane foams (foam boards, furniture and bedding foam);
		Wood adhesive/binders in OSB and as a formaldehyde substitute in particleboard
		Eastomers (automotive bumbers, door panels; flexible tubing and cable jacketing; gaskets)
	Hexmethylenetetramine (3%)	Thermosetting catalyst for Novolac/phenolic resins (principal use) Manufacture of RDX explosive (cylonite) Rubber vulcanization accelerators Unisolated intermediate in the manufacture of nitrilotriacetic acid
	Aminopolycarboxylic acids (EDTA and NTA), salts (3%)	Chelating agents in industrial and household cleaners and wastewater treatment
		EDTA is also a penetration enhancer in many cosmetic products
	Fertilizers	Controlled-release urea-formaldehyde concentrates for lawn chemicals
	Herbicides (2%)	Paraquat is made from pyridine chemicals
	Textile chemicals	Wrinkle resistance (UF, MF, gyloxal-UF resins); fire retardants

4.2 Formaldehyde Use Prioritization

Chemical Use in Massachusetts

Formaldehyde is not intentionally manufactured in Massachusetts, but formaldehyde and its derivatives are used here in manufacturing other materials and products. Of the 4.8 million pounds of formaldehyde reported under TURA in 2003 (uses of less than 10,000 lbs are not reported), resins manufacture accounted for 60%, chemical manufacture 39% and energy production by-product 1%. One facility in western Massachusetts, used 2.7 million pounds in urea and melamine resins used to make molding compounds (ball milling), which, in turn, are made into plastic dinnerware and other consumer products. Massachusetts companies, institutions and consumers are significant users of formaldehyde-based products made elsewhere.

Table 4.2 A: Massachusetts Companies Reporting Formaldehyde Use in 2003
(source: MA TURA Data, 2003)

Use	Total Used (lb)	Generated Byproduct (lb)	Shipped in OR as Product (lb)	Total Emissions (lb)
TOTAL	**4,758,984**	**162,096**	**4,572,626**	**65,053**
Chemical intermediate (dispersant)	505,794	828	504,966	614
Combustion by-product	26,872	26,872	0	26,871
Organic chemical manufacturing	14,100	6	14,094	123
Embalming chemicals	768,054	7,443	767,431	510
Paper resin	17,000	8,400	8,400	6,300
Byproduct of LNG liquification/vaporization	16,540	16,540	0	16,540
Resin and resin-coated fabric manufacture	41,366	21,694	19,671	599
Molding compounds (resins)	2,732,087	2,023	2,730,064	2,023
Electroless copper solution manufacturing	530,000	9,900	528,000	10
Electroless copper for printed wiring boards	40,727	1,179	0	728
Resins, coatings, laminates*	Trade secret	770	Trade secret	770

(*TURA quantities not available due to trade secret claim)

Table 4.2 B: Massachusetts Companies' Use of Formaldehyde in 2003
(source: MA TURA Data, 2003)

Use	% of Total
Chemical intermediate (dispersant)	16.4%
Combustion by-product	0.6%
Organic chemical manufacturing	10.8%
Embalming chemicals	0.3%
Paper resin	0.4%
Byproduct of LNG liquification/vaporization	0.4%
Resin and resin-coated fabric manufacture	0.9%
Molding compounds (resins)	58.2%
Manufacture of electroless copper solutions for printed wiring board industry	11.3%
Electroless copper for printed wiring boards	0.9%
Resins, coatings, laminates	(Claim Trade Secret)

Summary of Stakeholder Input

Stakeholders were particularly concerned with "emissive" uses of formaldehyde: manufacture and use of products with potential exposures to workers, consumers and children. The stakeholders reviewed the major use categories and types of uses including industrial, commercial, consumer and school settings. Due to concern about health effects related to indoor air exposures, stakeholders were interested to learn about alternatives to formaldehyde in building products. Formaldehyde in school settings and small businesses was also highlighted as a high priority. These settings took precedence over other larger volume uses. Wood floor finishes have been reported to emit significant amounts of formaldehyde, but manufacturers stated that no formaldehyde is added to the finishes and stakeholders prioritized uses where formaldehyde was an ingredient.

Priority Uses

Using the previously described stakeholder priorities, and the criteria listed in Section 2.3.3, uses that were representative of the major formaldehyde use categories in Table 4.1.3 were evaluated for further study. From the resin and building materials category, particleboard/wood building panels are a large use of formaldehyde in Massachusetts, with significant exposure potential for construction workers and building occupants. In addition, these panels were identified as a very high priority for stakeholders. Urea-formaldehyde resins used in fiberglass insulation, were designated as a secondary choice. In the disinfectant and consumer category, stakeholders placed a high priority on the use of paraformaldehyde sterilants, currently required by the Massachusetts Board of Cosmetology. Salon patrons, workers and students in cosmetology classes are exposed to this formaldehyde source. Stakeholders indicated that exposures experienced by children were a very high priority, leading to the selection of formaldehyde use in preserved educational specimens. Textile finishing chemicals (formaldehyde derivatives) were designated as a secondary choice, if resources became available.

The resulting high priority uses for formaldehyde were:

- Sanitary Storage in Barbering and Cosmetology
- Preserved Educational Specimens for Dissection
- Building panels

Secondary priorities, if resources had become available, were textile permanent press finishes and fiberglass insulation binders.

4.3 Formaldehyde Alternatives Prioritization

Given the limited time span and scope of this project the Institute searched for alternatives to formaldehyde for the high priority uses that seemed most feasible. Potential alternatives would be more likely to be feasible if they contributed positive values to the criteria listed in Section 2.4.3.: performance, availability, manufactured in Massachusetts, cost, environmental health and safety, and global market effect.

4.3.1 Alternatives Associated with Sanitary Storage in Barbering and Cosmetology

The Massachusetts Board of Cosmetology establishes requirements for sanitation in beauty salons. Their regulations include three references to formaldehyde. In section 3.03 of the regulations (Equipment and Hygiene Procedures), item (17) says: "One of the following methods must be used to sanitize instruments and equipment after use on any patron or model:

(a) Physical Agents.

1. Boiling water at 212°F for 20 minutes.
2. Steaming dry heat.
3. 70% grain or denatured alcohol for at least ten minutes.

4. Ultraviolet (UV) rays in an electrical sanitizer.
5. Immersion in 10% formalin for at least ten minutes.

(b) Chemical Agents.

1. Antiseptics and disinfectants (hospital grade required).
2. Vapors, formalin and steri-dry."

A bleach solution is also offered as an alternative. Item (18) says: "(a) In cosmetology salons, there must be at least two covered waste receptacles and at least one air-tight container for storing sanitized instruments. Dry sanitizer must be used in drawers." Dry sanitizer is para-formaldehyde dry sterilant, known by the trade name, "Steri-Dry." The perforated plastic containers containing the solid form of formaldehyde "leak" formaldehyde as it de-polymerizes naturally into formaldehyde gas, filling the tool boxes, cabinets and drawers where hair brushes are kept, and entering the salon and classroom air as drawers are opened.

Alternatives to use of formalin for disinfection in salons and schools were not evaluated. Alternatives are generally used, including the popular blue Barbicide disinfectant solution. Evaluation of overall proper procedures for disinfection, and testing of disinfectants' relative effectiveness was beyond the scope of this report.

Available Alternatives

While salons generally select non-formalin chemistries for the disinfection of instruments, the Board's requirement to use dry sanitizer in drawers and student tool boxes has meant that formaldehyde is present in salons and cosmetology training schools, including vocational high schools. The alternative to this use is either the use of another dry sterilant or alternative procedures that do not require use of a sterilant in storage cabinets. No alternative chemical dry sterilants were identified for use in storage drawers to "maintain" disinfection. An additional alternative is for brushes and combs and other beauty implements to be stored in an ultra-violet light cabinet where the UV light source would kill pathogens on exposed surfaces. In summary, the following available alternatives were identified:

- Process change to eliminate the need for dry drawer sterilants
- UV light cabinets for storage

Alternatives Screened Out

No alternatives were screened out because they were carcinogens, PBTs or TURA SAB more hazardous chemicals.

Priority Alternatives for Salon Disinfection and Storage

The priority alternatives for use of para-formaldehyde dry sterilants in sanitary storage are

- Process Change: Storage of implements in a disinfected, dry, covered container and isolated from contaminants
- UV light cabinets for sanitary storage

4.3.2 Alternatives Associated with Preserved Educational Specimens for Dissection

High school and college students in anatomy classes dissect preserved specimens, including fetal pigs, frogs, cats, sharks and other species, to learn from their direct experience of the animal's anatomy. Traditionally, educational specimens have been preserved with a formalin solution to prevent the natural decay of the tissues. Formaldehyde both kills the bacteria that would decay the tissue and it polymerizes the tissue to maintain, to some degree, its texture, structure and color. Formaldehyde off-gasses during the period of time of the storage, use and disposal of the specimen. Students, lab instructors and technicians are exposed to formaldehyde through their repeated contact with these specimens. Smaller animals are usually dissected within a couple of weeks, but larger animals, such as cats, might be used by students over two semesters.

Specimens are ordered by schools from scientific supply companies that specialize in providing preserved specimens for educational and scientific uses. Specimens are first "fixed" with a fixative (traditionally, formalin) and then may be sold with a holding solution that may be formaldehyde, or some other preservative such as propylene glycol. Specimens fixed with formaldehyde may be repeatedly washed by the vendors to remove as much formaldehyde as possible prior to shipment. They may then be placed in a "humectant" such as propylene glycol, to keep them from drying out. In addition to specimen sales, scientific supply companies also sell fixative and holding solutions to be used by researchers and advanced students who preserve their own specimens or who maintain specimens long term in jars. In response to consumer demand, scientific supply companies have developed their own formaldehyde-free fixatives, specimens and holding solutions. Formaldehyde-free alternative specimens are evaluated here, as well as the technological alternative of video and virtual dissection.

Available Alternatives

The Institute evaluated specimens fixed and preserved in alternative solutions available for purchase by educators, rather than the solutions themselves. Specimens did not appear to be available in the following alternative preservatives: Carnoy's Solution made of ethyl alcohol, chloroform and acetic acid; "Prefer" made of ethyl alcohol and glyoxal; Ultrum II Tissue Fixative made of water, sodium acetate, zinc chloride and glutaraldehyde; as well as Caro-Safe Preservative, NOTOXhisto, Nebanol Concentrate and phenoxyethanol solutions. Thus, these alternative preservatives were not evaluated. A complete list of available alternatives and their ingredients is included in Appendix C.

The following alternatives were identified:

- specimens preserved in Formalternate by Flinn Scientific
- specimens preserved in Wardsafe by Ward Scientific
- specimens preserved in S.T.F. (Streck Tissue Fixative) Preservative by Nebraska Scientific
- specimens preserved in Carolina Biological Supply's Carolina's Perfect Solution®
- unpreserved specimens
- video/virtual dissection

Alternatives Screened Out

Specimens fixed with formalin (typically 37% formaldehyde, a carcinogen, and 12% methanol), were excluded even if they were sold or maintained in holding or preserving solutions that were formaldehyde-free. Maryland State Anatomical Solution and Bouin's Fixative Solution contained formaldehyde and were screened out.

Priority Alternatives for Educational Specimens

Because Carolina Biological Supply did not provide a description of the proprietary ingredients, the Institute did not evaluate specimens in Carolina's Perfect Solution® (technical review is available in Dr. Foxall's report to the Institute). The alternative of dissecting live or recently deceased, unpreserved specimens was also excluded for legal, ethical and practical reasons.

Three specimen alternatives and video/virtual dissection were selected as high priority alternatives for assessment. Due to limited time, only one specie was evaluated for each. Other species may be preserved in different chemical mixtures of the same fixative. For example, Ward's fetal pigs are preserved in "WardSafe" (glutaraldehyde, propylene glycol, ethylene glycol phenyl ether, diethylene glycol phenol ether) but the product contains different ingredients to the frog's "WardSafe" (gluteraldehyde). The three alternative-preserved specimens were grass frogs preserved in

- Formalternate by Flinn Scientific,
- Wardsafe by Ward Scientific, and
- S.T.F. (Streck Tissue Fixative) Preservative by Nebraska Scientific.
- Virtual/video dissection

Formalternate is a combination of propylene glycol, ethylene glycol phenyl ether and phenol. Wardsafe is primarily glutaraldehyde. S.T.F. is diazolidinyl urea, 2-Bromo-2-nitropropane-1, 3-diol (Bronopol), zinc sulfate, and sodium citrate.

4.3.3 Alternatives Associated with Building Panels

Adhesives used to make plywood, particleboard and other manufactured wood products account for 64% of the total 24 million metric tons of formaldehyde consumed worldwide each year (Bizzari 2004). Building panel boards designed to withstand loads even when wet are designated as "structural use panels" and include exterior- and interior-grade softwood and hardwood plywood and oriented-strand board. Structural use panels' uses include exterior sheathing, roof decking, and floor decking. Particleboard, medium density fiberboard, and hardwood plywood are primarily used for furniture, shelving, built-in furniture and cabinetry, and interior decorative paneling and flooring. Softwood plywood or oriented strand board (OSB) may be used for carpet and tile underlayment and some built-in furniture and cabinetry that requires less visual appeal and durability. (The red-black color of phenol-formaldehyde resin prevents it from being used in high-end decorative applications.)

While certain types of panels are primarily used for certain uses, they may substitute for each other at times, and softwood plywood, in particular, is quite versatile. As for substitutes that may replace wood panels made with formaldehyde-based resins, the potential substitutions are limited at this time, but, as is described below, that may change in the near future. Many factors influence the choice of materials for building including design and aesthetic considerations, technical specifications, environmental and health considerations, availability and price. Substitutes may match

the expectations laid down by traditional products, or they may create new market niches, providing new qualities and stimulating new designs, specifications, and acceptable prices. Growing demand for "green" building products may also influence where and how these panels will be used. Additionally, use of alternative binders, such as the relatively benign polyvinyl acetate (PVA) glue, which is currently used on a special order basis because of its expense, may expand. Finally, "greener" resin technologies that are in the research and development stage may be commercialized in the next few years.

Available Alternatives

The following types of alternatives to formaldehyde-resin based wood panels were identified:

- "low emitting" phenol formaldehyde resin panels
- MDI (methylenediphenyl diisocyanate) based resin panels
- panels made with cement, sand and wood fibers
- Columbia Forest Products soy-based resin hardwood veneer core plywood panels
- Homasote's recycled paper panel boards
- Viroc's wood fiber-Portland Cement panels
- JER EnviroTech's plastic-wood fiber panel

Late in our review the Institute learned that PVA glue is used on a special order basis by many hardwood plywood manufacturers, especially for architects building interiors to the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED) specifications. Points under the LEED system are awarded for composite wood products that do not use urea-formaldehyde resins. PVA glue is a water-based synthetic latex glue that is used extensively in furniture and laminate manufacture. It is known as white or yellow glue (*i.e.*, Elmer's or carpenters' glue). It can be used with the equipment and processes that currently are used to make panels with urea-formaldehyde resins and has excellent performance characteristics for interior and possibly some exterior applications. It is relatively non-toxic with the exception of a very small amount of un-reacted vinyl acetate monomer (0.4%). Vinyl acetate is an animal and possible human carcinogen, an irritant and a cause of heart problems and other systemic effects in humans (Hazardous Substances Data Bank). Some PVA glues are enhanced with an isocyanate catalyst (isocyanates are sensitizers and can cause asthma and dermatitis). PVA-based panels do not appear to be advertised or readily commercially available. PVA is more expensive than urea-formaldehyde resins.

Alternatives Screened Out

Two categories of alternatives were screened out: "lower-emitters" of formaldehyde and products made with other hazardous chemicals. The "low-emitters," principally products made with phenol-formaldehyde that meet ANSI emissions standards, were excluded because they are made with formaldehyde and still emit low amounts during use. Therefore, they did not pass the carcinogenicity screen. Wood products may also generate formaldehyde as a natural process; products made with no "added" formaldehyde are evaluated here.

Some companies are producing boards made with polyurethane adhesives based on methylenediphenyl diisocyanate (MDI) in place of formaldehyde-based resins. MDI did not pass our initial health and safety screen because it is on the TURA SAB "more hazardous chemical list"

due to its acute toxicity and sensitizing properties (Toxics Use Reduction Institute (TURI)). Additionally, while lifecycle issues are not a major focus of this study, MDI is made from formaldehyde. A popular product made with a combination of Portland cement, silica sand and wood fibers was also screened out because of the significant amount of crystalline silica, an IARC Group 1 carcinogen, in the product. These products represent no known environmental threat or risk to building occupants, but significant silica dust is generated during construction activities. Forest Stewardship Council certified-sustainable wood or "agrifiber" composite panels are "green" products that were not included because they use either phenol-formaldehyde resins, MDI or similar resins (see for example http://www.agriboard.com/index.htm).

Priority Alternatives for Alternative Panels

The four remaining alternatives were identified as high priority for assessment as alternatives for formaldehyde resin-based building panels. The first of these is a hardwood veneer core plywood panel that could directly substitute for the equivalent traditional product used to make cabinets, built-in furniture, paneling, shelving, doors and other uses requiring a high end wood product. This alternative is Columbia Forest Product's PureBond panel made with a soy-based resin. This was the only alternative that used an alternative resin. (The other three products are formed by different processes.)

Two other products that were evaluated may substitute for plywood or OSB in building sheathing, roof decking or floor decking. They are Homasote's recycled paper panel boards and Viroc's wood fiber-Portland Cement panels. The fourth product, JER EnviroTech's plastic-wood fiber panel, is an "emerging technology" and may substitute for particleboard and possibly for structural uses as well. Four specific manufacturers' products were evaluated although similar products may be made by other companies. For example, another recycled paper board is ThermoPly by Covalence Coated Products (see http://www.covalencecoatedproducts.com/pages/thermoply.html). The selection of particular representative products does not constitute an endorsement by the Institute, or imply that other similar products are not worthy of further assessment.

Columbia Forest Product's PureBond veneer core plywood was a high priority for assessment because it was the only traditional type of product that used an alternative resin and that passed the screen.

In addition, there was a great deal of stakeholder interest in this product. PureBond is made with soy flour and a resin manufactured by Hercules Chemical called Kymene® 624 Wet Strength Resin. The resin is a cationic amine polymer-epichlorohydrin amine called polyamide-epichlorohydrin (PAE) and it is widely used in as a wet-strength resin in paper and textile manufacturing. Epichlorohydrin has been determined to be an animal and a probably human carcinogen by IARC and EPA's NTP Program and has several other serious potential health and environmental hazards. Epichlorohydrin is not listed on the Hercules' MSDS for Kymene® 624 nor is it listed on the PureBond MSDS. According to the manufacturer and the EPA, epichlorohydrin is completely consumed in the batch manufacturing process used to make the resin. There are no emissions from this process and no residual or "free" epichlorohydrin in PAE where it is irreversibly transformed in the polymer matrix (Steib 2006; USEPA 1984). Despite the lack of potential for worker, consumer or environmental exposure to epichlorohydrin during PureBond building panel manufacture, use or disposal, the health and safety and environmental assessment of this alternative will include a review of epichlorohydrin's potential hazards.

The final list of high priority alternatives to be assessed for wood panels is as follows:

- Columbia Forest Products hardwood plywood panels made with PureBond core and laminated veneers
- Homasote's recycled paper panel boards
- Viroc's wood fiber-Portland Cement panels
- JER EnviroTech's plastic-wood fiber panel

4.4 Formaldehyde Alternatives Assessment

4.4.1 Alternatives Assessment for Sanitary Storage in Barbering and Cosmetology

Two potentially feasible alternatives to the use of paraformaldehyde were found: elimination of the process step and UV storage cabinets. The technical, environmental and health and safety and financial evaluation of these alternatives follows.

Technical Assessment

Helen Peveri, the Executive Director of the Massachusetts Board of Cosmetology was interviewed about the Board's perspective on the use and alternatives for the use of paraformaldehyde dry sterilant. Ms. Peveri noted that, until recently, the Board had not been aware that paraformaldehyde was a potential hazard in salons and that they were interested in alternatives. She said that the Board required paraformaldehyde because they were concerned that hairdressers might not do a good job of cleaning and disinfecting brushes and the Board wanted to have some extra measure of security that the brushes were "clean." Ms. Peveri felt that the opening and closing of the drawer and putting used brushes back in would contaminate the brushes.

Denise Graham, Senior Director of Public Policy for the Association for Professionals in Infection Control and Epidemiology was consulted for the infection control perspective. Ms. Graham stated that she was unaware of guidance or requirements specific to beauty salons. Two industry groups were consulted. Both the Professional Salon Association and the National Accrediting Commission of Cosmetology Arts and Sciences said that they had no guidance, special concerns or other comments on the issue.

To represent the perspective of salon regulators and to determine best practices in infection control in salons, the Institute consulted Sue Sansom, of the Arizona Board of Cosmetology and Chair of the Health and Safety Committee of the National-Interstate Council of State Boards of Cosmetology. The National-Interstate Council's (NIC) mission is to establish best practices, standards and uniform requirements for Boards of Cosmetology and cosmetology exams in the United States is composed of members of licensing boards of cosmetology from each of the fifty states and the U.S. territories. Ms. Sansom stated that she was unaware of any state requiring use of paraformaldehyde. According to the NIC, formaldehyde-based dry sterilants are not recommended due to their carcinogenic potential. In place of dry sterilants, the NIC recommends an alternative procedure of proper cleaning, wet disinfection, drying and storage. NIC's Infection Control standard

for dry storage is "Disinfected implements must be stored in a disinfected, dry, covered container and be isolated from contaminants" (National-Interstate Council of State Boards of Cosmetology).

Ms. Sansom was also consulted on the use of UV sanitizers. Ultraviolet sanitizers can be used as dry sanitary storage, but she felt that they were an unnecessary expense and "sent the wrong message" about their role in infection control. She felt that use of UV cabinets can confuse the public and the licensee by suggesting that proper disinfection is occurring when it is not.

The disinfection and storage practices recommended by the NIC are reiterated in the rules of many other Boards of Cosmetology and in the instruction offered in Milady's Standard Cosmetology – the field's primary textbook and practice guidance. This text recommends the same process iterated by the NIC: proper cleaning followed by use of U.S. Environmental Protection Agency-registered disinfectants and storage in clean, sanitized storage (Alpert 2004). Milady's Standard Cosmetology does not discuss use of dry sterilants.

The primary performance criterion by which to evaluate alternatives in comparison to formaldehyde is the ability to control harmful pathogens and to maintain sanitary storage. No studies were found that evaluate the extent of pathogen contamination, transmission and control in the salon environment. Thus, paraformaldehyde sterilant's efficacy is unknown, as is the extent of the problem of growth and transmission of harmful bacteria, etc. in salon storage and instruments.

Because instruments are required to be cleaned and disinfected and storage cabinets are also required to be cleaned and disinfected, and instruments are not to be used and then replaced in the drawers, there is minimal likelihood for potential serious contamination if these procedures are followed. For this evaluation, it is assumed that Board of Cosmetology requirements for cleaning, disinfection and hygienic storage would be followed and therefore the pathogen load in drawers would not be significant.

Given this assumption, and the input of technical experts, it was determined that the alternative of eliminating paraformaldehyde and replacing it with a process of cleaning and disinfecting of a storage container that may be placed in a drawer, or the drawer itself is technically feasible. Following cleaning (dirty surfaces cannot be disinfected), disinfection of the container may be performed with a hospital-grade EPA-registered disinfectant (as already allowed by the Board's rules). From a technical perspective, all references to formaldehyde, formalin or dry sanitizer may be eliminated from the Board's rules without any compromise of infection control as long as the correct and recommended process of cleaning, disinfecting, drying and storing is required and followed. Cosmetology inspectors may inspect such containers to insure that nothing else is stored in them and that they are clean and dry. This process also meets best practice criteria as described in the previous section. The NIC's Infection Control standard for dry storage is "Disinfected implements must be stored in a disinfected, dry, covered container and be isolated from contaminants" (California's Board of Cosmetology rules follow this process).

Ultraviolet light sanitizing cabinets are available from many sources including from the PIBBS beauty supply company (www.pibbs.com). Milady's Standard Cosmetology says that these cabinets are "useful storage containers" but will not disinfect salon implements. UV germicidal light is effective at killing pathogens, but it must strike all surfaces and this is difficult to achieve on a brush. Additionally, the cabinets may become reservoirs of pathogens if they are not regularly cleaned and disinfected, which is difficult to do given the design of the cabinets. Texas has recently revised their regulations to permit the use of UV cabinets as storage containers (83.102. Health and Safety Standards--General Requirements http://www.license.state.tx.us/cosmet/cosmetrules.htm#83106) A further performance concern is the space required for these cabinets at each station.

Financial Assessment

The elimination of paraformaldehyde will result in a modest cost savings for schools and salons (approximately $3.00 for a two ounce container that lasts six months). UV storage cabinets cost approximately $160 each. Germicidal bulbs may cost as much as $30 to replace, and there is an operating cost for energy. It is difficult to gauge the financial comparison to use of Steri-Dry, but it is estimated that the initial equipment cost and replacement bulb "operating costs" of the sanitizing cabinet would generally exceed that of using Steri-Dry.

Human Health and Safety and Environmental Assessment

Elimination of paraformaldehyde is not expected to introduce any new environmental or health and safety concerns. If the cleaning and disinfecting processes are not followed, there is a risk that elimination of use of formaldehyde in storage containers could result in contaminated brushes. However, according to experts, no other state requires use of formaldehyde in salons. The public health risk of its elimination is, therefore, likely to be very low. Massachusetts Board of Cosmetology regulations currently require the cleaning and disinfection of dry storage containers and cabinets. It should be noted that EPA-registered disinfectants may contain gluteraldehyde or quaternary ammonium compounds, both of which are sensitizers. Evaluation of safer cleaning and disinfection strategies is beyond the scope of this project but is an important related concern.

As mentioned above, UV storage cabinets may become reservoirs of pathogens if salon workers encounter difficulty in disinfecting all surfaces inside them. Exposure to UV light can cause skin cancer or eye irritation, although exposure is unlikely if the cabinet is turned off when instruments are loaded or unloaded.

Summary

From a technical, health and safety, environmental and financial standpoint, it appears feasible for paraformaldehyde to be eliminated from barbering and cosmetology drawers and cabinets.

Table 4.4.1 A: Assessment Summary for Sanitary Storage in Barbering and Cosmetology

Assessment Criteria		Steri-Dry (Reference)	Comparison Relative to Formaldehyde	
			Elimination	UV Storage
Technical/ Performance Criteria	Protects Public from Pathogens	?	=/+	-
	Meets Best Practice Guideline	**No**	+	+
Financial Criteria	Cost/yr/drawer	**$6.00**	+	-
Environmental Criteria	Hazardous Air Pollutant	**Yes**	+	+
	Drinking Water Contaminant	**No**	=	=
	Persistent/ Bioaccumulative	**No**	=	=
Human Health Criteria	Carcinogen	**Yes**	+	+
	Irritation	**Yes** (Dermal, Ocular, Respiratory)	+	+
	LD50, oral, mg/kg	rat 100 mouse 385	+	n/a
	Fire Hazard	**Yes** (NFPA 4)	+	+
	Exposure Potential	Low levels, high probability of exposure	+	+

COMPARISON KEY

+ Better = Similar - Worse ? Unknown

4.4.2 Alternatives Assessment for Preserved Educational Specimens for Dissection

Because there are no published studies comparing the performance characteristics of preserved biological specimens for dissection, the Institute relied on an evaluation by an outside technical expert. Professor Thomas Foxall, Chair of the Department of Animal and Nutritional Sciences at the University of New Hampshire evaluated the alternatives with regard to their technical issues and performance. He developed criteria and used these to compare the alternatives to a formalin-preserved specimen. He used his own extensive experience in teaching gross anatomy, consultation with other anatomy teachers, his direct examination of the alternatives specimens and consultation with pathologists at the New Hampshire Veterinary Diagnostic Laboratory at the University of New Hampshire. He also evaluated a number of virtual and video dissection materials and collected cost information for all alternatives. The health, safety and environment evaluation was conducted by the Institute staff.

The following alternatives for preserved grass frogs were assessed:

- Formalternate by Flinn Scientific,
- Wardsafe by Ward Scientific, and
- S.T.F. (Streck Tissue Fixative) Preservative by Nebraska Scientific.
- Virtual/Video dissection

Technical Assessment

The main technical criteria are those that impact the educational potential of the dissection experience. Those criteria are the color, texture, and stiffness of the specimen tissue. The texture and the stiffness of the tissue directly relate to the ease of "blunt dissection," i.e., separation of the tissues without using a knife. While no preserved specimen's qualities will be true to the living animals, the preserved specimen should approximate them. Other important qualities are the odor of the specimen and whether the specimen lasts long enough for students to complete the dissection. Special handling, training and equipment requirements due to the potential hazard of the specimen are both health, safety and environment concerns and a technical concern as they impact the laboratory experience and duties of the laboratory personnel. The availability of alternatives and if they are available from reputable companies are also important considerations. Finally, a "composite" criterion representing the potential for desirable educational experience for the student was also utilized to compare the specimens. The first three criteria do not apply to video/virtual dissection.

In general, results of the expert's study showed that all of the frog specimens would be acceptable as alternatives to formaldehyde fixed animals, preserving reasonably good color, shape, size and orientation of organs so as to teach basic vertebrate anatomy. Other anatomy professors who had used alternatives were consulted and reported good experiences with them. The criteria are discussed in turn, followed by a discussion of video/virtual dissection:

Color

The color of the alternative specimens was as good as or better than the formalin-preserved specimen. S.T.F. specimen was very good; the Formalternate and Wardsafe frogs had better (more life-like) color than the formalin frog in the skin, skeletal muscle and organs.

Texture

The tissues of the frog preserved in Formalternate were the softest (softer than the formalin frog). It was pliable and easy to move organs and blunt dissect skeletal muscle. The S.T.F. frog's tissues were very soft and it was easy to move organs and blunt dissect. The Ward's frog's tissues were more hardened and less easy to blunt dissect.

Stiffness

The S.T.F. frog was the least stiff and much less stiff than the formalin frog; the Formalternate frog was also less stiff than the formalin frog. The Ward frog was rigid and more like the formalin frog.

Odor

Formalternate had no offensive or intense irritating odor; S.T.F.'s frog had a very slight "chemical" odor; and the Ward frog had an "aldehyde" odor similar to formalin.

Longevity

Longevity could not be evaluated in the timeframe of this study, however formalin will preserve specimens indefinitely. Nebraska Scientific guarantees their S.T.F. specimens for 90 days. This is within the typical timeframe of an anatomy course, but would require that specimens be ordered close to the time of the beginning of the course or dissection. The anatomy professors who had used these alternatives had not experienced problems with the longevity of the specimens as long as they were stored according to instructions (generally sealed in plastic bags).

Special Handling and Training

The alternative specimens do not require any special handling or training other than good laboratory practices. Formalin-fixed specimens may need to be disposed of as hazardous waste. These procedures may be mostly avoided with alternative specimens. With either formaldehyde or the alternatives, students must be made aware of the potential for skin reactions to chemicals and safe procedures such as washing thoroughly after dissection, not ingesting any of the specimen, and following proper storage procedures. Instructors and students should be aware that specimens in S.T.F. may release formaldehyde due to the presence of diazolidinyl urea, a formaldehyde-releasing chemical.

Availability

The alternative products are readily available from well-established companies.

Educational Value

The educational value of these alternatives is equivalent to that of the formalin-fixed specimen.

Dr. Foxall summarized his findings by saying "Anatomy professors and pathologists interviewed agreed that the alternative specimens were less noxious, had good color and texture, and were easier to dissect. Gross preservation was very good and would serve as excellent educational tools to demonstrate anatomy. The alternatives provide for a better and safer laboratory environment with less potential hazard, less odor and less protection needed."

While virtual/video dissection experiences have no detectable odor or special chemical handling and their longevity should be comparable to formalin, many experts have the opinion that watching a video is not the same as, and does not substitute for, hands-on dissection of specimens in a laboratory class. However, the educational utility of video and/or virtual dissection may vary with

the class or instructor. Such on-line or video tools (see for example the virtual pig dissection at http://www.whitman.edu/biology/vpd/main.html) may, however, be a useful adjunct to actual dissection. Several sites are free and videos are inexpensive1. Virtual, video and CD-ROM software programs also potentially expand the learning opportunity to include study of human anatomy. CD-ROM based programs such as Bodyworks and A.D.A.M. are very well produced, comprehensive, interactive, colorful and provide a very good human anatomy learning experience for even very young children. Although these software packages can be expensive, they are a one-time cost to a school. They may be used as a complete lesson or in addition to actual animal dissections.

Financial Assessment

The prices of alternative specimens were similar to each other and generally less expensive than the formalin-fixed frog from NASCO. Formalin-fixed specimens that are also shipped in formalin without washing may be less expensive, but Dr. Foxall did not believe that educators were likely to purchase such specimens. All companies offered bulk discounts. Regulatory costs associated with formaldehyde use are avoided.

Table 4.4.2 A: Specimen Costs

Grass Frogs	Cost Each in a Package of 10
Formalternate	$2.85
Ward's	$4.10
S.T.F.	$3.63
NASCO Formalin-Fixed, Washed and Propylene Glycol Shipped	$5.60

Human Health and Safety Assessment

Educational specimens themselves contain very little preservative chemical when shipped—no more than a few percent of the specimen is preservative. Handling and dissecting specimens potentially exposes students and instructors to skin and inhalation hazards. The exposures are likely to be short in duration on any given day, but extend over a period of weeks. For instructors, these exposures occur with the teaching of every class. None of the alternatives contain ingredients known to be carcinogens or to cause long-term or reproductive health effects. However, all of them have some potential for skin irritation and some have potential to sensitize after repeated exposure, leading to allergic skin reactions and sometimes asthma. Both Formalternate and S.T.F. are chemical mixtures making evaluation of their potential impact more complicated. For example, Formalternate contains propylene glycol which, by itself, has very low toxicity. However, it may enhance skin penetration of other chemicals.

Flinn's Formalternate is a proprietary mixture of propylene glycol, ethylene glycol phenyl ether, and phenol in undisclosed proportions. Propylene glycol can be assumed to be the main ingredient by the MSDS's description of Formalternate as a "propylene glycol-based formaldehyde substitute." Propylene glycol—a main component of anti-freeze and de-icing solutions—is accepted by the Food and Drug Administration as a food, cosmetic and drug additive and is considered "generally recognized as safe." It has an extremely low vapor pressure and is unlikely to get into the air to be inhaled. In a very few people, especially those with underlying conditions, it may cause skin

1 $30 at http://www.educationalimages.com/it030022.htm

irritation, hives or an allergic contact dermatitis. It will cause eye irritation if placed directly in the eye.

Ethylene glycol phenyl ether, also known as 2-phenoxyethanol, has an even lower vapor pressure and lower potential for inhalation. It is not readily adsorbed through the skin, although it may cause some irritation.

Phenol is toxic and highly corrosive to the skin. Since it has a low vapor pressure but is absorbed by the skin, the skin is the most likely route of exposure. Phenol is an EPA-registered pesticide and animal studies have shown high acute oral toxicity (USEPA 2006). Its male rat LD50 is 317 mg/kg (compared to formaldehyde's 100 mg/kg). There are no known potential long-term or reproductive health effects of the chemical ingredients in Flinn's Formalternate.

Ward's frogs are preserved with glutaraldehyde with the MSDS reporting that the frog contains less than 1% glutaraldehyde. Glutaraldehyde is a strong irritant and a sensitizer. Acute health reactions including irritation, nausea, headaches and nosebleeds, and allergic reactions including asthma are have occurred in workers in healthcare settings where glutaraldehyde is a common disinfectant (and registered as such by EPA)(NIOSH 2001). OSHA does not have a PEL for glutaraldehyde although it has proposed a limit of 0.2 ppm which is the California OSH PEL for an eight-hour exposure (this compares to the 0.75 ppm OSHA standard for formaldehyde.) ACGIH has a ceiling TLV of 0.05 ppm (15 min maximum exposure) for glutaraldehyde which is approximately the odor threshold. This compares to the formaldehyde OSHA ceiling limit of 2 ppm. Glutaraldehyde becomes irritating at about 0.3 ppm whereas formaldehyde can irritate at 0.1 ppm although these are subjective values. Acute toxicity values reported for glutaraldehyde vary widely, with oral-rat LD50 values varying from 134 mg/kg to 820 mg/kg, carrying a determination of moderately to slightly toxic. The EPA is currently reviewing glutaraldehyde in order to determine its eligibility for re-registration and will most likely publish consensus values in this process. In summary, glutaraldehyde has many of the same hazards as formaldehyde although it has not been judged a carcinogen by any agency. Glutaraldehyde is a liquid at room temperature with a fairly low vapor pressure of 17 mm Hg (at 68° F). Thus, a 1% solution of glutaraldehyde is likely to result in a lower air concentration than the formaldehyde concentration released from an equivalent amount of formalin.

Nebraska Scientific's S.T.F. or Streck Tissue Fixative is composed of diazolidinyl urea; 2-Bromo-2-nitropropane-1, 3-diol (Bronopol); zinc sulfate and sodium citrate. Percentages are only given for Bronopol (less than 3%) and zinc sulfate (less than 2%). This mixture is slightly acidic and therefore potentially irritating to the skin, eyes and respiratory system, but is not likely to be inhaled based on the low vapor pressures of constituents. All of the ingredients are irritants.

Diazolidinyl urea and Bronopol have been found to be skin sensitizers in patch testing studies and case reports, although sensitization is rare. In a study of 8,149 patients in European dermatology practices, 0.5% of patients had allergic reactions to Bronopol (Frosch et al. 1990). The male rat LD50 is 307 mg/kg (compared to formaldehyde's 100 mg/kg). Diazolidinyl urea is a "formaldehyde-releaser" in aqueous solutions. An aqueous product containing 0.5% diazolidinyl urea (the US and European standard for cosmetics), will thus contain and potentially release 0.215% free formaldehyde (Scientific Committee on Cosmetic Products and non-Food Products Intended for Consumers 2002). There is no information about the long-term effects of exposure to diazolidinyl urea, zinc sulfate and sodium citrate, but all are FDA-approved for use in cosmetics, drugs and food. Zinc sulfate was once an EPA-registered pesticide, but is no longer used in pesticide products on the market.

Like formaldehyde, many of the chemicals used in alternative preservatives are irritating to the skin, eyes and respiratory tract, and some may be sensitizers. Phenol may penetrate latex gloves, but this is not likely given the limited contact time and the low concentration of the chemical in the specimens. The alternatives do not have other known long-term health effects or reproductive health effects. Additionally, none of the alternatives contains chemicals that are especially volatile, thus the potential for exposure through the inhalation route is low.

Environmental Assessment

Like formaldehyde, phenol is classified under the Clean Air Act as a "hazardous air pollutant," but unlike formaldehyde, which is a gas at normal temperatures, pure phenol is a solid at room temperature with a low vapor pressure. Phenol is also acutely toxic to fish and several other species. Zinc compounds are also toxic to fish. Phenol, bronopol, and glutaraldehyde are EPA-registered pesticides and therefore toxic to some organisms. Neither formaldehyde nor any of the alternatives are likely to persist or bioaccumulate. Specimens preserved in these alternatives can be disposed of with regular waste.

Summary

All of the alternatives assessed here, with the exception of video/virtual dissection, match or exceed the important technical and performance criteria for educational specimens. Additionally, while the alternatives contain chemicals that can irritate the skin, eyes and respiratory system, they are less likely to do so than formalin-preserved specimens. The alternatives contain ingredients that have been found in some people to be sensitizers, with gluteraldehyde the most likely of the chemicals to cause dermatitis and asthma. The alternatives do not contain any chemicals known to have long-term or reproductive health problems and are not classified as carcinogens as is formaldehyde. However, S.T.F. includes a formaldehyde-releasing chemical. Specimens preserved with this fixative may, in fact, release some formaldehyde. Additional studies may be required to determine the long-term effects of exposure to these alternative chemicals.

Formaldehyde must be disposed of as hazardous waste and formalin-preserved specimens may require special waste handling, but the alternatives and specimens preserved in them do not. Some of the chemicals used in the alternative fixatives are more toxic to fish and other species than is formaldehyde. In general, the low volatility and small amounts of preservative in the alternative specimens suggests that exposure to humans and the environment are likely to be very low. Life cycle considerations for the alternatives include the use and disposal of some ingredients, such as phenol and zinc sulfate that are potential environmental pollutants. Table 4.4.2 B summarizes the findings of this assessment.

Table 4.4.2 B: Assessment Summary for Preserved Specimens for Educational Dissection

Assessment Criteria		Formalin-Fixed Specimen (Reference)	Comparison Relative to Specimens in Formalin			
			Form-alternate (propylene glycol based)	**STF** (includes Diazolid-inyl urea)	**Ward's** (glutar-aldehyde based)	**Video/ Virtual Dissection**
Technical/Performance Criteria	Color	Not life-like	+	+	+	n/a
	Texture	Hardened	+	+	=	n/a
	Stiffness	Rigid	+	+	=	n/a
	Odor	Irritating	+	+	=	+
	Longevity	Indefinite	?	?	-	+
	Special handling	Extensive	+	+	+	+
	Availability	Good	=	=	=	=
	Educational value	Good	=	=	=	-
Financial Criteria	Cost (per specimen)	$5.60	+	+	+	n/a
Environmental Criteria	EcoToxicity	Not acutely toxic, except to zooplakton	-	-	-	+
	Hazardous Waste Storage/ Disposal	Regulated	+	+	+	+
	Carcinogen	Yes	+	+	+	+
Human Health Criteria	LD50 (oral rat)	100 mg/kg	+	+	+	+
	Sensitizer	Yes	+	+	=/+	+
	Skin Adsorption	Yes	=	=	=	+
	Irritation	Severe	+	+	+	+

COMPARISON KEY

+ Better = Similar - Worse ? Unknown

4.4.3 Alternatives Assessment for Hardwood Plywood and Structural Use Building Panels

The choice of building materials by architects, engineers, specifiers, and builders is based on many different criteria: the expected performance of materials, client demands, codes and standards, site specific concerns, project constraints, marketing opportunities, available supply, current and costs and many intangibles such as aesthetic appeal and familiarity. The assessment presented here is a product of the Institute's interviews with product manufacturers, marketers and users; input from stakeholders; and evaluations by outside experts.

Technical Assessment

Different technical criteria apply to building panels depending upon the specific application. For example, exterior panels need to be able to withstand the elements during construction and over time. Interior panels used for high-end applications need to look good and many need to tolerate kitchen and bathroom moisture. Non-structural panels do not need to meet mechanical requirements related to bearing loads. Because of these varying technical criteria, the alternatives are evaluated below in groups:

1. Hardwood plywood
   - traditional hardwood veneer core plywood with formaldehyde-based adhesive (baseline)
   - hardwood plywood with PureBond soy-based adhesive
2. Structural use building panels
   - OSB/softwood plywood using formaldehyde-based adhesive (baseline)
   - Homasote recycled paper-based panels
   - Viroc wood fiber-Portland cement panels
3. A separate discussion of JER Envirotech plastic-wood composite panel board as a potential "near-horizon" particleboard alternative is also included.

Hardwood veneer core plywood

Columbia Forest Products began producing PureBond no-added formaldehyde hardwood plywood with a no-added formaldehyde veneer core in 2005. The design of the proprietary soy-based resin used in the PureBond products is based upon the work of Dr. Kaichang Li at Oregon State Universities' School of Forestry and has been commercialized by Hercules Incorporated (Liu, Li 2002). Soy resins have failed in the past because they lacked strength in the presence of moisture and degraded with time. Dr. Li combined soy proteins with a nylon polymer manufactured by Hercules, Inc. *i.e.*, Kymene® 624 Wet Strength Resin, a product based upon polyamide-epichlorohydrin (PAE). Kymene is typically used by the paper industry to impart wet-strength to paper products such as tissues and towels. (Hercules is marketing this product as ChemVisions™ CA1000 for application in wood products.)

Columbia has further developed the application of this resin to the manufacture of wood panels. This has involved an extensive research and development effort including substantial capital investment in new equipment and processes. Columbia is in the process of converting all of its

operations, including the manufacture of flooring, plywood, particleboard, MDF, and agrifiber board, to the use of this new resin. Currently, only the hardwood veneer core plywood is available, but they expect the flooring products to be available soon. (They report that they have succeeded in producing particleboard with PureBond, as well, and will be contracting with a particleboard plant to begin commercial production soon.) Columbia is the largest manufacturer of hardwood plywood in North America.

According to the Hardwood Panel and Veneer Association, the principal performance criteria and characteristics for hardwood panels are: appearance characteristics per wood species, such as number of knots and burls; panel construction; fire resistance; core and back grades; glue bond performance; formaldehyde emissions; moisture content; dimensions; and finish of the panel (Hardwood Plywood & Veneer Association (HPVA)). The association has developed its own voluntary standard called the "ANSI/HVPA HP-1" standard that incorporates these criteria.

No independent test results were available for the Purebond product, so the assessment relied on the manufacturer's own testing and input from those who had used the product. Appearance characteristics are the most important technical criteria. The adhesive generally does not affect appearance characteristics, so these are considered equal between the PureBond product and the traditional product. (Columbia provides a full comparison of their products with the ANSI on their website at: http://www.columbiaforestproducts.com/products/default.asp.)

The second important characteristic is the glue bond performance. Columbia in-house tests found significantly improved water resistance in comparison to a board made with urea-formaldehyde adhesive. They found that the PureBond board performs as well as type II urea formaldehyde adhesive construction in hardwood plywood as defined by ANSI/HPVA HP-1-2004 standards. These standards require manufacturers to conduct three-cycle boil and three-cycle soak tests. Ninety percent of PureBond panels passed the boil test (vs. 0% of traditional urea-formaldehyde bonded panels) and 100% passed the soak test. Because PureBond panels do not pass the boil test 100% of the time, Columbia's panels are not rated as structural or exterior-grade.

A third important characteristic is the fire resistance of the product. The standard for fire resistance is the ASTM-E-84 test which rates products by a flame spread index. The test determines the distance and the rate of travel of flame in ten minutes. Columbia reports that its PureBond product rates within the requirements for Class C Flame spread index of 76-200. The HPVA reports the flame spread of other veneer core plywood panels as between 114-173 (American Forest & Paper Association, Inc. 2002). Generally, products that have a flame spread index of less than 200 will meet all building code requirements for interior applications.

An outside expert, Mark Kalin, received feedback that a woodworking firm that had found that the PureBond panel did not lay flat. Columbia's response was that the PureBond panel is as flat as any veneer core hardwood plywood panel and that they have not had returns or complaints. According to the Architectural Woodwork Institute, the veneer core panel type rates "fair" in comparison with alternatives like particleboard and MDF panel types that are rated as "excellent" for flatness (American Woodworking Institute (AWI) 2003). Veneer core panels may buckle with climate-related temperature and humidity changes and the PureBond product is no different from others in this respect, according to a product supplier (Laing 2006). Paul Quimby of Neil Kelly Cabinets of Portland, Oregon uses PureBond for a small amount of their business and has not had problems with the product. Columbia's PureBond products are available in Massachusetts from Atlantic Plywood Supply in Woburn. They have had no customer complaints about the product. They also anticipate a significant market for no-added formaldehyde products.

While the resin chemistry is not exclusive to Columbia Wood Products, other manufacturers who want to use it will have to invest significant process development and redesign resources, as Columbia has done.

Structural Use Panels

Homasote's recycled paper panels and Viroc's wood-Portland cement panels may be used in place of softwood plywood and OSB in exterior sheathing, roof decking and floor decking. Homasote has been made in New Jersey since 1909 and is primarily marketed as an acoustical barrier (see www.homasote.com). Homasote also makes a product (ComfortBase) that may be used in place of plywood as a carpet or tile underlayment over concrete and one that may be used in place of plywood for concrete forming. Due to time limitations, those uses could not be evaluated. Viroc is made in Portugal and represented and distributed in the US by Allied Building Supply (see www.viroc.pt and www.alliedbuilding.com). The company began producing the product in 1994 and it is used extensively in Europe.

Technical and performance criteria for these uses relate to strength, weight, how they handle moisture, storage, handling, fastening, finishing, fire resistance, thermal resistance, and mold, rot and insect resistance. (Some of the values for these criteria are shown in Table 4.4.3 A) The APA (the Engineered Wood Association formerly known as the American Plywood Association) has developed a rating and grading scale for plywood and OSB that manufacturers use to mark their products according to the accepted use. Panels are given one of four "exposure durability" ratings: Exterior, Exposure 1, Exposure 2 and Interior (the U.S.'s sister organization in Canada uses a similar Can-Ply rating system). This rating system is based upon the strength of the glue bond, as weather will delaminate the boards and cause them to deteriorate. Only member mills can use these ratings and markings, thus imported products and non-wood panels will not be APA-rated. Because Homasote and Viroc are not members of the APA and do not use glue, they are not APA-rated.

The strength of a panel is measured in several ways and is a very complex phenomenon. ASTM has standardized tests for panels for shear strength, compressive strength, impact resistance, wind resistance and tensile strength. Additionally, structural panels have span ratings that reflect both the load that can be carried and the stiffness of the board. Panels used for roof and floor decking must meet building codes designed to prevent collapse. The span rating or load value is how much load a panel can take when fastened to joists at various distances from each other. The span rating can be increased by using thicker panels, but that will increase the weight of the panel. One reason why wood panels are so popular is their excellent strength to weight ratio.

Homasote's floor deck product is sold in either 1-11/32 in. thick panels for 16 in. spans or 1-3/4 in. thick panels for 24 in. spans and is designed to withstand live loads of 100 lb/in^2. The latter material weighs 4.1 lb/ft^2 compared to about 2.3 lb/ft^2 for a similarly span rated ¾ in. plywood or OSB panel. Viroc will bear a 100 lb/in^2 load with 24 in. span in the 7/8 in. thickness and weighs 5.7 lb/ft^2. Thus, relative to plywood or OSB, Homasote and Viroc both must be thicker and heavier, to carry the same load.

Dimensional stability, or the ability of a material to retain its shape when exposed to changes in temperature or moisture, is an important characteristic of a structural board. Changes in dimensional stability can affect the structural integrity of the board and therefore the building. Moisture induced buckling may persist even after a board has dried out. There are several tests that assess factors related to dimensional stability and the results of which may predict the success of a product in an exterior application. Linear expansion is evaluated with ASTM D1037 and is how much the panel will grow when exposed to a change in humidity. Like plywood and OSB, Viroc and Homasote will

absorb and desorb moisture according to the climate, and therefore potentially grow or shrink. Both companies stress the need to condition the products at the site prior to use.

In plywood and OSB, significant expansion and shrinkage will wear the glue bonds; its impact on differently bound panels is difficult to predict. Viroc has a slightly better value for this metric, while Homasote does not perform as well as plywood or OSB. In addition, how quickly and thoroughly a panel dries out or "wicks" moisture is also important, but there are no standardized tests for wicking ability. While exterior sheathing is not designed to be constantly exposed to the elements, water may get under cladding or siding and so an overall assessment of weatherability is important and will be discussed below. In additional to the structural integrity of the panel, moisture may lead to mold problems.

Permeance is a measure of the ability of a material to retard the diffusion of water vapor, which is measured in ASTM test E-96 in units called "perms." Traditional softwood plywood and OSB are classified as "semi-vapor permeable" or vapor-retarders (Lstiburek 2002). In cold climates, it is better to have a more permeable exterior sheathing because buildings will dry from the inside out. Less permeable exterior sheathing may trap moisture leading to mold problems. Homasote and Viroc have greater permeance results than plywood and OSB.

A very important criterion is the structural integrity of the product over time given exposure to actual conditions, with the most important condition being moisture. Unfortunately, there are no standards or ASTM tests for "weatherability" outside of the APA's rating system which is based on glue bond integrity. Because Homasote is made of recycled paper, architects and others have assumed that it will fall apart when exposed to moisture. The company claims that it will dry out and maintain its structural integrity (see http://www.homasote.com/about.html). Homasote is reportedly a very good "wicker" (there are no standard values for this) and when place in a vertical plane, moisture will run to the bottom of the panel via gravity. In a horizontal plane when exposed to moisture, it is likely not to hold up. However, plywood and OSB will also delaminate under such conditions.

Homasote was used extensively in exterior applications from the 1930's until the 1980's when OSB became the less expensive alternative to plywood. (With the increasing cost of OSB, the manufacturer notes increased sales of Homasote for exterior applications.) Homasote's website has pictures of a demonstration of weatherability that show it holding up to the elements as experienced in New Jersey. Consisting of 80% Portland Cement, Viroc's weatherability is reported to be excellent. Despite the importance of this technical criterion, until there are long-term standardized tests of weatherability, it is not possible to definitively compare these products on this measure.

While Homasote and some plywood and OSB panels are treated with borate to improve insect and fire resistance, Viroc is not combustible and will not be attacked by termites, mold or other organisms. Homasote has the same fire rating as plywood and OSB (Class C), but like other composite products, it can be treated with fire retardants to become a Class A product (N.C.F.R. Homasote). Homasote claims that its panels are not very attractive to insects. Viroc reports independently conducted tests of its impact and wind resistance and claims these qualities as a particular benefit of the product (ICC Evaluation Services, Inc. 2003). Viroc is being used to construct temporary school units in Florida and was specified because of its expected durability in the face of Florida's complement of termites, mold, moisture, and hurricanes. Homasote gives a "Janka ball" hardness test result of 230 lb, meaning that only 230 lb of force are required to imbed a 0.444 in. steel ball halfway into the material. This compares with a 660 rating for soft Douglas fir.

Product handling is very important and the principal concerns are weight, storage conditions, cutting, fastening and finishing. These factors differ between plywood/OSB and Homasote and Viroc. Viroc is considerably heavier than the other products. Homasote is lighter in the equivalent thicknesses, but as was mentioned earlier, may need to be thicker and therefore, heavier, to withstand the same loads.

All of the panels, including plywood and OSB, need to be stored and handled in such a way as to prevent warping, contact with moisture, and impact by forklifts – generally covered with tarps on pallets. All would need to dry out prior to being "sealed" in a building under cladding or flooring. Plywood may be more forgiving than the others of rough handling and Viroc stresses the importance of avoiding "breakage." Viroc can be machined like wood, but thicker boards will need to be cut with tungsten carbide tipped saw blade (preferably equipped with vacuum extraction) and pilot holes will need to be first drilled or self-drilling ("grabber") screws need to be used. It may be difficult to use nails with Viroc. It is likely to wear out bits and blades at a quicker rate than the others.

Ringshank nails or drywall screws can be used with Homasote, but the company specifies that distance between nails be 3 in. or 6 in. depending on the span and location of the panel. It may be easier to nail Homasote, but more nailing is required—plywood and OSB need fasteners 6 in. or 12 in. apart for sheathing and subfloors. Homasote is easy to cut with a saw and can be cut with a mat knife depending upon the thickness. Nails in Homasote and Viroc are much more secure than in plywood or OSB according to results of ASTM dry "nail pull" tests. Both Viroc and Homasote can be finished with latex paint. The unpainted surfaces of both are a dull gray with some texture.

The "R" factor, or thermal resistance factor, of Homasote is twice that of plywood and OSB making it a better insulator. Viroc's R factor is considerably lower than plywood and OSB.

Both Homasote and Viroc are available in Massachusetts. Viroc is distributed in the U.S. by Allied Building Supply (www.alliedbuilding.com); their supplier in Massachusetts is United Builders Supply (40 Waverly St, Framingham, MA (508) 879-1000). Homasote is available through Home Depot and dozens of other building products suppliers in Massachusetts.

Table 4.4.3 A: Performance Values for Structural Use Panels

	Softwood Plywood	OSB	Homasote	Viroc
Weight (1/2 in.) lb/ft^2	1.6	1.7	1.2 (heavier at equivalent span rating)	3.1
Tensile Strength lb/in^2	1,500-4,000	1,000-1,500	450-700	793
Shear	165 lb/ft	175 lb/ft	225 (field)	n/a
Permeance	.8	.8	12	2.7
Linear Expansion (50-90% RH)	.15	.15	0.25%	0.14%
Nail Pull (Dry)	50 lbs	40 lbs	125	325
R Value	.6	.6	1.2	0.36

Human Health and Safety Assessment

Columbia's Purebond veneer core panel is made with hardwood species wood glued together with soy flour "blended with a very small amount of proprietary resin," according to Columbia's website.

That resin is Hercules Inc. chemical Kymene® 624 Wet Strength Resin, now called ChemVisions™ CA1000, a liquid cationic amine polymer-epichlorohydrin amine called polyamide-epichlorohydrin (PAE). Neither the PureBond MSDS nor the Kymene® 624 MSDS notes the inclusion of any hazardous ingredients. The Kymene® 624 MSDS warns that repeated contact with the resin may cause skin, eye and respiratory tract irritation and skin sensitization in "susceptible" individuals resulting in dermatitis. Columbia reports that the addition to and mixing of the PAE with the soy flour is a closed process and manufacturing workers do not have contact with the PAE or the mixed PAE-soy resin.

Although life cycle considerations are limited within the scope of this report, it is important to consider that the PAE chemical is manufactured with epichlorohydrin, a probable human and confirmed animal carcinogen. Epichlorohydrin is also acutely toxic to humans and overexposure can cause severe damage to the liver, kidneys, eyes and respiratory tract (Hazardous Substances Data Bank). It is also a skin and respiratory sensitizer, causing asthma and dermatitis. It is mutagenic and may cause infertility in men. According to the manufacturer and the EPA, epichlorohydrin is completely consumed in the batch manufacturing process used to make the resin. There are no emissions from this process and no residual or "free" epichlorohydrin in PAE where it is irreversibly transformed in the polymer matrix (Steib 2006; USEPA 1984). Because of this, there is apparently no potential for worker, consumer or environmental exposure to epichlorohydrin during PureBond building panel manufacture, use or disposal.

Those employed in the manufacture of epichlorohydrin are likely to have to greatest potential for exposure, followed by those exposed in the Kymene manufacturing process. NIOSH conducted industry wide surveys of epichlorohydrin exposures in five facilities in the 1970's. Three of these were plants that manufactured kymene resins, including a Hercules plant in Georgia. In that survey, the two sampled production workers were exposed well below the PEL of 5 ppm and also well below the ACGIH TLV® of 0.5 ppm. Their time weighted average exposures were 0.15 and 0.05 ppm (Bales 1978). Epichlorohydrin has a vapor pressure similar to water and can be absorbed through the skin.

Soy flour is not known to have any negative health effects. Wood dust can cause skin and respiratory tract irritation and even sensitization. Additionally, both IARC and the EPA's NTP program have designated wood dust as a carcinogen with hardwood dust, specifically, associated with adenocarcinoma of the nasal cavities and paranasal sinuses (Hazardous Substances Data Bank).

Like PureBond, Viroc and Homasote do not present a health and safety or environmental hazard to building occupants. Since they are not bound with a resin, per se, the health and safety issues they present relate to the substrate itself. Considerable dust may be generated in cutting Viroc and Homasote. Viroc recommends that vacuum fitted cutting tools and dust masks be used. The dust generated would be composed of wood dust and Portland cement dust both of which present potential hazards. As mentioned above, wood dust is a potential carcinogen and a respiratory irritant. Cement dust may contain free silica.

Homasote dust is recycled newspaper (cellulose). Studies of paper and pulp workers have found exposure-related chronic bronchitis and excess cancers, but these mills workers were exposed to many chemicals in addition to cellulose. Exposure to cellulose dust and fibers was found to cause reversible respiratory tract inflammation in rats, and cellulose dust is thought to be of low toxicity, despite the durability of cellulose fibers in the lung (Cullen et al. 2000). Pulmonary and intraperitoneal inflammation induced by cellulose fibres.)

Portland cement is made of calcium compounds including tri and dicalcium silicate, tricalcium aluminate, tetracalcium aluminoferrite, and gypsum (calcium sulfate dihydrate). Due to its alkalinity, Portland cement can be irritating to the respiratory tract, skin and eyes. Trace contaminants of hazardous metals and minerals may be present in Portland cement including free crystalline silica, chromium, nickel, calcium and magnesium oxide, potassium and sodium sulfate. Crystalline silica is a human carcinogen according to EPA's NTP program and IARC. The trace amounts of chromium in Portland cement are thought to contribute to allergic contact dermatitis in a small percentage of exposed workers, although such skin problems may also be due to repeated exposure to the drying effects of prolonged skin contact with wet cement (Sahai 2001).

European Union Directive 2003/53/EC limits the amount of chromium IV in Portland Cement to 0.0002% or 2 ppm due to its sensitizing properties. This is being done through selection of raw materials less likely to contain trace chromium and by the addition of reducing agents. Both the OSHA standard and the ACGIH TLV for Portland Cement are set at 10 mg/m^3 (compared to 0.5 mg/m^3 for lead, for example).

Potential manual material handling hazards are significant for Viroc due to its greater density. Company materials address this concern and recommend that panels be lifted and carried by two or more people and that trollies and other devices be used to transport panels.

Environmental Assessment

The PureBond hardwood plywood board is not expected to have any environmental impact beyond those of traditional boards. (Customers may specify PureBond veneer core hardwood panel certified sustainable by the Forest Stewardship Council). Soy flour has no known environmental impact. The Kymene resin, itself, is acidic (pH 2.6-3) and therefore toxic to several aquatic species. Safe disposal of the resin requires pH neutralization. It does not readily biodegrade. Epichlorohydrin is a hazardous air pollutant, a regulated water pollutant, and must be treated as hazardous waste. It will volatilize from soil and water and has a half life of 36 days in air. It does not bioaccumulate.

Epichlorohydrin is not a potential environmental release from the panel manufacturing process. It is released from Hercules manufacturing facilities, however. According to TRI data, Hercules reported over 19,500 pounds of epichlorohydrin environmental releases in 2002 (combining all facilities' releases), almost all of these were releases to air (Green Media Toolshed, Inc.). The amount of these releases attributable to the manufacture of the PAE resin for the production of PureBond is not known, but is likely to be very small considering that the main use of PAE is in paper manufacture and that Hercules uses epichlorohydrin to make other chemicals. Nevertheless, a dramatic increase in the use of PAE resin for the production of wood products could result in increases in epichlorohydrin environmental releases.

Neither Homasote nor Viroc (nor their constituents cellulose and Portland Cement) are expected to have any negative impact on the environment from a toxicity standpoint. From a resource conservation standpoint, Viroc is only 20% wood and can be made with waste wood thus avoiding harvest of virgin forests. However, Portland cement must be mined and therefore is not a renewable resource. Homasote not only does not use any virgin wood, it is at least 80% post-consumer recycled materials that otherwise would be headed for landfills or incinerators. Homasote touts its environmental performance as follows:

> Each year Homasote building products help conserve more than 1,370,000 trees and eliminate more than 100,000,000 pounds of solid waste each year. Each production day up to 300 tons of post-consumer paper are recycled into Homasote, diverted from waste stream disposal into landfills or

other methods. All water used to manufacture Homasote® products — hundreds of thousands of gallons per day — is completely recycled in a "closed loop" system.

From an energy use standpoint, Viroc has several concerns. The making of Portland Cement in one of the world's most energy intensive industrial activities resulting significant greenhouse gas, dioxin, NO_x, SO_2, and particulates emissions. For every ton of Portland cement produced, one ton of carbon dioxide is released to the atmosphere (Portland Cement Association). Additionally, significant amounts of fossil fuels are consumed in the production of Viroc as the Portland Cement and wood fibers are transported to Portugal and then back to the United States and then around the country. Building Green Inc., publishers of Environmental Building News, have not given Viroc its imprimatur as a "green" product because of this extreme energy intensivity.

Financial Assessment

Veneer core hardwood plywood is a high quality, high cost product. Columbia PureBond product costs the same as the traditional product produced with urea-formaldehyde resin (approximately $1.25/ft^2.)

Homasote's sheathing panels are more expensive at $15-25 for ½ in. 4x8 panel, than OSB ($13) and plywood ($14), but costs are within reach, especially if OSB mill problems arise. Homasote's floor decking is much more expensive than traditional alternatives.

At $96 for a ½ in. 4x8 panel, Viroc is more than seven times the cost of OSB and plywood, but offers qualities such as fire, wind, impact and insect and mold resistance that may make it attractive to certain markets nonetheless. Viroc can be used without cladding, thus saving some portion of the additional expense.

Near Horizon Alternative: JER Envirotech plastic-wood composite panel

In British Columbia and in Malaysia, with support from the Canadian government, the JER Envirotech company is in process of developing an extruded building panel made of wood fiber and polypropylene thermoplastic (JER Envirotech Ltd.). They expect to begin selling these panels in the US in the next year. Currently, they view this product as a substitute for particleboard and not a structural product although they will be submitting it to a testing protocol and ultimately expect it to perform as a structural product. Wood-plastic composite products are used extensively in this country as substitutes for wood lumber, but JER Envirotech will be the first to produce a panel from this material. Their website describes the JER panel as superior to plywood due to its superior high temperature heat deflection, superior fire resistance, resistance to biological degradation (*e.g.,* insects, decay, termite etc.), very low water absorption, superior mechanical properties (tensile, flexural, and impact resistance), resistance to thermal degradation and its lack of formaldehyde. They also suggest that the price will be competitive. Polypropylene thermoplastic does not have recognized health and environmental effects except for a potential for respiratory irritation from exposure to polypropylene fumes during manufacture of the raw material (Hazardous Substances Data Bank). Wood dust is recognized as a carcinogen.

Summary

Columbia's PureBond compares well to the traditional product in the technical and financial assessment. While it eliminates potential formaldehyde exposures, it does introduce a new potential hazard, epichlorohydrin, into the lifecycle of building panels. This hazard is unlikely to threaten

building occupants or workers exposed to the Kymene resin, but is a potential (although low) worker and environmental hazard in the manufacture of the intermediates.

Viroc and Homasote panels may satisfy enough technical requirements to be considered for structural uses in buildings, especially for those interested in "green" or low toxicity construction. Each has unique advantages and potential disadvantages. Advantages for Homasote include is lack of toxicity and beneficial environmental impact. Additionally, due to its high perm rating and wicking ability, it may prove to be a durable material that helps to prevent mold problems. Viroc has entered the US market at a time when builders in the South and around the country may be looking for hurricane, fire, mold and insect proof building materials that will not negatively impact indoor air quality. Its high cost is likely to prevent it from substituting directly for plywood or OSB, except where these qualities are highly desirable, or where designs utilizing Viroc can eliminate cladding or insulation. Although the Portland cement industry is working to reduce its environmental impact, Viroc's inherent energy intensivity will not appeal to green builders and customers with lifecycle perspectives.

"Green" building products are developing at a rapid pace. Concerns with resource and energy conservation and indoor air quality for building occupants has driven the development of programs such as the U.S. Green Building Council's LEED certification program. These types of initiatives have fostered innovation in new materials development and a market for greener construction materials. Additionally, traditional product suppliers may begin producing plywood and composite wood products made with soy-based (or other) resins and plastic-wood. If the demand for no-added formaldehyde products increases, plywood makers may use more polyvinyl acetate glue in their existing presses despite the increased cost and production challenges. In the meantime, in addition to the "no added formaldehyde" products evaluated here, use of wood products made with low-emission formaldehyde resins will continue to reduce exposures to formaldehyde.

Table 4.4.3 B: Assessment Summary for Hardwood Plywood Building Panels

Assessment Criteria		Traditional Formaldehyde-based Resin Plywood (Reference)	Comparison Relative to traditional formaldehyde resin Plywood PureBond soy-based adhesive
Technical/ Performance Criteria	Appearance/ Construction	ANSI/HVPA HP-1-2004	=
	Glue bond under moisture	Good (ANSI 3-cycle soak)	=
		Poor (ANSI 3-cycle boil)	+
	Fire Resistance	Good (ASTM E-85 Flame Spread Class C)	=
	Warp Resistance	Variable	=/?
	Product Availability	Good	=
Financial Criteria	Cost (1/2 in. 4x8)	$1.25/ft^2 (Columbia's price)	=
Environmental Criteria	Ecotoxicity	Minor	=
Human Health Criteria	Carcinogen in Resin	Yes	+
	Toxic Intermediate in Resin	Yes	=
	Irritant in Resin	Yes	+

COMPARISON KEY

+ Better = Similar - Worse ? Unknown

Table 4.4.3 C: Assessment Summary for Structural Use Building Panels

Assessment Criteria		Softwood Plywood with formaldehyde-based resin (Reference)	OSB (Oriented Strand Board) (Reference)	Comparison Relative to formaldehyde-based resin Softwood Plywood and OSB	
				Homasote	Viroc
Technical/Performance Criteria	Weight (1/2 in.) lb/ft^2	Acceptable	Acceptable	+	-
	Fire Resistance	Good (Class C)	Good (Class C)	=	+
	Insect/Rot/Mold Resistance	Acceptable	Acceptable	+	+
	Load bearing/weight	Good	Good	-	-
	Impact Resistance	Good	Less than plywood	-	+
	Tensile Strength lb/in^2	Excellent	Excellent	-	-
	Shear	Good	Good	+	?
	Permeance	Acceptable	Acceptable	+	+
	Linear Expansion (50-90% RH)	Good	Good	-	+
	"Weatherability"	Acceptable	Acceptable but worse than plywood	?	?
	Nail Pull (Dry)	50 lbs	40 lbs	+	+
	R Value	.6	.6	+	-
Financial Criteria	Cost (1/2 in. 4x8)	$14	$13	-	-
Environmental Criteria	Ecotoxicity	Minor	Minor	+	+
	Natural Resource Conservation	Poor	Better than plywood	+	?
	Energy Intensity	Neutral	Neutral	?	-
Human Health Criteria	Carcinogen in Binder	Yes	Yes	+	+
	Irritant in Binder	Yes	Yes	+	=

COMPARISON KEY

+ Better = Similar - Worse ? Unknown

4.5. Summary and Conclusions

Formaldehyde, a gas a room temperature, is widely used in industry and is a basic building block for the manufacture of many other chemicals and products. More than half of formaldehyde manufactured is used in the production of resins and adhesives and most of these are used in the manufacture of wood products such as plywood. Most formaldehyde is sold as formalin, a water solution of formaldehyde and some methanol to prevent polymerization. Formaldehyde is highly toxic to bacteria and other pathogens and, thus, it is used as a sterilizer. In addition to manufactured sources, formaldehyde can be a product of combustion.

Exposure to formaldehyde can cause irritation and dermatitis and has been found to cause nasopharyngeal cancer in some occupational groups, including embalmers who use formaldehyde to preserve the deceased. Because formaldehyde is highly reactive, water soluble and readily metabolized by almost all human cells, overexposures tend to do damage at the point of contact, most commonly the eyes and the upper respiratory tract.

Rising concerns about indoor air quality have drawn formaldehyde into the spotlight because of the tendency for formaldehyde-containing building elements and furniture to "off-gas" formaldehyde thereby causing irritation to occupants. In response, manufacturers have improved their processes to reduce the potential for off-gassing and standards have been set to certify products as "low-emitters."

We looked at alternatives to the use of formaldehyde in sanitary storage for barbering and cosmetology, preserved educational specimens for dissection, and building panels. These uses were chosen because of their potential to expose students, workers and the public to formaldehyde emissions.

Sanitary Storage in Barbering and Cosmetology

In salons and cosmetology classrooms in Massachusetts, paraformaldehyde sanitizers known as Steri-Dry tubes are required by the Board of Cosmetology to be placed along with brushes and combs in storage cabinets and drawers to maintain an extra level of protection for customers. However, national best practices experts recommend that paraformaldehyde not be used; that storage cabinets be cleaned and disinfected with standard procedures. Thus, the alternative to this use of formaldehyde is to not use it and to abide by sanitary standards.

A second alternative, the use of UV light cabinets, has potential maintenance concerns and could result in UV light exposure. They also represent a significant initial capital expenditure. They also could be used effectively as an alternative to Steri-Dry, however, eliminating the EH&S concerns associated with exposure to formaldehyde.

Educational Specimens

Students and instructors have been exposed to formaldehyde through the off-gassing of specimens such as fetal pigs and frogs dissected in gross anatomy classes. Several scientific supply companies are offering formaldehyde-free alternative specimens and these are generally less expensive, deemed equivalent or better from a technical standpoint, and are generally less toxic. However, these alternative preservatives do contain ingredients that can be irritating to the skin and should be used with skin protection.

Another viable alternative to formaldehyde-preserved specimens is the use of virtual/video dissection technology, which eliminates any exposure concerns associated with formaldehyde. From a technical standpoint, the use of virtual/video dissection offers certain advantages, but many instructors prefer physical dissection. It may also be a useful adjunct to dissection for classroom instruction.

Building Panels

The Institute identified and assessed acceptable alternatives being used by manufacturers of building panels. Two products, one that is recycled paper board and one that is cement-wood fiber board, are made without the use of formaldehyde-based resins, and are feasible alternatives for many structural panel applications. These alternatives are generally superior to the formaldehyde-based structural panels from an EH&S perspective, but are more expensive. In addition, the cement-wood fiber board uses significant amounts of energy in its manufacture.

In addition to material alternatives made without resins, one company is manufacturing wood panels (currently only veneer core hardwood plywood) with a soy-based resin. Because of the addition of a wet-strength ingredient borrowed from the paper industry, this soy-based resin has equivalent or better technical performance to the traditional product. The cost is also equivalent to the traditional product. While there are not expected to be environmental or health and safety hazards related to the use of this alternative resin, the lifecycle of this chemistry includes an intermediate chemical that is a carcinogen.

Finally, an emerging technology, extruded building panel made of wood fiber and polypropylene thermoplastic, is currently being developed as an alternative decorative wood panel. The Institute was not able to assess this alternative compared to formaldehyde-based building panels, however we encourage further study to determine how this alternative compares from an EH&S, technical and cost perspective

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Attachment 1-6

"Guidance on the Preparation of an Application for Authorisation"
(ECHA-11-G-01, January 2011)

"Guidance for the Preparation of an Annex XV Dossier for Restrictions"
(ECHA, June 2007)

See introductory memorandum from GRSP member Timothy Malloy which identifies the most relevant sections of each document.

MEMORANDUM

To: GRSP Chairs

Odette Madriago, DTSC

Kathy Barwick, DTSC

From: Timothy Malloy

Re: Suggested Documents for GRSP Consideration

Date: May 20, 2011

I am attaching two documents prepared by the European Chemicals Agency as part of the REACH program that may be useful to the subcommittees in their work on alternatives analysis: *Guidance on the Preparation of an Application for Authorisation* (January 2011) and *Guidance for the Preparation of an Annex XV Dossier for Restrictions* (June 2007). I am not necessarily endorsing the procedures and policy choices set out in these documents; indeed, I think there are some significant limitations and problems with various aspects of them. That said, I believe that they do offer carefully considered approaches to alternatives analysis, particularly with respect to areas of concern of subcommittees 1 and 2.

The *Guidance on the Preparation of an Application for Authorisation* lays out the manner in which applicants for authorization of Annex XIV substances (such as manufacturers or end users) should conduct and document the alternatives analysis required as part of the authorization process. This "permitting" type approach, in which the business (or group of businesses) performs an analysis for its particular use, is similar to the approach proposed by DTSC previously. The most relevant sections for alternatives analysis are pages 40-93. For subcommittee 2, there is explicit discussion of some form of tiering on pages 66-68.

The *Guidance for the Preparation of an Annex XV Dossier for Restrictions* sets out a procedure to be followed by member states in considering the proposed imposition of restrictions (including but not limited to bans and phase-outs), which includes alternatives analysis. This is more of a centralized "*rule-making*" approach in which the agency performs the analysis with respect to an industry sector, in contrast to the entity-centric permitting approach for authorization. There are notable differences in the alternatives analysis approach flowing from the different orientation between a permitting and rule-making perspective. . The most relevant sections for alternatives analysis are pages 68-75. For subcommittee 2, there is explicit discussion of some form of tiering on pages 66-68, and in Appendix VI. Also of interest regarding regulatory response (which I realize is not directly part of the next GRSP meeting agenda), this guidance has an extensive discussion of factors to be considered by a member state in developing the specific nature of the restriction. See pages 54-68.

ECHA

http://echa.europa.eu

Guidance on the preparation of an application for authorisation

Version 1

January 2011

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Please note that this is the only authentic version of the guidance and takes precedence over the draft version of this guidance that has been published in the Official Journal of the European Union.

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Guidance on the preparation of an application for authorisation

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PREFACE

This document describes the REACH procedure on applications for authorisation. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving stakeholders from Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/reach_en.asp). Further guidance documents will be published on this website when they are finalised or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006.[1]

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, corrected version in OJ L136, 29.5.2007, p.3).

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ABBREVIATIONS

BREF	Best Available Technology Reference Document (guidance under IPPC directive)
CAS	Chemical Abstracts Service
CBI	Confidential Business Information
CMR	Carcinogenic, Mutagenic or toxic to Reproduction
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No-Effect Level
DU	Downstream User
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ES	Exposure Scenario
GD	Guidance Document under REACH
IPPC	Integrated Pollution Prevention and Control (Directive 2008/1/EC)
IUCLID	International Uniform Chemical Information Database
MS	Member State
M/I	Manufacturer/Importer
OC	Operational Conditions
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No Effect Concentration
POP	Persistent Organic Pollutants (Regulation (EC) No 850/2004)
QSAR	Quantitative Structure Activity Relationship
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
R&D	Research and Development
RMM	Risk Management Measure
SEA	Socio-Economic Analysis
SDS	Safety Data Sheet
SIEF	Substance Information Exchange Forum
SVHC	Substance of Very High Concern
vPvB	Very Persistent and very Bioaccumulative
WFD	Water Framework Directive (Directive 2000/60/EC)

GLOSSARY OF TERMS

A glossary of technical terms used within this guidance document is provided below. The European Chemicals Agency (ECHA) also has a general glossary of terms relevant to REACH which can be found using the following link: REACH Navigator - Glossary

Adequate control route (for authorisation): An authorisation shall be granted if it is demonstrated that the risk to human health or the environment from the use of the substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with section 6.4 of Annex I {Art. 60(2)}, taking into account Article 60(3).

Agency: The European Chemicals Agency (ECHA) as established by the REACH Regulation.

Annex XIV: Annex XIV of REACH lists all substances which are subject to authorisation under REACH. The use and placing on the market for a use of substances listed on Annex XIV, either on its own, in a mixture or for incorporating into an article, is prohibited from the "sunset" date unless an authorisation has been granted for that use or unless an exemption applies.

Annex XIV substance: The substance listed on Annex XIV that is the subject of the authorisation procedure.

Annex XV: Annex XV of the REACH regulation lays down general principles for preparing Annex XV dossiers to propose and justify

(a) harmonised classification and labelling of CMRs, respiratory sensitisers and other effects

(b) the identification of a substance as a CMR, PBT, vPvB or a substance of equivalent concern in accordance with Article 59

(c) restrictions of the manufacture, placing on the market or use of a substance within the Community.

Proposals for restrictions and identification of substances of very high concern can be prepared by a Member State or by the Agency on a request from the Commission. Proposals for harmonised classification and labelling can be prepared by a Member State.

Annex XV dossier: A dossier produced in accordance with Annex XV. The dossier consists of two parts, the Annex XV report and the Annex XV technical dossier supporting the Annex XV report.

Applicant: The legal entity or group of legal entities submitting the authorisation application.

Authorisation: The REACH Regulation sets up a system under which the use of substances with properties of very high concern and their placing on the market can be made subject to an authorisation requirement. Such substances are included in Annex XIV of the Regulation, and may not be placed on the market or used without an authorisation after the sunset date. This authorisation requirement ensures that risks from the use of such substances are either adequately controlled or outweighed by socio-economic benefits. An analysis of alternative substances or technologies will be a fundamental component of the authorisation process.

Authorisation application: The documentation submitted to the Agency applying for authorisation in order to (continue to) use of substances included in Annex XIV.

Authorisation review: Authorisations granted will be subject to a review period.

Candidate List: The candidate list refers to the list of substances of very high concern (SVHC) from which the substances to be included in Annex XIV (list of substances subject to authorisation) are selected. The candidate list is established in accordance with Article 59.

Carcinogenic, mutagenic or toxic to reproduction (CMR): Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1 or 2, in accordance with Directive 67/548/EEC, are substances of very high concern[2]. They may be included in Annex XIV and by that made subject to authorisation requirement. CMRs may be non-threshold (i.e. it is not possible to define a Derived No-Effect Level (DNEL)) or threshold (i.e. it is possible to define a DNEL)

Chemical Safety Assessment (CSA): Chemical Safety Assessment is the process aimed at determining the risk posed by a substance and, as part of the exposure assessment, develop exposure scenarios including risk management measures to control the risks. Annex I contains general provisions for performing a CSA. The CSA consists of the following steps:

- Human health hazard assessment
- Human health hazard assessment of physicochemical properties
- Environmental hazard assessment
- PBT and vPvB assessment

If, as a result of this hazard assessment, the registrant concludes that the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC (for substances)[3] or has PBT/vPvB properties, this triggers further steps in the chemical safety assessment:

- Exposure assessment
- Risk characterization.

Chemical Safety Report (CSR): The chemical safety report documents the chemical safety assessment for a substance on its own, in a mixture or in an article or a group of substances.

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2 From 1 December 2010, this should read: "Substances meeting the criteria for classification in the hazard classes carcinogenicity, gem cell mutagenicity or reproductive toxicity category 1A or 1B in accordance with Annex I to Regulation (EC) No 1212/2008".

3 From 1 December 2010, ths should read: "If, as a result of this hazard assessment, the registrant concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

(c) hazard class 4.1;

(d) hazard class 5.1,"

In other words the chemical safety report (CSR) is a document, which details the process and the results of a chemical safety assessment (CSA). Annex I of the REACH Regulation contains general provisions for performing CSAs and preparing CSRs.

Committee for Risk Assessment (RAC): is an Agency committee that is responsible for preparing the opinion of the Agency on evaluations, applications for authorisation, proposals for restrictions and proposals for classification and labelling under the classification and labelling inventory task and any other questions that arise from the operation of the REACH Regulation relating to risks to human health or the environment. The RAC consists of at least one but no more than two members from the nominees of each Member State appointed by the Management Board for a renewable term of three years. The Committee members may be accompanied by advisers on scientific, technical or regulatory matters.

Committee for Socio-economic Analysis (SEAC): is an Agency committee that is responsible for preparing the opinion of the Agency on applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of the REACH Regulation relating to the socio economic impact of possible legislative action on substances. The SEAC consists of at least one but no more than two members from the nominees of each Member State appointed by the Management Board for a renewable term of three year. The Committee members may be accompanied by advisers on scientific, technical or regulatory matters.

Downstream User: Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user.

Exposure scenario: Set of conditions including operational conditions and risk management measures that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposure of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.

Gross profit of a substance or a product is the difference between the sales revenue and the variable and fixed costs of producing the product. Fixed and variable costs (also known as “cost of goods sold”) include e.g. materials and labour. Gross Profit = Revenue − variable costs − fixed costs

Importer: Any natural or legal person established within the Community who is responsible for import.

Interested Third Party: Any organisation, individual, authority or company other than the applicant or the Agency/Commission with a potential interest in submitting information on alternatives for the consideration of the Agency Committees in forming their opinions on the application for authorisation.

Joint application: An application for authorisation made by a number of legal entities forming a group of applicants consisting of manufacturer(s) and/or importer(s) and/or downstream user(s) of the Annex XIV substance.

Latest application date: Annex XIV (list of substances subject to Authorisation) will specify for each substance included in that Annex a date or dates, at least 18 months before the sunset date(s), by which applications for authorisation must be submitted if the applicant wishes to

continue to use the substance or place it on the market for certain uses after the sunset date(s) until a decision on the application for authorisation is taken.

Legal entity: Any natural or legal person established within the Community.

Manufacturer: Any natural or legal person established within the Community who manufactures a substance within the Community

Operational Conditions (OC): All conditions which have a quantitative impact on exposure, e.g. product specifications, duration and frequency of exposure, applied amount of substance per use or capacity of surroundings (e.g. room size, receiving environmental compartment)

Persistent, Bioaccumulative and Toxic (PBT): Annex XIII of the REACH Regulation defines criteria for the identification of substances that are Persistent, Bio-accumulative and Toxic (PBTs) and Annex I lays down general provisions for PBT assessment. PBTs are substances of very high concern (SVHC) and may be included in Annex XIV and by that be made subject to authorisation.

Regulatory procedure: procedure for the adoption of implementing legislation that involves a vote by a Committee composed of the representatives of the Member States. The Council and the European Parliament have a role to play in accordance with Article 5 of Council Decision 1999/468/EC as amended by Council Decision 2006/512/EC. Authorisation proposals under REACH will be adopted in accordance with this regulatory procedure.

Regulatory procedure with scrutiny: procedure for the adoption of implementing legislation that involves a vote by a Committee composed of the representatives of the Member States and foresees a role for the Council and the European Parliament in accordance with Article 5a of Council Decision 1999/468/EC as amended by Council Decision 2006/512/EC. Decisions on the inclusion of substances in Annex XIV will be taken in accordance with the regulatory procedure with scrutiny.

Review report: In order to continue placing on the market or using a substance, the holder of the authorisation must submit a review report at least 18 months before the expiry date of the time-limited review period.

Risk Management Measures (RMM): Measures in the control strategy for a substance that reduce the emission and exposure to a substance, thereby reducing the risk to human health or the environment.

Socio-economic analysis (SEA): The socio-economic analysis (SEA) is a tool to evaluate what costs and benefits an action will create for society by comparing what will happen if this action is implemented as compared to the situation where the action is not implemented. Although according to Article 62(5) the inclusion of a SEA is optional it should be included as part of an application for authorisation whenever the risks to human health or the environment from the use of an Annex XIV substance are not adequately controlled. Also when adequate control can be shown, an SEA may be produced by the applicant in support to his application. An SEA may also be produced by any third party in support to information on alternatives.

Socio-economic route (for authorisation): An authorisation may be granted if it can be demonstrated that the risk to human health or the environment from the use of the substance is outweighed by the socio-economic benefits and if there are no suitable alternative substances or technologies {Art. 60(4)}.

Substance function: The function of the Annex XIV substance for the use/s being applied for is the task or job that the Annex XIV substance is performing.

Substances of very high concern (SVHC): SVHC in the context of the REACH Regulation are:

1. CMRs category 1 or 2 in accordance with Directive 67/548/EEC[4].

2. PBTs and vPvBs meeting the criteria of Annex XIII and

3. substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of Annex XIII - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points 1 and 2 and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

Substitution plan: Is a commitment to take the actions needed to substitute the Annex XIV substance with an alternative substance or technology within a specified timetable.

Sunset date: Annex XIV (list of substances subject to Authorisation) will specify for each substance included in that Annex the date (called 'the sunset date") from which the placing on the market and the use of that substance shall be prohibited. That is unless an exemption applies or an authorisation is granted or an authorisation application has been submitted before the latest application date also specified in Annex XIV, but the Commission decision on the application for authorisation has not yet been taken.

Supply chain: Is the system of organisations, people, activities, information and resources involved in moving a substance from (supplier to customer) i.e. manufacture/importers to downstream users and end users.

Very Persistent and very Bioacccumulative (vPvB): Substances of very high concern, which are very persistent (very difficult to break down) and very bio-accumulative in living organisms. Annex XIII of the REACH Regulation defines criteria for the identification of vPvBs and Annex I lays down general provisions for their assessment. vPvBs may be included in Annex XIV and by that be made subject to authorisation.

[4] As from 1 December 2010 this should read: "substances meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity category 1A or 1B in accordance with Annex I to Regulation (EC) No 1272/2008"

1. GENERAL INTRODUCTION AND OVERVIEW OF THE AUTHORISATION PROCESS

1.1. About this guidance

This document provides technical guidance on how to apply for an authorisation for the use of substances included in Annex XIV under Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, concerning the registration, evaluation, authorisation and restriction of chemicals (the REACH Regulation). In particular it includes guidance on the mixture of an analysis of alternatives, a substitution plan and how interested third parties can contribute to the authorisation process.

1.2. Structure of the guidance

The introductory sections (Chapter 1) contain a general overview of the authorisation process, including links to other REACH guidance. Chapter 2 provides more detailed guidance how to put together an application for an authorisation, and on the specific information and considerations needed for an application. Chapter 3 considers what is needed when carrying out an analysis of alternatives; Chapter 4 describes the production of a substitution plan; and Chapter 5 deals with the submission of information by third parties.

1.3. Who is the guidance for?

This guidance is primarily intended for use by manufacturers, importers and downstream users placing on the market or using a substance included in Annex XIV of REACH (List of substances subject to authorisation). The guidance is also intended to be used by third parties that may have information on alternative substances or alternative technologies in relation to a substance included in Annex XIV. In general, the user is assumed to have suitable experience for the part of the guidance they are using.

The guidance may also be useful for those within the Member State Competent Authorities and the Agency involved in the authorisation process.

1.4. Links to other REACH guidance

This guidance is not intended to be used as stand alone guidance and takes into account other REACH guidance relevant for preparing an authorisation application. The intention of this guidance is not to repeat guidance that is available elsewhere, and the relevant sources of further guidance are referenced as appropriate. The most relevant other parts of the REACH guidance are as follows.

- **Guidance on information requirements and chemical safety assessment (CSA).** This provides further guidance on carrying out a Chemical Safety Assessment and documenting it in a Chemical Safety Report. This guidance also includes advice, for instance, on identification/description of uses and on grouping of substances.

- **Guidance on data sharing**. This provides guidance on data sharing mechanisms under REACH, and includes the communication within SIEF and cost sharing guidance.
- **Guidance for Downstream Users**. This provides further guidance on the obligations of downstream users in relation to substances listed in Annex XIV.
- **Guidance on Socio Economic Analysis – Authorisation**. This provides detailed guidance for carrying out a socio-economic analysis.

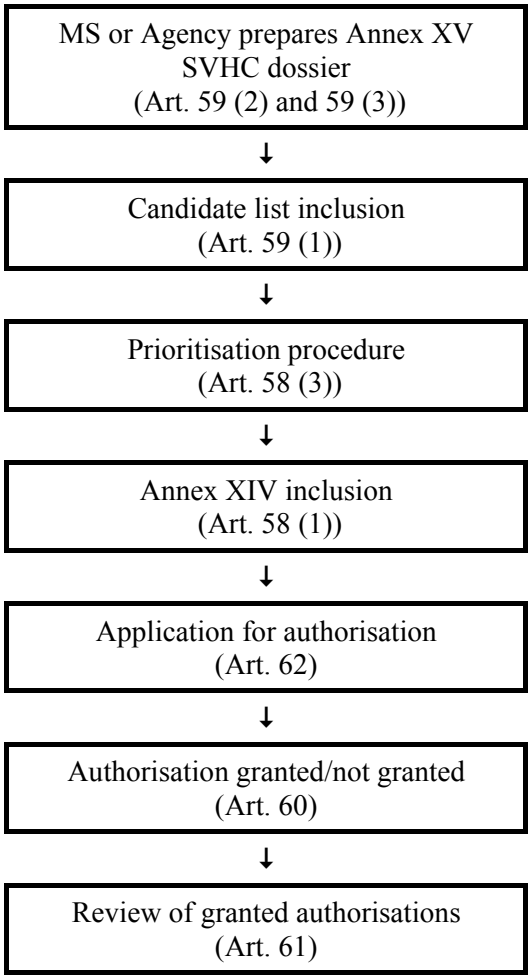
In addition, separate guidance documents are available for authorities concerning the identification of substances of very high concern, priority setting and the inclusion of a substance on Annex XIV, and so these stages of the overall process are not considered in detail in this guidance. However it is essential for a potential applicant for an authorisation and other interested third parties to understand the process that leads to inclusion of a substance on Annex XIV, as there are a number of formal opportunities for commenting and submitting information prior to the substance being included on Annex XIV. Early involvement of potential applicants and interested third parties in the process is encouraged in order to improve the quality of decision making. Therefore a brief overview of the overall authorisation process is given here. The guidance documents on identification of substances of very high concern and inclusion of a substance on Annex XIV should be consulted for more details on the authorisation procedure concerning inclusion of a substance on Annex XIV.

1.5. General overview of the authorisation procedure

The aim of this Title (VII, authorisation) *is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution* {Art. 55}.

Authorisations apply to substances of very high concern (SVHC) that are included in Annex XIV of REACH. There is no tonnage limit for the authorisation requirement. The overall authorisation process involves several steps including identification of substances of very high concern, prioritisation of these substances for inclusion in Annex XIV, the listing of these substances on Annex XIV, application for authorisations, granting or refusing of authorisations and reviewing of granted authorisations. A simplified description of the overall process is shown in Figure 1. The process up to inclusion of the substances on Annex XIV is described in detail in the Guidance on inclusion of substances in Annex XIV, but some background is included in Sections 1.5.1 and 1.5.2 of this guidance. The rest of this guidance relates to the steps following inclusion on Annex XIV.

Figure 1 Simplified description of the identification of substances of very high concern and the authorisation procedure



1.5.1. How substances get included in Annex XIV

The process is started by a Member State or, on request from the Commission, by the Agency, when they produce Annex XV dossiers for identification of substances of very high concern in accordance with the procedure laid down in Article 59. Only substances with the following properties can be included in Annex XIV and therefore, be subject to authorisation {Art. 57}.

a) *Substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Council Directive 67/548/EEC.* [5]

b) *Substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Council Directive 67/548/EEC.*

[5] The references to Directive 67/548/EEC will be replaced from 1 December 2010 by references to Regulation 1272/2008 (CLP Regulation).

c) *Substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Council Directive 67/548/EEC.*

d) *Substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of the Regulation.*

e) *Substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of the Regulation.*

f) *Substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis.*

The Annex XV dossier should outline the scientific evidence for identifying the substance as a substance of very high concern and candidate for eventual inclusion on Annex XIV. Direction on preparing an Annex XV SVHC dossier is included in the Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern. Comments on the Annex XV dossier are invited from the Member States, the Agency and interested parties (stakeholders), in the latter case via a notice published on the Agency's website with a deadline set by the Agency {Art. 59(4)}. These notices include, e.g., information from the Annex XV dossiers on substance identity (name, EC and/or CAS numbers), the reason why the substance is believed to meet one or more of the criteria set out in Article 57 and the deadline for comments. Guidance on how to submit comments is provided in the Guidance on inclusion of substances in Annex XIV.

Once an agreement has been reached that the substance meets one or more of the intrinsic properties outlined in Article 57 (see above), the substance will be placed on the candidate list. The main implication of placing a substance on the candidate list is that it then becomes eligible for eventual inclusion in Annex XIV. The Agency, taking into account the opinion of the Member State Committee, recommends priority substances to be included on Annex XIV. Priority will normally be given to substances with PBT or vPvB properties, or wide dispersive uses, or high volumes {Art. 58(3)}.The Agency will submit a recommendation for substances to be included in Annex XIV to the Commission at least every second year {Art. 58(3)}.

Before the Agency sends a new recommendation to the Commission, the recommendation is made public via the Agency's website, and all interested parties are invited to submit comments within three months of the date of publication. In particular, comments on uses which should be exempted from the authorisation requirement are requested. The recommendation may then be updated to take account of the comments received {Art. 58(4)}. For consultation purposes, a template for provision of comments is made available on the Agency's website. Guidance on how to submit comments is provided in the Guidance on inclusion of substances in Annex XIV. The Commission takes the decision on the inclusion of substances in Annex XIV in accordance with the Regulatory procedure with scrutiny referred to in Article 133(4) {Art. 58(1)}.

1.5.2. Annex XIV entries

The Annex XIV entry for each substance will specify the following {Art. 58(1)}.

- *The identity of the substance as specified in Section 2 of Annex VI;*

- *the intrinsic property (or properties) of the substance referred to in Article 57* (i.e. properties leading to the inclusion in Annex XIV);
- *transitional arrangements:*
    - *the date(s) from which placing on the market and use of the substance is prohibited unless an authorisation is granted (hereafter referred to as the sunset date) which should take into account, where relevant, the production cycle specified for that use;*
    - *a date or dates, at least 18 months before the sunset date(s) by which applications for authorisation must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken;*
- *review periods for certain uses if appropriate;*
- *uses or categories of uses that are exempted from the authorisation process, if any, and conditions for such exemptions, if any.*

After the sunset date, substances that are included in Annex XIV cannot be used by a manufacturer, importer or a downstream user, or be placed on the market by a manufacturer, importer or a downstream user for a use unless an authorisation has been granted for that use (or where an application for an authorisation has been submitted to the Agency before the deadline specified in Annex XIV but no decision has yet been reached) or the use is exempt from authorisation. The process for setting sunset dates takes into account, where appropriate, the production cycle specified for the use under consideration. Therefore it is important for the potential applicant(s) to be involved at an early stage in the process and provide information that is relevant for setting sunset dates. The Guidance on inclusion of substances in Annex XIV should be consulted for further details of the process for setting sunset dates.

Certain uses of substances are exempted from the authorisation process. These general exemptions are listed in Table 1.. In addition, the Annex XIV entry may include substance specific exemptions for uses or categories of uses, along with any conditions that apply to such exemptions. Such exemptions may be included provided that, on the basis of existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled {Art. 58(2)}. The Guidance on inclusion of substances in Annex XIV gives further examples of existing specific Community legislation that could be considered in this respect. The ultimate responsibility for deciding on which uses should be exempted lies with the Commission in accordance with the Regulatory procedure with scrutiny. In establishing such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.

Table 1.Uses exempted from authorisation

On-site isolated intermediates and transported isolated intermediates {Art. 2(8b)}.
Use in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC {Art. 2(5a)}.
Use in food or feedingstuffs according to Regulation (EC) No 178/2002 including use as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC, as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC and Commission Decision 1999/217/EC or on foodstuffs drawn up in application of Regulation (EC) No 2232/96, as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003 and in animal nutrition within the scope of Council Directive 82/471/EEC {Art. 2(5b)}.
Use in scientific research and development {Art. 56(3)} (Annex XIV shall specify if the authorisation requirement applies to product and process research and development) {Art. 56(3}.
Use on plant protection products within the scope of Council Directive 91/414/EEC {Art. 56(4a)}.
Use in biocidal products within the scope of Directive 98/8/EC {Art. 56(4b)}.
Use as motor fuels covered by Directive 98/70/EC {Art. 56(4c)}.
Use as fuel in mobile or fixed combustion plants of mineral oil products and use of fuels in closed systems {Art. 56(4d)}.
Use in cosmetic products within the scope of Council Directive 76/768/EEC (this exemption applies to substances listed on Annex XIV on the basis of their hazard to human health only) {Art. 56(5a)}.
Use in food contact materials within the scope of Regulation (EC) No 1935/2004 (this exemption applies to substances listed on Annex XIV on the basis of their hazard to human health only) {Art. 56(5b)}.
Use of substances when present in mixtures below a concentration limit of 0.1% by weight. This applies only to substances listed in Annex XIV on the basis of being persistent, bioaccumulative and toxic (PBT) as defined by Art. 57(d), very persistent and very bioaccumulative (vPvB) as defined by Art. 57(e), or listed in Annex XIV on the basis that there is scientific evidence of probable serious effects to human health or the environment which give an equivalent level of concern to substances with PBT or vPvB properties, or an equivalent level of concern to substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1 and 2 in accordance with Directive 67/548/EEC, as defined by Art. 57(f) {Art. 56(6a)}.
Use of substances when present in mixtures below the lowest concentration limits specified in Directive 1999/45/EC or in Part 3 of Annex VI to Regulation (EC) No 1272/2008 which results in the classification of the mixture as dangerous. This applies only to substance listed in Annex XIV on the basis of their classification as CMR category 1 and 2 in accordance with Directive 67/548/EEC{Art. 56(6b)}.

As noted in Section 1.5.1, there are two opportunities for formal comments from interested parties prior to the substance being included in Annex XIV, firstly a commenting period on the non-confidential content of the Annex XV dossier itself {Art. 59(4)} and secondly a commenting period on the recommendations for inclusion of the substance in Annex XIV {Art. 58(4)}. This second commenting period in particular, allows comments on uses that have been proposed by the Agency for exemption and further uses that should be exempted from the authorisation requirement, and information on the production cycle, to be put forward. Guidance on submitting information at these points in the process can be found in Guidance on inclusion of substances in Annex XIV.

If new information becomes available to show that the substance no longer meets the criteria of Article 57 then the substance shall be removed from Annex XIV {Art. 58(8)}. In addition, substances for which all uses are prohibited, either by the restrictions procedure under Title VIII of the regulation or by other Community legislation, shall not be included in Annex XIV or shall be removed from it (Art. 58(7)).

1.5.3. Application for an authorisation

This section outlines the general requirements for an application. More detailed guidance on how to put together an application is given in Section 2. A simplified description of the process following listing of a substance on Annex XIV is shown in Figure 2. The detailed process is presented in Figure 3,

Figure 4 and Figure 5. Figure 6 outlines the time line for applications for authorisation. Further details of the timetable are included in Table 2.

Figure 2 Simplified description for granting of authorisations

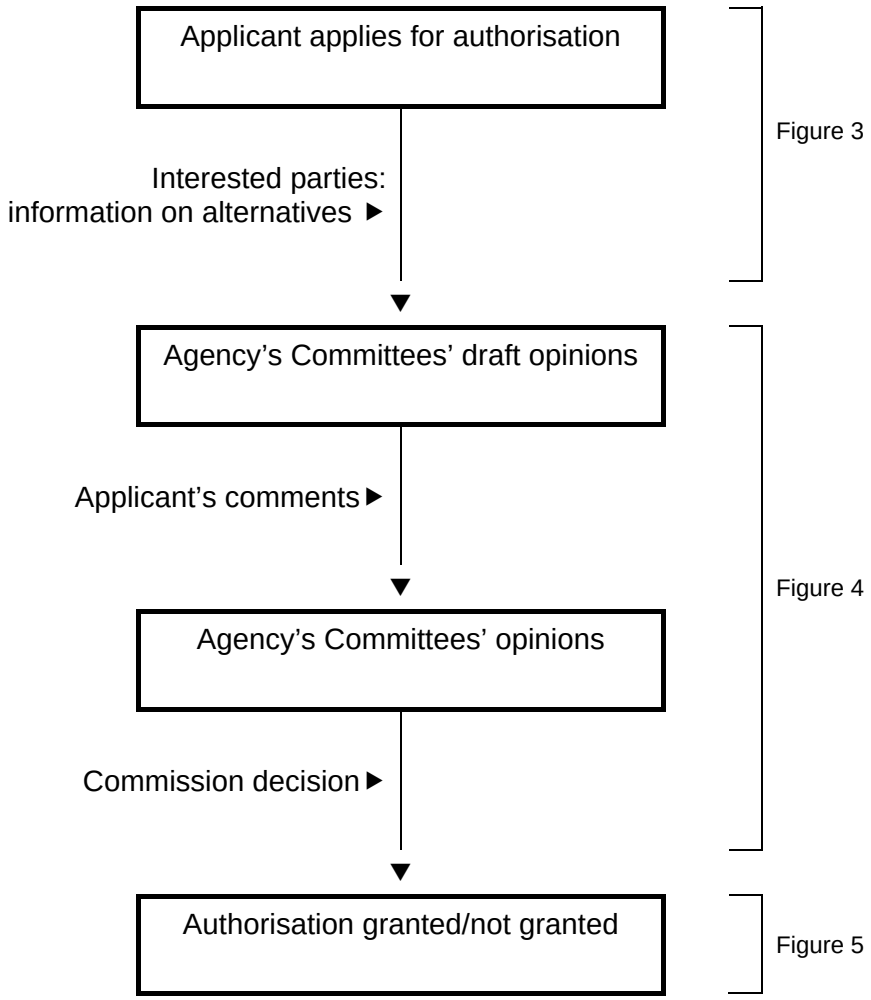


Figure 3 Granting of authorisations part 1

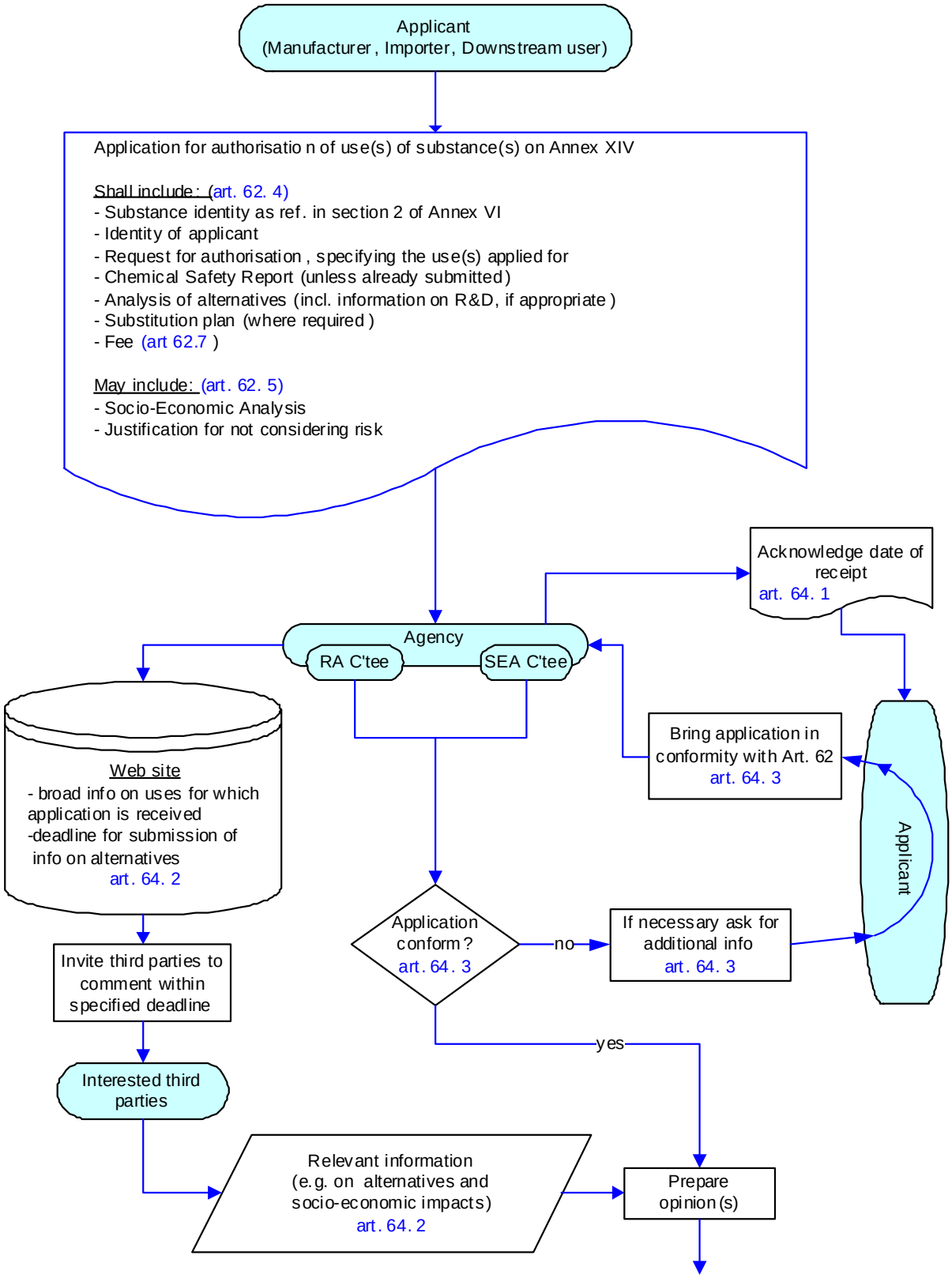


Figure 4 Granting of authorisations part 2

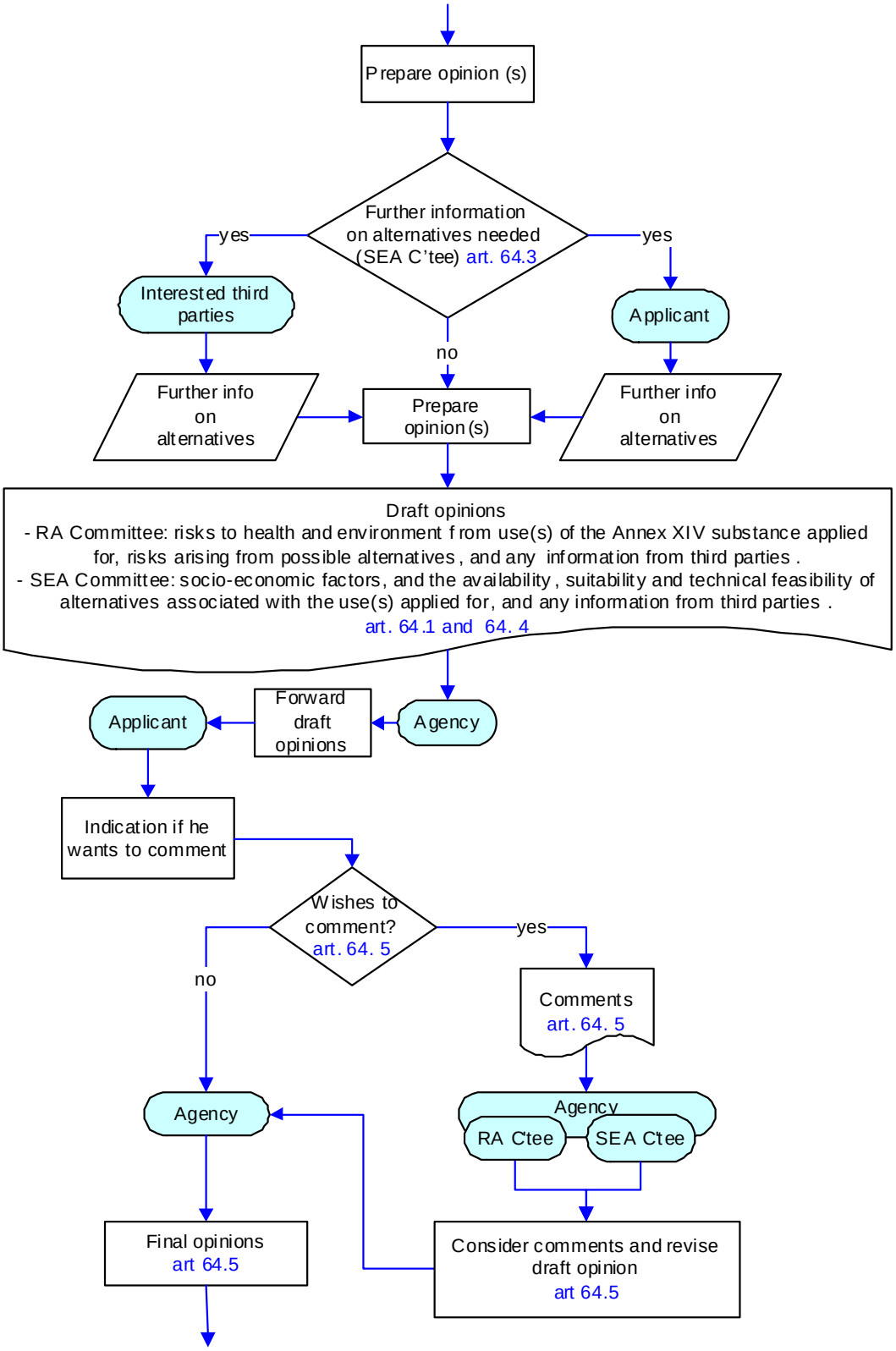


Figure 5 Granting of authorisations part 3

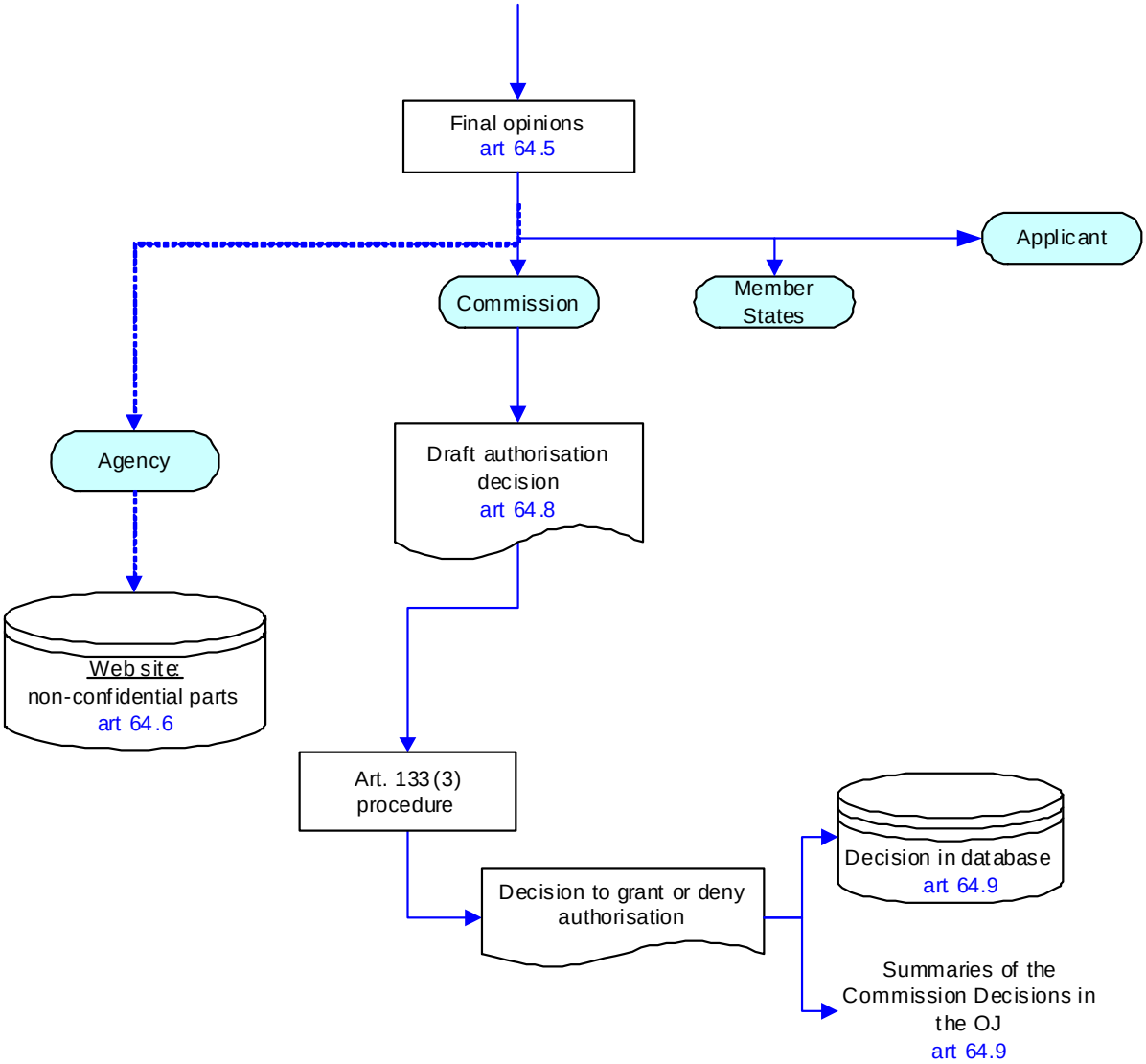
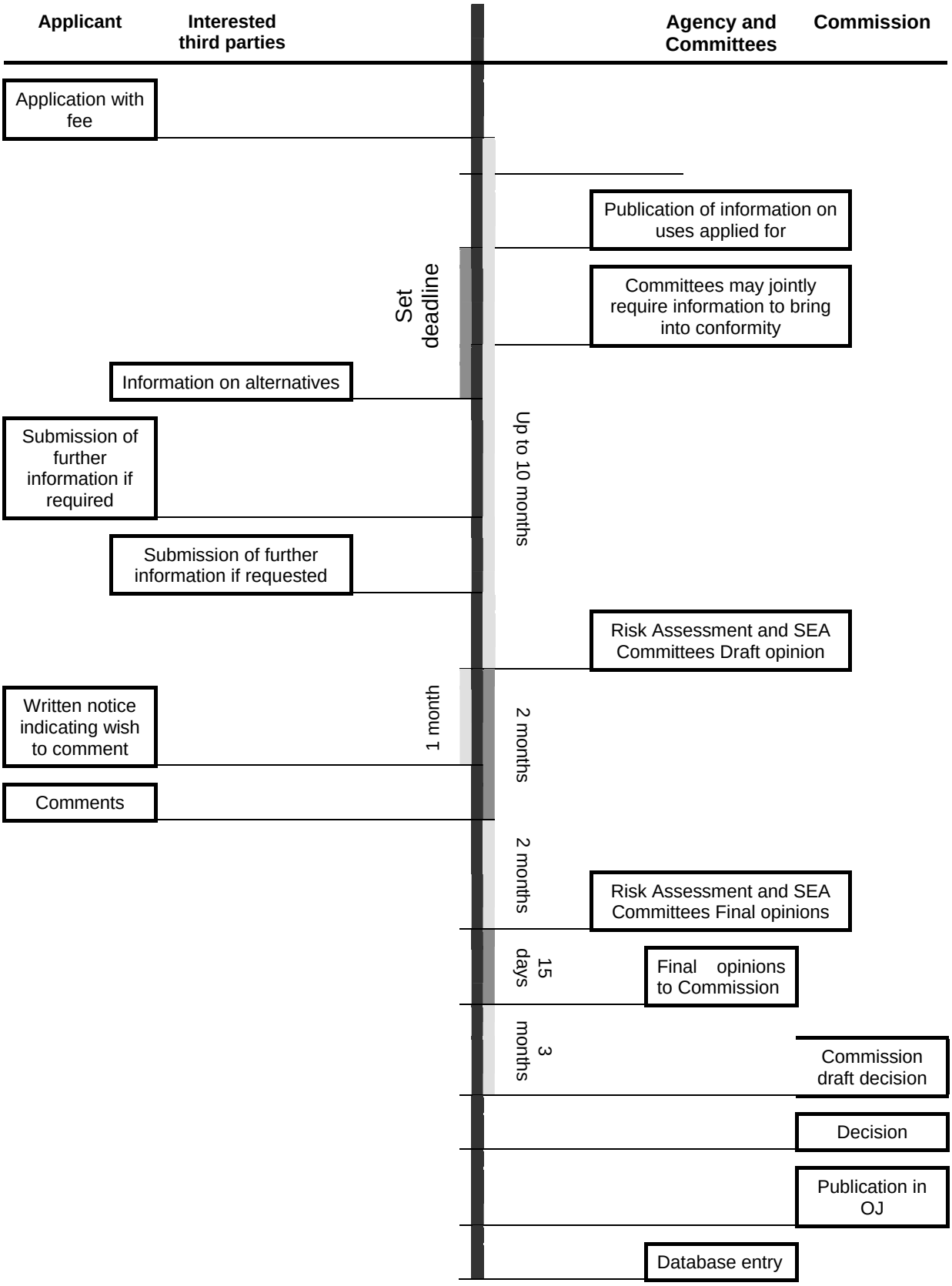


Figure 6 Timeline for granting of an authorisation. See also Table 2.



Applications for authorisations must conform to the requirements of Article 62 of the Regulation. These requirements are outlined below.

The applications for authorisation are made to the Agency {Art. 62(1)}. Applications can be submitted by the manufacturer(s), importer(s) and/or downstream user(s) of the substances, and one or several of these {Art. 62(2)} can make an application for authorisation for the same substance covering one or more uses {Art. 62(3)}. The uses applied for can be the applicant's own use(s) and/or uses for which the applicant intends to place the substance on the market. If an actor applies for an authorisation for a use(s) of his downstream user(s), he needs to cover all uses in the supply chain that are necessary to enable that use(s). For example, if a manufacturer or importer applies for a use of his downstream user, but there is a formulator in between him and the DU, his application has also to cover the use of the substance in formulation.

Applications can also be made for a group of substances for one or more uses {Art. 62(3)}. Grouping of substances can be made on the basis of similarity of physicochemical, toxicological and ecotoxicological properties, or where these follow a regular pattern as a result of structural similarity (Annex XI 1.5).

Each application should be accompanied with the fee required in accordance with Title IX {Art. 62(7)} and Commission Regulation N° EC 340/2008 on the fees and charges payable to the European Chemicals Agency (Annex VI and VII).

The information that must be included in an application for an authorisation is as follows {Art. 62(4)}:

(a) the identity of the substance(s), as referred to in Section 2 of Annex VI;

(b) the name and contact details of the person or persons making the application.

(c) a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in mixtures and/or the incorporation of the substance in articles, where this is relevant;

(d) unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV;

(e) an analysis of alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant.

(f) where the analysis referred to in point (e) above shows that suitable alternatives are available, taking into accounts the elements in Article 60(5), a substitution plan including a timetable for proposed actions by the applicant.

The application may also include {Art. 62(5)}:

(a) a socio-economic analysis conducted in accordance with Annex XVI;

(b) a justification for not considering risks to human health and the environment arising either from:

(i) emissions of a substance from an installation for which a permit was granted in accordance with Directive 96/61/EC; or

(ii) *discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive.*

Article 60(7) provides that an authorisation shall be granted only if the application has been made in conformity with the requirements set out in Article 62. Since the authorisation procedure is legally subject to a time frame (provided in Article 64), it is important that the application is in conformity with these requirements at the submission stage.

Where an application for authorisation has already been made, or where an authorisation has already been granted for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application provided that they have permission from the previous applicant. The parts of the previous application that can be referred to include the following aspects {Art. 63(1),(2)}:

- Chemical Safety Report(s),
- analysis of alternatives,
- substitution plan, and
- socio-economic analysis.

In this case the subsequent applicant shall update the information in the original application as necessary {Art. 63(3)}. Other information needed for the application shall be provided by the subsequent applicant. In cases where an application for the same substance has already been made, the Agency shall treat the applications together provided the deadlines outlined in Section 1.5.4 can be met for the first application {Art. 64(7)}.

The deadline for submission of an application for authorisation will be specified in the Annex XIV entry. Manufacturers, importers, or downstream users of a substance that is listed in Annex XIV are entitled to submit an application to the Agency after that date, but cannot place the substance on the market, or use it themselves, until they have obtained the authorisation.

1.5.4. What happens after an application for an authorisation has been submitted

An overview of the processes that should be followed after submission of an application for an authorisation is outlined in Table 2.

Table 2. Procedure following submission of an application

Step	Organisation responsible	Timeframe
Check appropriate fee paid.	Agency	
Acknowledgement of date of receipt of application {Art. 64(1)}.	Agency	
Broad (non-confidential) information on uses for which applications have been received is made available via the Agency's web-site, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.	Agency	Deadline for information on alternative substances or technologies will be set by the Agency, within the 10 month window for the Agency's Committees draft opinions.

Step		Organisation responsible	Timeframe
Check to ensure all information specified in Article 62 of the Regulation is included in the application. If necessary request further information from the applicant to bring the application into conformity {Art. 64(3)}.		Agency's Committees for Risk Assessment and Socio-economic analysis	Deadline for further information will be set by the Agency's Committees within the 10 month window as above.
If it is considered necessary, require further information from the applicant or request further information from third parties on possible alternative substances or technologies {Art. 64(3)}.		Agency's Committee for Socio-economic analysis	Deadline for further information will be set by the Agency's Committee within the 10 month window as above.
Draft opinions on the application are sent to the applicant {Art. 64(1, 5 and 10)}.		Agency's Committees for Risk Assessment and Socio-economic analysis	Within ten months of the date of receipt of the application. If the application is for a use of a substance for which an authorisation has already been granted, this will be reduced to five months.
If the applicant wishes to comment on the draft opinion{Art. 64(5)}.	Written notice of the intention to comment shall be sent to the Agency.	Applicant	Within one month of receipt of the draft opinion. The draft opinion will be deemed to have been received seven days after the Agency has sent it.
	Comments/argumentation from applicant. These shall be sent in writing to the Agency.	Applicant	Within two months of receipt of the draft opinion
	Finalisation of opinion on the application taking into account the written comments/argumentation from applicant.	Agency's Committees for Risk Assessment and Socio-economic analysis	The final opinion will be adopted within two months of receipt of the written comments/argumentation. The final opinion along with the written comments/ argumentation will be sent to the Commission, Member States and the applicant within a further 15 days.
If the applicant does not wish to comment on the draft opinion, the draft opinion is sent to the Commission, the Member States and the applicant {Art. 64(5)}.		Agency	Within 15 days of the end of the period within which the applicant may comment, or within 15 days of receipt of notice from the applicant that they do not intend to comment.
Non-confidential parts of the opinions and any associated documentation made publicly available on the website {Art. 64(6)}.		Agency	
Draft authorisation decision {Art. 64(8)}.		Commission	Within three months of receipt of the opinion from the Agency.
Final decision granting or refusing authorisation {Art. 64(8)}.		Commission in accordance with comitology procedure in Article 133(3)	
Summaries of the Commission decisions, including the authorisation number and the reason for the decision, published in the Official Journal of the European Union, and made publicly available in the Agency database {Art. 64(9)}.		Commission	

Opinions on the applications will be drafted by the Committee for Risk Assessment and the Committee for Socio-economic analysis as appropriate. The Committees will take into account the information submitted in the application, any information submitted by third parties and any other

relevant information available to the Committees. The draft opinions will be given within ten months of the date of receipt of the application and will contain the following elements {Art. 64(4)}.

Committee for Risk Assessment

- *An assessment of the risk to human health and/or the environment from the use(s) of the substance including the appropriateness and effectiveness of the risk management measures as described in the application.*
- *If relevant, an assessment of the risks arising from possible alternatives.*

Committee for Socio-economic Analysis

- *An assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when the application is made in accordance with Article 62.*
- *Any third party contributions submitted under Article 64 (2).*

Once the draft opinions of the Committees are available there will be an opportunity for the applicant to comment on the opinions before the opinions are finalised and sent to the Commission, Member States and the applicant. If the draft opinion is to grant an authorisation, the applicant may wish to comment on the proposed conditions, the length of the time-limited review period or monitoring arrangements. If the draft opinion is to reject the application, then the applicant will need to look at the reasons given for rejecting the application. They will have to consider whether further information or argumentation can be provided, to give further support to the application and to argue against the reasons given for the rejection. This will need to be clearly focussed on the specific reasons given.

If the applicant wishes to comment on the draft {Art 64 (5)}, written notice of the intention to comment shall be sent to the Agency within one month of receipt of the draft opinion. The actual comments/argumentation should be sent to the Agency within two months of receipt of the draft opinion. Within two months of the receipt of the applicant's comments or 15 days if the applicant does not wish to comment, the Committees will adopt their final opinion on the application taking into account the written argumentation from the applicant. The opinion will be sent to the Commission, which will, in accordance with the comitology procedure, decide whether or not to grant the authorisation. A summary of the decision will then be published in the Official Journal and made publicly available in the Agency database.

1.5.5. Factors that are taken into account in granting or refusing an authorisation

In order to decide whether or not to proceed with an application for an authorisation, it is important to understand the factors that will be taken into account in granting an authorisation. This is elaborated further later in the guidance (Section 2). The responsibility for granting an authorisation lies with the Commission {Art. 60(1)}.

Authorisations can be granted on two bases.

a. An authorisation shall be granted if it is demonstrated that the risk to human health or the environment from the use of the substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with section 6.4 of Annex I {Art. 60(2)}

and taking into account Article 60(3). In this guidance this is referred to as the adequate control route.

b. Otherwise, an authorisation may only be granted if it can be demonstrated that the risk to human health or the environment from the use of the substance is outweighed by the socio-economic benefits and if there are no suitable alternative substances or technologies {Art. 60(4)}. In this guidance this is referred to as the SEA route. This is the only possible basis to get an authorisation in the following cases.
    - Where adequate control of the use of a substance according to a) cannot be shown.
    - For substances included in Annex XIV on the basis of meeting any of the following criteria and for which it is not possible to determine a threshold in accordance with section 6.4 of Annex 1:
        - classification as carcinogenic category 1 or 2 in accordance with Council Directive 67/548/EEC[6],
        - classification as mutagenic category 1 or 2 in accordance with Council Directive 67/548/EEC[7],
        - classification as toxic for reproduction category 1 or 2 in accordance with Council Directive 67/548/EEC[8],
        - substances identified under Art. 57(f) with the exception of substances having PBT or vPvB properties (see below).
    - For substances included in Annex XIV on the basis of meeting the criteria in Annex XIII for persistent, bioaccumulative and toxic (PBT) substances and very persistent and very bioaccumulative (vPvB) substances.
    - For substances included in Annex XIV on the basis of having PBT or vPvB properties giving rise to an equivalent level of concern (identified under Art. 57(f)).

For substances to be authorised through the adequate control route the Commission's decision will be taken based on the evidence presented in the Chemical Safety Report (CSR), taking into account the opinion of the Committee for Risk Assessment. Guidance for this process is available elsewhere (Guidance on information requirements and CSA).

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[6] From 1 December 2010, it should read:

- substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008

[7] From 1 December 2010, it should read:

- substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/20082

[8] From 1 December 2010, it should read:

- substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation(EC) No 1272/2008

In granting the authorisation and setting any conditions the Commission will take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision. The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC, Council Directive 93/42/EEC or Directive 98/79/EC {Art. 60(2)}.For substances to be authorised through the SEA route, in cases where adequate control cannot be demonstrated or Article 60(3) applies, the Commission's decision will take into account the opinions of both the Committee for Risk Assessment and the Committee for Socio-economic Analysis and the following {Art. 60(4a to d)}.

- *The risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed.*
- *The socio-economic benefits arising from the use of the substance, and the socio-economic implications of a refusal to authorise the substance as demonstrated by the applicant or other interested parties.*
- *The analysis of the alternatives submitted by the applicant under Article 62 (4e) or any substitution plan submitted by the applicant under Article 62 (4f) and any third party contributions submitted under Article 64 (2).*
- *Available information on the risks to human health or the environment from any alternative substances or technologies.*

Planning for substitution: One of the fundamental aims of authorisation is the progressive replacement of the substances listed in Annex XIV by suitable alternative substances or techniques which are economically and technically viable. To this end, the applicant's planned activities with a view to switching to economically and technically feasible alternatives is a crucial factor in the decision to grant an authorisation. The applicant's planning for substitution is mainly reflected in the following elements of the application:

1. An analysis of alternatives: this is a required element in all applications for authorisation, and provides (together with information eventually supplied by third parties) the basis to assess whether alternative substances or techniques are available.

   When assessing whether suitable alternative substances or technologies are available, the Commission shall take all relevant aspects into account {Art. 60(5)}, including:

   - *whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures;*
   - *the technical and economic feasibility of alternatives for the applicant.*

2. A substitution plan: where the analysis of alternatives shows that suitable alternatives are available, taking into account the above mentioned elements in Art. 60(5), the applicant must submit a substitution plan, including a timetable for proposed actions. It is noted that this element will only be required in those cases where an alternative substance or technique is available for the applicant, which by definition is only possible in applications under the adequate control route.

Where a restriction exists for a use of a substance, an authorisation will not be granted if this would result in a relaxation of the existing restriction {Art. 60(6)}.

All authorisations granted will be subject to a time-limited review {Art. 60(8)}. The duration of this review period will be determined on a case-by-case basis. The decision over this review period will

consider all relevant information, including the elements listed in Article 60 (4a to d) as outlined above.

In particular it is noted that the credibility of the substitution plan and the expected time-frame for the replacement of the substance submitted by the applicant under the adequate control route will determine the length of the review period. In cases where no suitable alternatives have been identified by the applicant, the information provided in the analysis of alternatives and the information submitted by third parties under Article 64(2) will be crucial to determine the length of the review period.

Likewise, under the socio-economic route, the length of the review period will be determined by the information on analysis of alternatives as well as on information submitted by third parties. Specifically, applicants should explain as part of the analysis of the alternatives the actions that would be required, as well as the time-lines, to switch to an alternative substance/technology. This should apply in particular in cases where there is an alternative available on the market but not yet ready for an immediate substitution (i.e. within the "sunset date") by the applicant, or another operator in the same market is already or will switch in the near future to alternatives. Having a robust analysis of the alternatives is critical for the application under the socio-economic route to be considered favourably and the absence of a justification as to the existence and suitability of alternatives may lead to a negative decision, particularly if third parties (who may provide information under Art. 64(2)) or other applicants have already switched. Absence of research and development activities should lead to fixing shorter review periods.

The information that will be specified in the authorisation when granted {Art. 60(9)} is summarised in Table 3.

Table 3. Information specified in an authorisation

Information specified
The natural or legal person(s) to whom the authorisation is granted.
The identity of the substance(s).
The use(s) for which the authorisation is granted.
Any conditions under which the authorisation is granted.
The time-limited review period.
Any monitoring arrangements.

1.5.6. Requirements following granting or refusal of an authorisation

Once the authorisation number has been published in the Official Journal, the holder of the authorisation is required to include without delay the authorisation number on the label before placing the substance, or a mixture containing the substance, on the market for the authorised use. The same applies to downstream users using an authorisation granted to an actor up his supply chain for that use {Art. 65}.

The Safety Data Sheet shall also be updated without delay following granting (or refusal) of an authorisation {Art. 31(9b)}. If a Safety Data Sheet is not required, the downstream users and/or

distributors shall otherwise be informed of the details of any authorisation granted or denied {Art. 32(1b)}.

In cases where a downstream user uses the substance on the basis of the authorisation granted to his supplier, the downstream user shall notify the Agency within three months of the first supply of the substance {Art. 66(1)}. Such notifications will be kept in a register maintained by the Agency that will be made available to the Competent Authorities of the Member States on request {Art. 66(2)}.

The requirements following granting of an authorisation are summarised in Table 4.

Table 4. Requirements following granting of an authorisation

Requirement	Organisation responsible	Timeframe
Update the registration to take account of the granted authorisation {Art. 22(2)}.	Holder of authorisation.	Within the deadline specified in the decision.
Update the Safety Data Sheet or provide downstream users and/or distributors with details of the authorisation {Art. 31(9b) and Art. 32(1b)}.	Holder of authorisation.	Without delay following publication of the authorisation number in the Official Journal.
Inclusion of authorisation number on relevant label for substance and/or mixtures containing the substance {Art. 65}.	Holder of authorisation and downstream users using the substance in accordance with Art. 56 (2).	Without delay following publication of the authorisation number in the Official Journal.
Notify the use of a substance on the basis of an authorisation granted to the supplier of the substance {Art. 66(1)}.	Downstream users using the substance in accordance with Art. 56(2).	Within three months of first supply for the Authorised use.
Maintenance of a register of downstream users who have made a notification of supply of a substance for an Authorised use {Art. 66(2)}.	Agency.	Continuous.

In addition to any conditions of use specified in the authorisation, there also is an obligation on the holder of the authorisation to ensure that exposure is reduced to as low a level as is technically and practically possible {Art. 60(10)}.

If an authorisation request is refused, the applicant needs to update the registration taking into account the decision {Art. 22(2)} within the deadline specified in the decision. Article 22(1) sets out the areas of the registration which may need to be updated.

1.5.7. Review of authorisations

As indicated in Section 1.5.5 authorisations granted for certain uses will be subject to a review period. Further details on how these review periods are determined can be found in the Guidance on inclusion of substances in Annex XIV. During such a review the Commission may decide to amend or withdraw the authorisation {Art. 61(3)} if circumstances have changed including situations where suitable alternatives have now been identified. This latter point applies to both routes of

authorisation. In order to continue to benefit from an authorisation the holder must submit a review report at least 18 months before the expiry of the time-limited review period. The review report should cover only those parts of the original application that have now changed and should contain the following elements {Art. 61(1)}.

- Number of current authorisation.
- An update of the analysis of alternatives, including information about any relevant research and development activities by the applicant, if appropriate.
- An update of any substitution plan included in the original application.
- If the update of the analysis of alternatives shows that there is a suitable alternative available, then a substitution plan, including a timetable for proposed actions by the applicant, should be included.
- If the holder cannot demonstrate that the risk is adequately controlled, then an update of the SEA included in the original application is required.
- If the holder can now demonstrate that the risk is adequately controlled, then an update of the CSR is required.
- Updates of any other elements from the original application that have now changed.

In addition to the review period specified in the authorisation, the authorisation can be reviewed by the Commission at any time in light of {Art. 61(2), (4), (5) and (6)}

- a change in circumstance of the original authorisation so as to affect the risk to human health or the environment, or the socio-economic impact, or
- new information on possible substitutes that becomes available, or
- failure to meet an environmental quality standard referred to in the IPPC Directive (Directive 2008/1/EC), or
- failure to meet the environmental objectives referred to in Article 4(1) of the Water Framework Directive (Directive 2000/60/EC) in a river basin relevant to the authorised use, or
- if the use of a substance is subsequently prohibited or otherwise restricted in Regulation (EC) No 850/2004 on Persistent Organic Pollutants (in this situation the Commission will withdraw the authorisation for that use).

In these cases, the Commission will set a reasonable deadline for the holder(s) of the authorisation to submit further information necessary for the review.

In the review, the Commission will, taking into account the principle of proportionality[9], decide if there is a need to amend the authorisation or withdraw the authorisation, if under the changed circumstances the original authorisation would not have been granted, or if suitable alternatives become available. If suitable alternatives become available to the applicant, then the Commission shall require the holder of the authorisation to present a substitution plan if it was not already done

[9] In accordance with the principle of proportionality, as set out in Article 5 of the Treaty on European Union, the REACH regulation does not go beyond what is necessary in order to achieve its objectives.

as part of the application or update {Art. 61(3)}. In the case of an authorisation under the SEA route, if suitable alternatives become available to the applicant, the Commission will have to withdraw authorisation, taking into account the proportionality principle (Article 60(4) makes the granting of an authorisation under the SEA route conditional upon the non-existence of suitable alternatives). Should suitable alternatives become available on the market but not yet ready for an immediate substitution or has another operator in the same market switched or will switch in the short future to alternatives, the applicants should explain as part of the updated analysis of the alternatives the actions that would be required, as well as the time-lines, to switch to an alternative substance/technique.

In cases where there is a serious and immediate risk for human health or the environment, the Commission may decide to suspend the authorisation pending the review, taking into account the principle of proportionality {Art. 61(3)}.

At the start of the review process, the Agency will make available via the web-site broad (non-confidential) information on uses covered by the application, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties {Art. 64(2)}.

1.6. Summary of important deadlines for applicants and interested third parties in the authorisation process

The key deadlines for applicants and interested third parties in the authorisation process are summarised in Table 5. The various deadlines in the process for any given substance up to granting of the authorisation will be made available via the Agency's website.

Table 5. Summary of key deadlines

Task	Deadline	Stakeholders
Comment on Annex XV dossier proposing identification of SVHC.	To be set by the Agency, within 60 days of circulation of dossier to Member States.	(potential) Applicant. Interested third parties.
Comment on recommendation for inclusion in Annex XIV (Substances subject to authorisation).	Within three months of the date of publication.	(potential) Applicant. Interested third parties.
Submission of application for an authorisation.	To be set by the Agency (a minimum of 18 months prior to the sunset date).	Applicant.
Submission of information on alternative substances or technologies and socio-economic impacts.	To be set by the Agency.	Interested third parties.
Notify Agency of intention to comment on the draft opinion of the Agency's Committees for Risk Assessment and Socio-economic analysis.	Within one month of receipt of the draft opinion.	Applicant.
Comment on draft opinion of the Agency's Committees for Risk Assessment and Socio-economic analysis.	Within two months of receipt of the draft opinion.	Applicant.
Update the Safety Data Sheet or provide downstream users and/or distributors otherwise with details of the authorisation.	Without delay following granting of an authorisation.	Holder of authorisation.
Include the authorisation number on relevant label for substance and/or mixtures containing the substance.	Without delay following publication in the Official Journal.	Holder of authorisation and downstream users using the substance in accordance with Art. 56(2).
Notify the use of a substance on the basis of an authorisation granted to a supplier.	Within three months of first supply.	Downstream users using the substance in accordance with Art. 56(2).

It should also be taken into account that the time needed to put together an authorisation application could be considerable. The Guidance on inclusion of substances in Annex XIV estimates that around 12 months may be needed to prepare a new application, but this could be as long as 24 months for applicants with less experience of the process. The time needed to prepare a review report is estimated at between 6 and 12 months. However, it should be noted that these estimates are made on the basis of other procedures under other legislation and need to be revisited when there is practical experience from the authorisation procedure.

2. HOW TO MAKE AN APPLICATION FOR AN AUTHORISATION

2.1. Introduction

Authorisation is required for placing on the market and use(s) of a substance listed in Annex XIV after the sunset date. Applications for authorisation can be made by the manufacturer(s), importer(s) and/or downstream user(s) of the substance, covering one or more uses and/or one substance or a group of substances. In addition applications can be made by separate legal entities or group of legal entities.

This Chapter provides detailed guidance on how to put together an application for an authorisation, and on the specific information and considerations needed for the application.

2.1.1. Main elements of an application for authorisation

As described in Section 1.5.3, Article 62(4) and (5) define the content of an application. Tables 6 and 7 provide a brief description of the content of the application, and also indicate where guidance on each item can be found.

Table 6. Basic information that shall be included in an application for an authorisation

Information		Guidance that is available
Identity of substance or substances covered by the application.	Specifying: • reference to Annex XIV entry • other information based on Section 2 of Annex VI of the Regulation which can be deemed sufficient to enable each substance to be identified. If it is not technically possible or if it does not appear to be scientifically justified to give information on one or more of the items, the reasons shall be stated.	Guidance on substance identification. Guidance on registration.
Name and contact details of the person or persons making the application.		
Request for authorisation(s) for specific use(s)	Specifying, • the use(s) for which authorisation is sought • covering the use(s) of the substance(s) on its own, in mixtures and/or the incorporation of the substance(s) in articles, where this is relevant.	This guidance Guidance on information requirements and CSA, Chapter R.12: Use descriptor system
Chemical Safety Report(s) (CSR(s))	This is required if it has not already been submitted as part of a registration (although in some cases it may be necessary to update the existing CSR(s) so as to provide more detailed	Guidance on information requirements and CSA.

Information		Guidance that is available
	information). The CSR(s) shall cover all uses applied for. It shall cover the risks to human health and/or the environment from the use(s) of the substance(s) arising from the intrinsic properties of the substance(s) specified in Annex XIV of the Regulation.	
An analysis of the alternatives	The analysis of alternative substances and techniques shall cover all uses applied for and should consider: • the risks from the alternatives, • the technical and economic feasibility of substitution, • if appropriate, information on any relevant research and development activities by the applicant, and • if there is a suitable alternative available on the market but not yet ready for an immediate substitution (i.e. within the "sunset date") or another operator in the same market has already or will switch in the short future to alternatives, the applicants should explain as part of analysis of the alternatives the actions that would be required, as well as the time-lines, to switch to an alternative substance/technique.	This guidance.
Substitution plan	Where the analysis of alternatives shows that suitable alternatives are available for specific use(s), taking into account elements in Article 60(5), the applicant shall also include a substitution plan, including a timetable for proposed actions.	This guidance.

Table 7. Other information that may be included in an application for an authorisation

Information		Guidance that is available
A socio-economic analysis (SEA).	This is needed in cases where the applicant cannot show adequate control of risks in accordance with section 6.4 of Annex I (taking into account article 60(3)) and the authorisation is applied for on the basis that the risk to human health or the environment from the use of the substance is outweighed by the socio-economic benefits and there are no suitable alternatives.	Guidance on Socio-Economic Analysis – Authorisation.
A justification for not considering the risks to human health or environment.	This is applicable to the following situations. • Emissions of a substance from an installation for which a permit has been granted in accordance with the IPPC Directive (Council Directive 2008/1/EC). • Discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of the Water Framework Directive (Directive 2000/60/EC) and legislation adopted under Article 16 of that Directive.	This guidance.

2.1.2. Application content

As stated in section 1.5.5, an authorisation can be granted on the basis of two different lines of argumentation, i.e., adequate control or socio-economic reasons. Therefore, this guidance refers to two routes:

- the adequate control route {Art. 60(2)}; or
- the socio-economic (SEA) route {Art. 60(4)}.

2.1.2.1. Adequate control route

The 'adequate control route' applies when it can be demonstrated that the risk to human health or the environment from the use of the substance is adequately controlled in accordance with section 6.4 of Annex I {Art. 60(2)}.

If the application is based on the adequate control of risks, it must include:

- a CSR (if not already submitted as part of the registration);
- an analysis of alternatives; and
- where the analysis of alternatives shows that suitable alternatives are available, taking into account elements in Article 60(5), a substitution plan.

The basis for demonstrating adequate control of risk arising from the intrinsic properties of the substance specified in Annex XIV is a chemical safety assessment (CSA) which is recorded in a

CSR. The Guidance on information requirements and CSA provides direction on carrying out the assessment.

The evidence whether suitable alternatives are available is presented in an analysis of alternatives. The analysis must take into account the reduction in overall risks and technical and economic feasibility of the alternatives for the applicant. It must be noted that having a robust analysis of alternatives is critical for the application to be considered favourably and that absence of appropriate justification as to the existence of alternatives may lead to a negative decision, particularly if third parties under Article 64(2)} or other applicants have submitted information on the existence of alternative substances or techniques. In addition, the content and robustness of the analysis of alternatives will be a critical element to set the review period.

Where suitable alternatives are available, a substitution plan must be included in the application outlining the applicant's commitment to take actions in a specified timetable to replace the Annex XIV substance with the suitable alternative(s).

It should be kept in mind that the Committee for Risk Assessment may in its opinion disagree with the applicant's demonstration of adequate control which can lead to a decision to refuse the authorisation. Therefore, the applicant may consider to also include a socio-economic assessment to provide evidence to the Committees that the socio-economic benefits outweigh the risks arising from the use of the substance {as per Art. 60(4)}. This applies in cases where the analysis of alternatives demonstrates that there are no suitable alternatives available because then, the authorisation may still be granted on the basis of the SEA consideration. This, however, requires that the application includes all necessary information in support of the SEA argumentation.

Although not strictly required by REACH, a socio-economic analysis can also bring valuable information for defining the length of the review period and/or authorisation conditions for applications demonstrating adequate control. Guidance for carrying out a socio-economic analysis is available (Guidance on Socio- Economic Analysis – Authorisation).

The applications may also include a justification for not considering the risks to human health or environment for the use(s), as set out in Article 62(5), if applicable.

2.1.2.2. Socio-economic assessment (SEA) route

The 'SEA route' applies where it can be demonstrated that the risk to human health or the environment from the use of the substance is outweighed by the socio-economic benefits and there are no suitable alternative substances or techniques {Art. 60(4)}. It applies in circumstances when adequate control has not been demonstrated and/or for substances meeting the criteria of Article 60(3). The latter include:

- CMR category 1 and 2 substances defined under Article 57 (a), (b) or (c)[10], or substances listed in Annex XIV as being of equivalent concern defined under article 57 (f), and for which it is not possible to determine a threshold;

[10] Article 57 (a), (b) and (c) will be amended from 1 December 2010, and from that date this sentence should read: "substances meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity category 1A or 1B in accordance with Annex I to Regulation (EC) No 1272/2008 defined under Article 57 (a), (b) or (c),(…)".

- PBT or vPvB substances meeting the criteria in Annex XIII (article 57 (d) and (e));
- substances which are listed in Annex XIV as being of an equivalent level of concern to PBT or vPvB substances defined under article 57 (f). (See section 1.5.5 of this guidance for further detail.)

The application under the SEA route should include:

- a CSR;
- an analysis of alternatives; and
- a SEA.

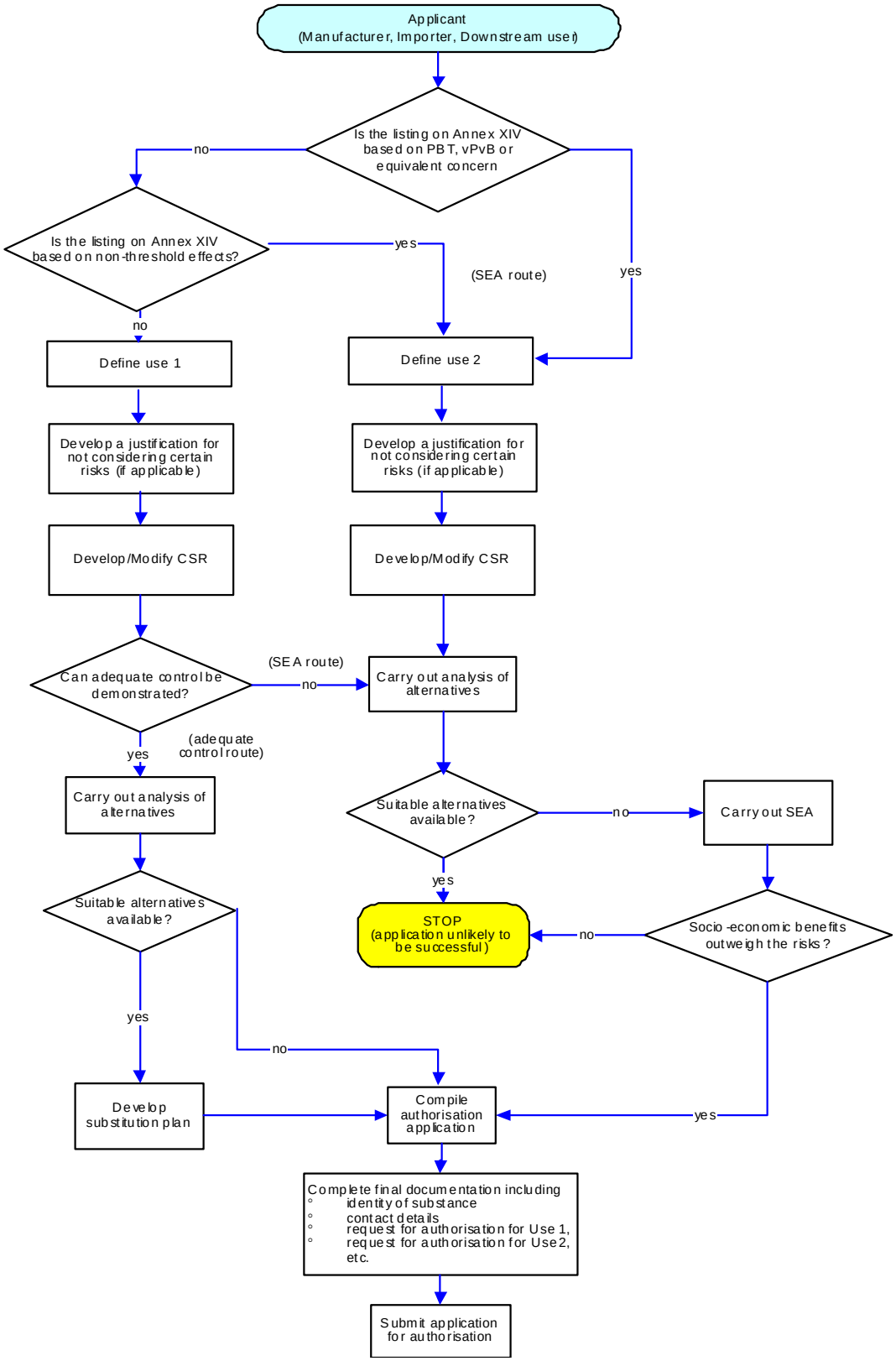
Although according to Article 62(5) the inclusion of a SEA is optional in all applications, it should be stressed that for applications under the SEA route (that is, for the substances referred to in Article 60(3) as well as for substances where adequate control has not been demonstrated) a SEA should always be included to provide evidence that the socio-economic benefits outweigh the risks arising from the use of the substance {as per Art. 60(4)}. Otherwise the granting of authorisation on socio-economic grounds is very unlikely.

If the application is made under the SEA route it should be noted that the authorisation may not be granted when suitable alternatives are available for the applicant. In the application the applicant must explain why he considers that there are no suitable alternatives and list the actions, including timelines that would be required to transfer to alternative substance or techniques, should suitable alternatives be available on the market but not yet ready for an immediate substitution.

Similar to the adequate control route, the applications may also include a justification for not considering the risks to human health or environment for the use(s), as set out in Article 62(5), if applicable.

Figure 7 outlines the information that should be included in the application.

Figure 7 Application content (based on Art. 60)



2.2. Compiling an application for an authorisation

The following sections go through each section of the application, indicating the information that should be provided. Specific technical guidance on how to compile the application for authorisation is contained in user manual(s) available on the Agency's website.

Further guidance on specific aspects of the authorisation application, for example analysis of alternatives and substitution plans, is given in Chapter 3 and Chapter 4. Appendix 1 provides guidance for substance grouping in the context of authorisation applications. Appendix 2 gives specific guidance for groups of applicants wishing to file jointly an application for an authorisation. More detailed guidance on carrying out a socio-economic analysis is given in the Guidance on Socio- Economic Analysis – Authorisation.

2.2.1. Substance identity

Basic information on the identity of the substance is needed for the application for an authorisation. The information on substance identity should be based on the Annex XIV entry and on Section 2 of Annex VI of REACH.

Substance identity information should be available as part of the registration dossier for the substance or the group of substances considered in the application. In cases where no registration is available the information should be collated following the Guidance on substance identification.

A single application can be made covering several substances that meet the definition of a group of substances in section 1.5 of Annex XI of the REACH Regulation. In this case the required information on identity will be extracted for each member of the group (see Appendix 1). An argumentation for substance grouping should be included in the application in cases where the substances are not grouped in Annex XIV but have similar physicochemical, toxicological and ecotoxicological properties or where these follow a regular pattern as a result of structural similarity. Appendix 1 gives further guidance for substance grouping.

2.2.2. Applicants

Applications for authorisation can be made by the manufacturer(s), importer(s) and/or downstream user(s) of the substance(s). In addition applications can be made by either separate legal entities or a group of legal entities {Art. 62(2)}.

Information for each legal or natural person submitting an application should be provided, including:

- name, address, telephone number, fax number and email address;
- contact person;
- financial and legal identifiers; and
- other relevant contact information.

In this guidance no distinction is made between situations where the applicant is a manufacturer or importer and where the applicant is a downstream user, as the main elements that need to be included in the application are broadly the same. However, the considerations when deciding

whether or not to make an application may be different for manufacturers and importers compared to downstream users. It is important to note that an authorisation granted to a downstream user also covers the supply of the substance to the downstream user holding the authorisation {Art. 56(1a)} irrespective of whether or not the manufacturer(s) or importer(s) have or have not made an application for an authorisation for that particular use.

In order to ensure that the process is effective, it is important that, where the potential applicant is not (or does not include) a downstream user, he keeps his downstream users of the substance informed of what will and will not be covered in the application. Similarly, it would be important for downstream users to provide information on their specific uses back to the applicant. Given the length of time it may take to put together an application (see Section 2.4.1) it is important that such dialogue starts at an early stage in the process.

As mentioned earlier, applications can be made by several legal entities. It will be up to each potential applicant (whether a manufacturer, importer or downstream user) to decide on a case-by-case basis whether he wishes to make an application, either as individual or as part of a group of applicants. Appendix 2 discusses further the reasons and approach for filing joint applications for an authorisation by several legal entities.

2.2.3. Request for authorisation for specific use(s)

2.2.3.1. Use(s) covered in an application

Each applicant can apply for an authorisation for his own use(s) of the substance and/or uses for which the applicant intends to place the substance on the market. If manufacturers and importers wish to prepare applications covering both their own use(s) and any use(s) for which they wish to place the substance on the market, the application would need to cover the downstream uses of the substance. In this situation, the downstream users themselves would not necessarily need to submit an application as long as their uses were covered by the application from the manufacturer or importer. However, it is important to note that such an application from the manufacturer or importer does not preclude the downstream user from making his own application if desired.

As it is up to each actor to decide, on a case-by case basis, whether or not he wishes to cover his downstream users' use(s) in his authorisation application, it is possible that a potential applicant may not wish to apply for an authorisation for a specific use he currently supplies for. Examples (non-exhaustive) of some of the many possible situations where this could arise include:

- the applicant does not wish to continue supply for economic reasons (e.g. the costs of preparing an application are high compared to the value of the product),
- the applicant cannot demonstrate safe use and there appear to be suitable alternatives available, or
- the applicant cannot demonstrate safe use and the risks to human health or the environment from the use of the substance appear likely to outweigh the socio-economic benefit of continued use of the substance.

In these cases the downstream users of the substance for the specific use may wish to consider developing their own application for their specific use(s). When deciding to do this, they would

need to consider their own specific case carefully. Non-exhaustive examples of some situations where this could arise include:

- the actual use or process used by the downstream user is confidential,
- adequate control can be demonstrated at the downstream user site as a result of specific risk management measures and operational conditions in place, or
- the downstream user can demonstrate that socio-economic benefits outweigh the risks for the specific use employed by him in cases where no suitable alternatives are available for him for this specific use.

In such cases it would be advisable for the downstream user to inform their supplier(s) and, if relevant, their downstream users (customers) of the substance that they intend to make an application for authorisation.

2.2.3.2. Describing use(s) in the application

The use or uses should be described in the authorisation application in accordance with user manual(s) for authorisation applications made available on the Agency's website. This section should be completed for all applications, irrespective of the basis on which the application is made. This should also cover any use(s) of the substance(s) in mixtures and/or incorporation of the substance into articles, where this is relevant. For applications for a group of substances it is important that the uses being applied for are clearly identified for each member of the group.

It should be remembered that an authorisation is granted for the use(s) described in the exposure scenario(s) and documented in the CSR (see Section 2.2.4.4). The key point is therefore that the description has to relate to the exposure scenario(s) for the use(s) for which authorisation is being requested, as included in the CSR, the analysis of alternatives, and SEA, when available. The development of the description of the use is an iterative process and it should therefore be finalised after the work on the CSR, analysis of alternatives and SEA has been carried out. Guidance on information requirements and CSA (Chapter R.12: Use descriptor system) has guidance on developing descriptions of uses and this should be consulted, but it may in many cases be necessary and useful for the applicants to develop the description further to specify more precisely what use is applied for.

Note that the CSR and in particular the exposure scenario(s) needs to cover all of the relevant life cycle steps of the substance associated with the use applied for. For example, if the end use applied for is part of a mixture, the step formulating the mixture will need to be included. The service life of articles containing the substance may also need to be considered.

Where the substance forms part of a mixture, the use descriptor system in Guidance on information requirements and CSA (Chapter R.12: Use descriptor system) characterises the use of the substance by the type of end-use product in which the substance is known to be used. Hence the use of a mixture is described in a similar way to the use of a substance. Further information on the specific purpose of the substance in the mixture can be added if needed. Where the substance is used in production of articles, the use descriptor system will include the category of article into which the substance is incorporated (it should be noted that the use of the articles themselves is not subject to authorisation).

2.2.3.3. Uses for which authorisation application is not required

The application shall not include the risks to human health arising from the use of a substance in a medical device regulated by Directives 90/385/EEC, 93/42/EEC or 98/79/EC {Art. 62(6)}.

In addition, Table 1 in section 1.5.2 includes other exempted uses from applications for authorisation. Further to these general exemptions, the Annex XIV entry for each substance may list substance specific exempted uses, or categories of uses, along with any conditions that apply to such exemptions.

2.2.3.4. Request for authorisation for several uses

As mentioned earlier the application can cover several uses. Some of the possible advantages of an application considering more than one use are to avoid repetitions and to include a more integrated picture of the use of the substance. A main disadvantage is having to produce a complex application where there are a high number of uses, or where the application requires both the adequate control and SEA routes in order to cover all the uses.

The applicant should decide on a case-by-case basis if the advantages of combining several uses in one application outweigh the drawbacks. Some of the disadvantages of combining several uses in one request for authorisation can be addressed through methodical organisation of the application. This could be achieved by either the development of separate reports (i.e., the CSR, the analysis of alternatives, the substitution plan, and the SEA, where appropriate) or the development of distinctly defined sections in each of these reports. This will facilitate the preparation of the application and its processing by the Agency and the Commission.

2.2.4. Documentation in support of the application for authorisation

As discussed in Section 2.1.2, the information contained in the application may be different depending on the basis for the argumentation in the application, i.e. adequate control or socio-economic benefits. Figure 7 presents in a graphical form the information that should be included in the application for each route. The sections below outline the specific information that will need to be provided in support of the application.

2.2.4.1. Chemical Safety Report

All authorisation applications need to include a CSR or refer to one submitted as a part of a registration dossier substances manufactured in quantities of 10 tonnes or more per year per registrant must include a CSR as a part of a registration dossier). The CSR(s) should cover the risks to human health and/or the environment (as appropriate) from the use or uses of the substance applied for arising from the intrinsic properties specified in Annex XIV of the Regulation.

a) Development and submission

Where a CSR has been submitted already as part of the registration, and no changes have been made for the authorisation application, there is no need to resubmit a copy.

However, the applicants may need to update their original (registration) CSR as part of their authorisation application. This may be required for instance where the applicant wishes to provide a

more precise exposure scenario and/or refine the exposure assessment. It may be advisable to submit a revised CSR where the original CSR covers several uses of the substance but the applicant only wishes to apply for an authorisation for some of these uses. This may be particularly important where some of the uses not applied for lead to high emissions that dominate the total emissions of the substance. Here, the update to the CSR could consider the effect of the change in the applicant's use pattern on the overall emissions and risk characterisation from the remaining uses.

If a CSR is not available, then it will be necessary to carry out a Chemical Safety Assessment (CSA), record the assessment in a CSR, and submit it as part of the application. In these cases and where a CSR is updated for the purposes of an application for authorisation, it only needs to cover the identified uses applied for and can be limited to the risks to human health and/or the environment arising from the intrinsic properties specified in Annex XIV. The hazard assessment part of the applicant's CSR needs to be based on the Annex XV dossier that led the substance to be included in Annex XIV. The remainder of the CSR has to be developed in accordance with Annex I for which the standard guidance on CSA/CSR can be used (see Guidance on information requirements and CSA[11]). Depending on the substance properties this includes a quantitative or a qualitative risk characterisation, in accordance with either Section 6.4 or 6.5 of Annex I and following the general CSA guidance.

The content of the CSA varies depending on the basis of the authorisation application. If an authorisation is applied for via the adequate control route, the CSR needs to demonstrate that for the uses(s) of the substance(s) concerned, the risks are adequately controlled in accordance with section 6.4 of Annex I. Therefore, iteration of the exposure scenario or the assessment is needed until adequate control can be demonstrated. This may include:

- refinement of exposure estimates to better reflect the implemented or recommended conditions of use, e.g. by
    - collecting further information on conditions of use,
    - use of measured data,
    - use of better models, or
- modification of risk management measures or operational conditions, or
- narrowing down the areas of use for which authorisation is applied for.

If an authorisation is applied for via the SEA route, possibilities to improve control of risks via iteration of the exposure scenario or the assessment need to be considered with a view to demonstrate minimisation of emissions and exposures as far as possible, and to show that the likelihood of adverse effects is reduced. This may include the same actions as listed under the adequate control route. Section A.4.3 of the Guidance on information requirements and CSA outlines further the steps in the CSA for the purpose of an authorisation application.

[11] The following sections of the Guidance on information requirements and CSA are of particular relevance: Parts A, C, D and E of the Concise Guidance and from the In Depth Guidance Chapter R.11.2 on emission and risk characterisation for PBT/vPvB substances and Chapters R14 – R18 on exposure estimation.

In cases where a new CSR has been generated for the application, or where an existing CSR has been modified, a copy of the new or revised CSR should be appended to the application as an assessment report.

b) CSR for several uses

In circumstances where one application covers several uses, it is important to clearly set out the exposure scenarios for each use. This can be achieved by developing distinctly defined sections for each use in the CSR. This will facilitate the preparation of the application and its processing by the Agency and the Commission.

c) CSR for a group of substances

In the event the application for authorisation is for a group of substances, CSR(s) needs to cover all substances in the group for which authorisation is sought. Although in principle it is possible to generate one CSR covering the grouped substances and all their uses, this may not be practical in case of applications for many substances with many different uses as documentation of all the many different combinations (of substances/uses) could result in a poor analysis that lacks transparency and consistency. In such situations a CSR for each member of a group may be more appropriate. Appendix 1 provides additional information for substance grouping.

2.2.4.2.Analysis of alternatives

All applications must include an analysis of alternatives. The purpose of this analysis is to determine if there are any suitable alternative substances or alternative techniques. There are three main aspects that at least should be considered, these are:

- risks from alternatives,
- technical feasibility of substitution, and
- economic feasibility of substitution.

It is important to stress the need for a robust analysis of alternatives. Applicants should explain as part of the analysis of the alternatives the actions and timelines required to transfer to an alternative substance or technique, in particular in cases where there is a suitable alternative available on the market but not yet ready for an immediate substitution (i.e. within the "sunset date") or other operators in the same market are already using or will transfer in the near future to alternatives.

Furthermore, if appropriate, the analysis of alternatives should include information on any relevant research and development activities by the applicant. In particular, applicants should include information about research and development that is considered appropriate for the understanding of the present or future availability of suitable alternatives to the Annex XIV substance. Future plans for research and development may also be documented in the application. This may be appropriate when no suitable alternatives have been identified.. The information on research and development will be taken into consideration in the determination of the review period. In the absence of any relevant programme by the applicant intended to allow him to transfer to an alternative, the review period will tend to be shorter than in cases where serious actions are taken. In the latter case the review period would normally take into consideration the timelines identified by the applicant to accomplish the programme.

It should be noted that in order for an authorisation to be granted under the SEA route, the analysis of alternatives must show that there are no suitable alternative substances or techniques taking into account elements mentioned in Article 60(5) (in addition to the demonstration that the socio-economic benefits outweigh the risks {Art. 60(4)}).

Detailed guidance on how to carry out an analysis of alternatives is given in Chapter 3. The analysis of alternatives should be submitted as part of the application as indicated in the user manual(s) made available on the Agency's website.

In circumstances where one application covers several uses, it is important to clearly set out the alternatives for each use. This can be achieved by developing a separate analysis of alternatives report for each use or by developing distinctly defined sections for each use in one report. This will facilitate the preparation of the application and its processing by the Agency and the Commission.

For applications covering a group of substances, it would need to be considered on a case-by-case basis whether the analysis of alternatives should cover the group or whether individual reports should be generated for each member of the group.

2.2.4.3. Substitution plan

The application must include a substitution plan if the analysis of alternatives shows that suitable alternatives are available, taking into account reduction of overall risks and technical and economic feasibility of alternatives for the applicant.

Detailed guidance on preparing a substitution plan is given in Chapter 4 of this guidance. The substitution plan should be submitted as part of the application as indicated in the user manual(s) made available on the Agency's website.

In circumstances where one application covers several uses, it is important to clearly set out a substitution plan for each use. This can be achieved by developing a separate substitution plan for each use or by developing distinctly defined sections for each use in one report. This will facilitate the preparation of the application and its processing by the Agency and the Commission.

For applications covering a group of substances, it would need to be considered on a case-by-case basis whether the substitution plan should cover the group or whether individual substitution plans should be generated for each member of the group.

2.2.4.4. Socio-economic analysis

SEA is an approach used to analyse and describe all relevant impacts of granting (or refusing) an authorisation. Although not strictly required by the Regulation, an SEA is particularly important in circumstances where adequate control of risks cannot be documented (see section 2.1.2.2), and the applicant will need to demonstrate that the risk to human health or the environment from the use of the substance or substances is outweighed by the socio-economic benefits {Art. 60 (3 and 4)}.

SEA can also be beneficial in adequate control route applications. For example, applicants can use socio-economic analysis to give the basis for defining the length of the review period or any conditions in the authorisation decision.

Annex XVI of REACH outlines the information that may be included in an SEA and more detailed guidance for carrying out a socio-economic analysis is given in the Guidance on Socio Economic

Analysis – Authorisation. The detailed report and supporting information should be submitted as part of the application as indicated in the user manual(s) made available on the Agency's website.

In case one application covers several uses, it is important to clearly set out the socio-economic impacts for each use. This can be achieved by developing a separate SEA report for each use or by developing distinctly defined sections for each use in one report. This will facilitate the preparation of the application and its processing by the Agency and the Commission.

Where a socio-economic analysis is needed for the application for authorisation for a group of substances, it will need to be considered on a case-by-case basis whether a single socio-economic analysis covering the whole group, or individual socio-economic analyses for each member of the group should be prepared.

2.2.4.5. Justification for not considering certain risks

All applications may include a justification for not considering the risks to human health or environment {Art. 62(5b)}. This applies to uses in installations where emissions of the substances are controlled by a permit granted in accordance with the IPPC Directive (European Parliament and Council Directive 2008/1/EC) or to point sources governed by the requirements of prior regulation referred to in Article 11(3)g of the Water Framework Directive (Directive 2000/60/EC) and legislation adopted under Article 16 of that Directive.

For a group of substances it would be possible to develop a justification for not considering certain risks provided that all substances in the group are used in installations where emissions of substances are controlled by permit in accordance with the IPPC Directive (European Parliament and Council Directive 2008/1/EC) or to point sources governed by the requirements of prior regulation referred to in Article 11(3)g of the Water Framework Directive (Directive 2000/60/EC) and legislation adopted under Article 16 of that Directive.

The justification should be submitted as part of the application as indicated in the user manual(s) made available on the Agency's website.

2.3. Subsequent Applications

It is possible for an application for authorisation to refer to previous applications for authorisation for the same substance(s) and use(s). Two possible situations exist {Art 63 (1) and (2)}:

a. Where an application has been made by other applicants for the same substance(s) and use(s).

b. Where an authorisation has been granted for the same substance(s) and use(s).

In both of these cases, a subsequent applicant can refer to the following parts of the previous application, provided they have permission from the previous applicant or authorisation holder:

- Chemical Safety Report(s).
- Analysis of alternatives.
- Substitution plan.

- Socio-economic analysis.

In this case the subsequent applicant should update the information in these parts of the original application as necessary {Art. 63(3)}, and complete the following parts of the application.

- General applicant information (see Section 2.2.2).
- Substance identity (see Section 2.2.1 – this should relate to the substance used by the subsequent applicant), including a description for substance grouping (if applicable – see Appendix 1)
- Request for authorisation for specific uses(s) (see Section 2.2.3 – this can refer to the previous applicant's CSR, SEA or analysis of alternatives and substitution plan as appropriate)
- Other information (if appropriate).

2.4. Submitting the application for authorisation

2.4.1. Deadlines for submitting applications for authorisation

The deadlines for applications for authorisation will be set by the Commission for each substance when it is listed in Annex XIV. Applications for authorisation will be made to the Agency {Art. 62(1)}.

The time needed to put together an application for authorisation should not be underestimated. The Guidance on inclusion of substances in Annex XIV estimates that around 12 months may be needed to prepare a new application, but this may be as long as 24 months for applicants with less experience of the process. This should be born in mind when planning an application for authorisation.

2.4.2. How to submit an application

Applications should be submitted to ECHA, via its website, in accordance with user manual(s) on how to submit an application made available on the Agency's website.

2.4.3. Fees

The applicant(s) must pay the required fee in accordance with Title IX {Art. 62(7)} and Commission Regulation N° EC 340/2008 on the fees and charges payable to the European Chemicals Agency (Annex VI and VII).

2.5. Review reports

Authorisations will be subject to a time-limited review period. The review period will be specified in the granted authorisation. In order to continue placing on the market or using a substance, the

holder of the authorisation must submit a review report at least 18 months before the expiry date of the time-limited review period.

The review report should address only the parts of the original application that have now changed but should contain the following elements {Art. 61(1)}.

- Number of current authorisation.
- An update of the analysis of alternatives, including information about any relevant research and development activities by the applicant, if appropriate.
- An update of any substitution plan included in the original application if appropriate.
- If the update of the analysis of alternatives shows that there is a suitable alternative available, then a substitution plan, including a timetable for proposed actions by the applicant, is required. It is noted that under the SEA route, when suitable alternatives become available for the applicant, the authorisation must be withdrawn, taking into account the proportionality principle.
- If the holder cannot demonstrate that the risk is adequately controlled, then an update of the SEA included in the original application is required.
- If the holder can now demonstrate that that the risk is adequately controlled, then an update of the CSR is required.
- Updates of any other elements from the original application that have now changed.

Review report can be created using the Agency recommended software as indicated in the user manual(s) made available on the Agency's website. Only the parts that have changed need to be completed. Any more detailed reports and information (e.g. updated CSRs, SEAs etc.) can be appended to the review report.

The review report will be assessed through the same process as used for the original authorisation request (see Section 1.5.7).

In addition, an authorisation may be reviewed at any time if circumstances change so that the risks to human health or environment considered in the original authorisation are affected, or the socio-economic impact is affected. A review can also be triggered by new information on possible substitutes becoming available. Under these circumstances, the holder of the authorisation will be invited by the Commission to submit any information necessary for the review within a deadline set by the Commission. The holder will need to address any specific aspects requested by the Commission, and may also wish to consider the impact of the new information on their CSR and SEA. The new information triggering the review and information provided by the holder will be considered according to the same procedure as for the original request (see Section 1.5.7).

3. PLANNING FOR SUBSTITUTION: GUIDANCE ON ANALYSIS OF ALTERNATIVES

3.1. Introduction

The progressive replacement of SVHCs by suitable alternatives is one of the fundamental aims of authorisation and is mainly translated into two elements of an application for authorisation: the analysis of alternatives and the substitution plan. The analysis of alternatives is the first step in the process of planning for substitution, where an assessment is made on the availability of suitable alternative substances or techniques, their risks for human health and the environment, and their economic and technical feasibility for the applicant. The analysis of alternatives may also include information about relevant R&D activities by the applicant. While such information is not mandatory, it will be a critical factor for fixing the review period, in particular in cases where the analysis of alternatives concludes that there are no suitable alternatives. Where the analysis of alternatives leads to the conclusion that a feasible alternative is available for the applicant, the latter must also provide a substitution plan, including a timetable for proposed actions.

This chapter provides guidance primarily directed to the applicant for authorisation on the analysis of alternative substances or alternative technologies to the Annex XIV substance. The chapter sets out:

- What is an alternative;
- What should be the focus and scope of an analysis of alternatives;
- How to conduct an analysis to identify and assess possible alternatives; and
- How to document the analysis in the application.

An analysis of alternatives is required in all applications for authorisation according to article 62(4)(e) of REACH. Therefore, the applicant for authorisation must document an analysis of alternatives in his application. Whilst this guidance focuses on the applicant, who may be a M/I or a DU or indeed a group including different legal entities, it is intended to describe a process by which a reasonable and logical analysis of alternatives may be approached, conducted and documented. Therefore, it may also help third parties to submit well documented information on alternatives[12] under the provisions in Articles 64(2) and 64(3).

The guidance is intended to provide considerations for the analysis of alternatives so that users of the guidance may provide information that documents their analysis in the best possible light for consideration by the Agency and ultimately by the Commission in the decision whether or not to grant an authorisation.

This chapter also addresses how, and under what circumstances, the analysis of alternatives links with a substitution plan and a socio-economic analysis (SEA). As described in previous sections (1.5.5, 2.2 and 2.4.4.2) authorisations can be granted on the basis of two principally different lines of argumentation, i.e. on the basis of adequate control or for socio-economic reasons, leading to

[12] The presentation of an analysis of alternatives by a third party may help to support the case that the alternative is suitable and available for the uses set out on the Agency web site. Guidance for third parties is at Chapter 5 of this GD.

applications via either of two routes, the so called adequate control route or the SEA route. The route for application influences the requirements for a substitution plan and the applicability of SEA.

Substitution plan: If an application under the adequate control route concludes in the analysis of alternatives that a suitable alternative(s) is available, then the applicant must prepare a substitution plan that sets out his commitment to transfer to that substitute(s), setting out the timing and other considerations for transferral. The detail of how to conduct and document a substitution plan is set out in Chapter 4 of this guidance document, but the links between the analysis of alternatives and the substitution plan are also highlighted in this chapter. It is noted that an authorisation under the SEA route may not be granted if there are suitable alternatives for the applicant.

Socio-Economic Analysis (SEA): Although according to Article 62(5) the inclusion of a SEA is optional in all applications, for applications under the SEA route it should be included and can also be submitted in the case of applications under the adequate control route on a voluntary basis. See section 1.5.5 for further details on which types of substances or situations that are applicable for the SEA route to authorisation. Guidance for compiling an SEA in support of an authorisation application and submission of an SEA or input to one from a third party as part of the authorisation process is set out in a separate document Guidance on Socio Economic Analysis – Authorisation. Key phases of the analysis of alternatives where links to the SEA are important are indicated in this guidance, e.g. in section 3.3 on the scope of the analysis of alternatives, in section 3.5 on how to identify possible alternatives, and in section 3.7 on comparing the risks of the alternative with the Annex XIV substance. Where an SEA is developed an assessment of human health and environment impacts will be a necessary part of the SEA. This assessment could be used in the analysis of alternatives to assist in the decision regarding comparison of risks for substances following the SEA route (see section 3.7.1).

3.2. What is an alternative?

An alternative is a possible replacement for the Annex XIV substance. It should be able to replace the function that the Annex XIV substance performs. The alternative could be another substance or it could be a technique (e.g. a process, procedure, device, or modification in end product) or a combination of technical and substance alternatives. For example, a technical alternative could be a physical means of achieving the same function of the Annex XIV substance or perhaps changes in production, process or product that removes the need for the Annex XIV substance function altogether.

Article 60(5) provides that when assessing the availability of suitable alternative substances or techniques, *all relevant aspects must be taken into account*, including:

a) whether the transfer to the alternative would result in *reduced overall risks* to human health and the environment (as compared to the Annex XIV substance) taking into account risk management measures,

b) the *technical* and *economic feasibility* of alternatives for the applicant for replacement of the Annex XIV substance.

The alternative must also be *available* for the applicant (i.e. can be accessed in sufficient quantity and quality) for transferral. As an application may be for a number of uses of the Annex XIV

substance, it may be that there will be different alternatives that are *suitable* and *available* for each different use of the Annex XIV substance that has been applied for.

3.3. The focus and scope of the analysis of alternatives

The analysis of alternatives may be relatively simple.For example, where an application is being compiled for a single use that is being applied for, the applicant may know of one or a few alternatives. In this case, a simple analysis may be able to fairly rapidly identify their capability to reduce the overall risk and whether they are technically and economically feasible. In addition, some of the work might have already been done in relation to requirements of other legislation, e.g. Directive 2004/37/EC ('the carcinogens Directive') requires employers to consider the substitution of the use of a carcinogen or mutagen as the first level of the risk management hierarchy.

However, the analysis may require a more detailed assessment. For example, the application may start from a position in which no alternatives are known, where the function is complex and where there are a number of constraints on the function (including, e.g., strict customer requirements for the use of specific substances) as well as the supply chain being complex.

The focus of the analysis of alternatives is to identify possible alternatives to the Annex XIV substance and to assess, on the basis of reduction in overall risks, economic and technical feasibility of substitution and availability whether they can be used in place of the Annex XIV substance. The documentation of that analysis needs to be presented in the application for authorisation and can be referred to as the analysis of alternatives report.

The applicant's analysis of alternatives will conclude that there is a suitable alternative available when an alternative substance(s) or technology/ies or their combination:

- provide an equivalent function to that provided by the substance or makes the substance' use redundant (note that a single alternative may not be suitable for all different processes or uses for which the original substance was suitable, thus the original substance could be substituted by more than one suitable alternative);
- will result in reduced overall risks to human health and the environment, taking into account appropriateness and effectiveness of risk management measures;
- are technically and economically feasible (for substitution in the uses applied for) and available, for the applicant.

The applicant should demonstrate whether the above criteria are satisfied or not by possible alternatives. It is in the interest of the applicant to be specific in the assessment of the suitability and availability of alternatives and to document the results of the assessment in a transparent way. It is also strongly recommended that the applicant demonstrates that a comprehensive and adequate assessment of alternatives has been done. This is because the Agency in its opinions and the Commission in its assessment of whether suitable alternatives are available will take "all relevant aspects" into account {Art. 60(5)}, including information submitted by interested third parties.

This means that in practice the applicant may be well advised to consider including in the scope of his analysis all possible alternatives, considering both substances and technologies. This applies also to cases where the applicant is a M/I and the alternatives may not be products from his own portfolio. An incomplete analysis of alternatives by an applicant may lead the Agency to question the accuracy of such an analysis and why some possible alternatives have not been assessed if the Agency has received well-documented information that suitable alternatives exist. It is also

advisable for the applicant to detail for example relevant research and development that he has carried out, with specific emphasis as to why a certain alternative substance or technology was not technically or economically feasible.

If the analysis of alternatives demonstrates that currently there is/are no suitable alternative(s) available for the applicant, the latter should provide information on what would be required to make possible alternatives suitable and available within an estimated timescale (further guidance is given in section 3.10). This information will be key to set the review periods. In particular, if no information is provided, the review period would be short, as it would be necessary to assess whether there have been any changes.

The applicant will be a manufacturer/importer (M/I) or downstream user (DU) of the Annex XIV substance. Joint applications may also be made (see Chapter 2 on who can make an application).

The focus and scope of the analysis of alternatives may be influenced by who makes the application for authorisation. Box 1 considers the perspective of the M/I and DU in the analysis of alternatives.

In order for the applicant to best understand what alternatives may be available and what the scope of the analysis of alternatives will be, it is recommended that consultation within the supply chain is begun at an early stage. This is so that applicants are in the best position to understand what information is available on use of the Annex XIV substance and on possible alternatives to the Annex XIV substance. Consultation within and outside the supply chain is considered in section 3.5.2 and issues relating to competition law and confidential business information (CBI) in Box 2.

Box 1 Perspective of the analysis of alternatives for different actors

A M/I may find it difficult to have full information on how possible alternatives may fulfil substance function for downstream uses and he may have to work with DUs to understand this fully if the M/I intends to cover downstream uses in his application.

A DU may wish to make an application because he does not wish to share information on exact use with his supplier for reasons of commercial confidentiality. Or he may need to apply because he finds that his use will not be supported in an application by his supplier (i.e. the M/I).

It may of course be an option for M/I and DU to make a joint application or share information through an independent party to ensure that confidential information is not shared within the supply chain.

Third parties may submit information on alternatives, which will be taken into consideration by the Agency and the Commission when assessing whether suitable alternatives exist

Annex XIV will set a deadline for submitting an authorisation application (see Chapter 2), so the amount of work that can be conducted in the analysis of alternatives will be limited by time and resource. In practice, it will make sense to undertake some of the tasks of the analysis of alternatives at the same time; as information from one part of the analysis may inform other parts. For example, gathering initial information to ‘screen’ the possible technical feasibility of an alternative may be combined with screening of alternatives on the basis of risks.

Where an application is via the SEA route the applicant may also wish to consider the information needs of the SEA when considering the analysis of alternatives. Consideration of the information needs of the SEA may prompt the applicant to collect information on the possible responses of the supply chain to not being able to use the Annex XIV substance, at the same time as gathering

information on possible alternatives. This is considered in section 3.5. Guidance on Socio Economic Analysis – Authorisation is provided in a separate guidance document.

A suggested check-list for the inclusion of information in the analysis of alternatives is given in Appendix 3. Guidance on what to document in the analysis of alternatives and a possible outline for the analysis of alternatives report is given in section 3.12.

3.4. Overview of how an analysis of alternatives is undertaken

This guidance chapter sets out how an applicant:

- may conduct an analysis of alternatives; and
- can document this in the analysis of alternatives report.

The process involves:

- identifying possible alternatives for each use applied for on the basis of the functional requirements (section 3.5);
- assessing the technical feasibility of possible alternatives identified (section 3.6);
- assessing possible alternatives for their potential risks to the environment and to human health. For this purpose the applicant should assess whether the alternatives represent a reduction in overall risk compared to the Annex XIV substance, taking into account risk management measures and operational conditions implemented and recommended (section 3.7);
- assessing the economic feasibility of possible alternatives identified (section 3.8);
- identifying relevant R&D that is appropriate to the analysis (section 3.9);
- assessing the suitability and availability of possible alternatives, on the basis of their technical and economic feasibility for the applicant, reduction in risk and accessibility (section 3.10); and
- determining the actions and timescales that may be required to make possible alternatives suitable and available for the applicant, taking into account relevant R&D where appropriate (section 3.11).

The process for undertaking an analysis of alternatives is illustrated in Figure 8. This diagram outlines the possible steps in an analysis of alternatives and the possible outcomes depending upon the status of the Annex XIV substance and the identification of available alternatives.

Clearly, in order to identify possible alternatives to the Annex XIV substance, the function of the Annex XIV substance needs to be identified first. However, the further analysis of technical and economic feasibility, the comparative safety of the alternatives and availability need not be addressed in the order set out in this guidance. The applicant should show and document analysis of these aspects, but the importance of different aspects of the analysis will be different in each case. For example, it may be clear to the applicant in his analysis of alternatives that all possible technically feasible alternatives do not represent a reduction in risk as compared to the Annex XIV substance. In this case there would be little merit in detailed analysis of the economic feasibility of these alternatives, once it is known that none of them is suitable on the basis of the risks.

Figure 8. Flow diagram for the analysis of alternatives

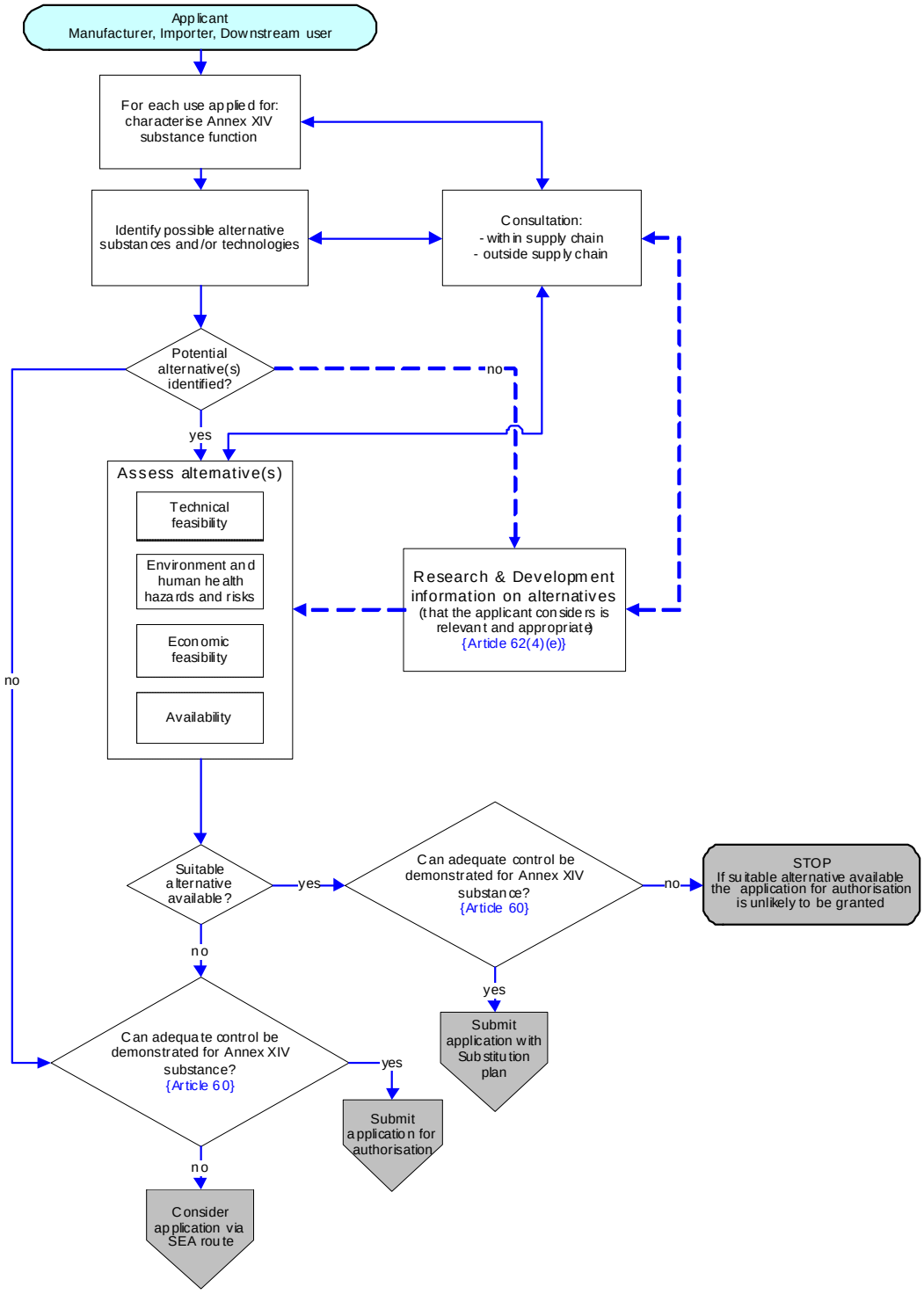


Figure 8 illustrates that to properly assess possible alternatives, consultation within and outside the supply chain is recommended. This is so that the applicants can:

- Fully understand the exact uses that are being applied for and therefore understand the function of the Annex XIV substance;
- Ensure that they are aware of the technical and economic feasibility of possible alternatives for the uses of the Annex XIV substance for which they are applying;
- Decide if past, ongoing or planned R&D is relevant and appropriate for the analysis;
- Decide if the alternative/s is/are suitable and available in order to enable a transfer to the alternative/s to take place; and
- Determine what actions and timescale would be required to make possible alternatives suitable and available.

Figure 8 includes consideration of relevant and appropriate R&D. As it is not obligatory to conduct R&D within the analysis of alternatives, this is indicated by a broken line in the figure. Applicants may have done or be aware of research and development (R&D) on possible alternatives. Such R&D may have highlighted the possibilities and difficulties for using particular alternatives. Therefore, it may help in the analysis of alternatives to refer to and explain R&D that is relevant to showing how alternatives may or may not be feasible. In addition, this information will be taken into account to fix the review periods. The absence of R&D activities should lead to fixing shorter review periods.

3.5. How to identify possible alternatives

3.5.1. How to identify the Annex XIV substance functions

The function of the Annex XIV substance for the use/s being applied for is the task or job that the Annex XIV substance is performing.

The process of identification of alternatives normally begins with the consideration of the function of the Annex XIV substance. A detailed and specific knowledge of the exact function that the Annex XIV substance is doing (and where and how, i.e. under what conditions, that function must be performed) for a particular use, will allow the applicant to look for other ways of performing that function. This may be by using another substance or technology or by changing the process or end product. In the latter cases it is possible that the original function of the substance may become redundant.

Knowledge of the precise function of the Annex XIV substance assists in consultation on alternatives within and outside the supply chain by setting out the technical requirements that any possible alternatives must meet. This allows users, suppliers and technologists to assess whether there may be possible alternatives and also what actions are needed to make them technically feasible (technical feasibility is considered in section 3.6). The users, through co-operation with suppliers, may have conducted possible research and development on existing alternatives, for example trials of alternative substances and technologies, and this may be helpful in identifying and assessing possible alternatives (R&D is considered in section 3.9).

The function of a substance could be related to its physical or chemical properties as well as the form it is used in (for example, for a solid this may be as a powder, pellets or granules), the physical state may also be dependent upon process conditions. Key questions to be considered for each use when determining the functions of a substance can be divided into two main groups:

1. **Task** that the substance performs: This will require an understanding of the exact use of the substance including a description and outcome of the process where the use is applied. Key questions addressing the task performed by the substance include:

   - What is the exact use of the Annex XIV substance and what task does it perform?

     This will need to be as specific as possible and the exact function will determine within which limits possible alternatives can be identified. For example, a substance that functions as a solvent to degrease metal may be replaced by a number of possible substance and technical alternatives. However, if the specific function is to degrease fine-bore metal tubes to a particular standard of cleanliness, then this will narrow down the possible alternatives that can perform this function.

   - What are the critical properties of the substance for this use?

     The function will depend upon key properties of the Annex XIV substance. For example this could be its persistence (e.g. a flame retardant or plasticiser; both of which need to have longevity in the final product in order to continue to impart their function for the lifetime of the product), or a physical property such as its viscosity or vapour pressure. The key properties could be a critical combination of properties that make the function possible.

2. The **conditions** under which the substance is used: This will require an understanding of the specific process conditions for using the substance and of any conditions or requirements on possible end-products resulting from the process. These may impose constraints under which the desired function must be performed and thereby influence which alternatives that may be used. Key questions addressing the process **conditions** where the use is applied include**:**

   - What are the physical and chemical (process/operational) conditions under which the function must be performed?

     Physical conditions will include, for example, temperature and pressure of the process. Also there may be considerations of increased or decreased electromagnetic radiation (e.g. photosensitivity). Chemical conditions may include; the presence or absence of other chemicals (introducing issues of chemical compatibility such as reactivity and flammability), the process pH, and the gaseous atmosphere (for example increased or decreased oxygen partial pressure or other gases including potentially explosive atmospheres), amongst numerous others.

   - Are there any specific timing conditions for the substance function?

     There may be constraints on the timing for technical delivery of the function – i.e. the function may be delivered in a particular part of a process that is time-critical and dependent on the properties of the substance; or the function may need to continue for a minimum or maximum time period. Note that for some functions the performance cannot be judged in the short-term (e.g. coatings and lubricants) because the function is based on the longevity of the function and this can only be evaluated over time.

- How could the quality of the final product be affected if the substance/process is altered?

  This requires consideration of how the use of an alternative may affect the end products in terms of final function. Qualities of the final product may need to be considered over a longer timescale. For example, some coatings may need to provide resistance to weathering over a specific product lifetime. This may also include consideration for the final disposal of the product and/or its potential recycling.

- Is the function associated with another process that could be altered so that the use of the substance is limited or eliminated?

  For example the Annex XIV substance may be used to control emissions of another substance or produce another substance. If the need for control is removed or the end product is altered so that the second substance is no longer needed then the Annex XIV substance may be more easily substituted or not required at all.

- Are there features of the end product that determine the requirement for use of the substance?

  For example the specific use of the substance may be required because it imparts certain characteristics to an end product (e.g. due to customer or legal requirements). Using a different end product that performs the same function may enable an alternative to be used or may mean the substance is no longer required for the use.

Appendix 4 presents a check-list for determining the functional requirements for possible alternatives (it is not exhaustive) based on functional aspects of the Annex XIV substance. While the check list is not mandatory, it gives an indicative list of aspects that should be considered when identifying the substance function.

Example 1 illustrates how substance function might be considered for a particular situation. Available information has been used to simulate the possible answers to the questions posed in Appendix 4. The functional aspects numbered 1 to 2 in the example and the checklist in Appendix 4 address the function of the Annex XIV substance (i.e. the task it performs), aspects 3 to 7 address the process conditions for the Annex XIV substance (i.e. what process requirements must be fulfilled, including possible legal requirements).

Example 1. Considerations for substance function

Defining substance function is an essential step in understanding the exact use of the Annex XIV substance. Clear definition of function and tolerances allow possible alternatives to be assessed on the basis that it may be possible to use them to perform the function of the Annex XIV substance. The example below illustrates a possible process for determining substance function for the uses that are to be applied for and how this can be documented for presentation in the analysis of alternatives report.

Substance A is an organic solvent with a strong solvent action, a medium boiling point and high vapour density. It is used as an industrial solvent, primarily for vapour degreasing and cleaning of metal parts. More specifically, it is used for the removal of substances such as oils, greases, waxes and buffering compounds, or soils. The specific use for this example is:

Degreasing and cleaning of components that have a complex construction including details that have complex construction.

Components must be free from grease and dirt and dried quickly; corrosion, staining and remaining oil/grease deposits are not acceptable. For intricate articles the low surface tension of Substance A allows the cleaning of folds, double folds and fine tubes.

In terms of defining substance function the checklist set out in Appendix 4 is used:

1 *Task performed by Annex XIV substance*:

What is the task that must be performed by the substance?

The substance is used for degreasing very fine seamless stainless steel tubes (e.g. internal diameter ranging from 1 to 5 mm, straight lengths and coils) in particular for use in the aviation industry and for medical devices. The function is the rapid removal of grease leaving no residue and no oxidation or staining. See table below for further description of applicable criteria.

2. *What critical properties and quality criteria must the substance fulfil?*

Production of clean and dry metallic parts; where the metallic part needs to be dry for the treatment following (e.g. coating). The cleaned item must be grease/oil free and free of any staining/oxidation (e.g. from contact with water/aqueous solutions.)

3. *Function conditions*:

Task timing and through-put required are indicated in table below. The use of solvent in vapour degreasing baths is efficient because solvent is recycled. Primary and secondary cooling coil systems reduce vapour and hence solvent loss and use of covers that seal the degreasing bath work chamber from the atmosphere virtually eliminate evaporative losses during downtime.

4. *Process and performance constraints*

To produce clean and dry metallic parts, where the metallic part needs to be dry for the following treatment (e.g. coating), a solvent cleaning should be used. Intricate parts and fine tubes limit access for mechanical cleaning means.

5. *Is the function associated with another process that could be altered so that the use of the substance is limited or eliminated?*

Eliminating any oil or grease on the surface of metal tubing components would negate the need for vapour degreasing. However, metal parts would need to be grease/oil/dirt free to the standards required. No staining or oxidation is acceptable. Currently tubing production methods require the use of oils to ensure that components remain free of oxidation.

Although aqueous-based cleaning systems are effective in many applications, some aspects of aqueous-based cleaning can make it impractical or unusable for certain types of work pieces. Solvent degreasers must be used for the removal of oil, flux, grease wax and other stubborn solvent-soluble soils from the metal surface. Intricate metal tubes and parts for aerospace and medical instruments are routinely cleaned in vapour degreasers prior to assembly, inspection, or further processing. Because no water is used in the process, nearly any part can be cleaned in a solvent degreaser without concern for quality control issues like the effects of part oxidation, soap residue, water stains, and ineffective drying.

Possible alternatives include other hydrocarbon solvents, aqueous formulations and water blasting or soft blasting (shot blasting using a relatively soft medium such as limestone). Continuing improvements in solvent recovery technology on hot vapour degreasing baths has reduced the amount of substance A used for hot vapour degreasing. These reductions are as a result of better working practices and the use of newer technology. Some companies are also attempting to find other hydrocarbon solvents or water-based cleaning agents as alternatives.

6. *What customer requirements affect the use of the substance in this use?*

Customers (including the aerospace industry) require (through operating procedures that must be used) the use of solvents for cleaning. Any process change requires customer approval; the time taken and technical and cost justification for product change in these sectors are considerable. Quality control inspection criteria demand the components be grease/oil stain and oxidation free (non destructive testing applied).

7. Are there particular industry sector requirements or legal requirements for technical acceptability that must be met and that the function must deliver?

Medical device and aerospace industries are required to use solvents for cleaning. There may be implications for fulfilling legal requirements for product safety in these two product areas such as stringent airworthiness and

safety requirements (e.g. European Aviation Safety Agency (EASA) Airworthiness Directives) and the Medical Devices Directive (93/42/EEC). These need to be assessed to estimate the minimum time needed for changes.

The Table below provides an example of how to summarise and document functional aspects and/or criteria for determining substance function based on the solvent example in this box:

Functional aspect	Considerations	Criterion	Tolerance	Testing	Quality control	Consequence
Grease/oil removal	Necessary degree of cleanliness	No oil grease residue staining of tubes upon heating to 200°C	None	Part of non destructive testing prior to use/fitting	Quality system ensures inspection according to testing schedule that parts are grease free. Criteria are set out in customer specific requirements.	Residual grease could cause malfunction of instrumentation. Therefore, if testing reveals residual grease parts are rejected and cannot be fitted.
Limitation of oxidation	Necessary degree of cleanliness Requirements from further processing (gluing, electroplating, painting or coating)	No oxidation or staining as result of contact with water or moisture	<60% humidity	Part of non destructive testing prior to use/fitting – inspection for oxidation	As above	As above
Drying time	Acceptable or necessary duration of the cleaning process Requirements from further processing (gluing, electroplating, painting or coating Quantity of parts to be cleaned per hour/per day;	Must be < 1 minute to ensure no staining prior to application of other coatings	+ 15 seconds	None	As above for application of coatings	As above for effect on application of coatings.
Task timing	Quantity of parts to be cleaned per hour/per day Acceptable or necessary duration of the cleaning process	Degreasing and drying must be completed in 7 minutes	+ 1 minute	N/A	N/A	Increase in degreasing time would significantly decrease the output of components and affect the efficiency of the process. This affects downstream processes such as coating of tubes.

3.5.1.1. Information on use and function of the Annex XIV substance in the CSR

Information on the use of the Annex XIV substance will be documented in the CSR (see Guidance on information requirements and CSA). This can either be parts of the CSR from substance registration or a CSR for authorisation; in the latter case the CSR has only to focus on the properties of the substances that have caused it to be listed on Annex XIV {Article 62(4)(d)}. The key part of the CSR in this context will be the exposure scenarios (ES) for the uses applied for, as the authorisation will be possibly granted on the basis of those exposure scenarios. It should be noted that use descriptions developed according to guidance for preparing the CSR may not be sufficient

on their own to describe the use in sufficient detail to determine exact use function[13]. Some suppliers may have used questionnaires to request information from DUs on uses in order to prepare the CSA and CSR. These may be a useful source of information on use.

The applicant will need to elaborate upon the information set out in the CSR based on his knowledge of the specific uses being applied for and the function that the substance must perform for each use. This can be used to determine the function for each use and will include information on the substance's physicochemical properties, biological properties and operational conditions as well as its functionality.

3.5.1.2.Other sources for information on use and function of the Annex XIV substance

Information specifying the exact function of the Annex XIV substance can be found, for example in company records (e.g. operating procedures, customer specifications for substance use and product specifications) and the wider literature (e.g. industry technical literature describing specific uses, standard operating procedures and technical research papers). Communication with the supply chain can be useful to further define function and use conditions and to ensure that all functions for uses applied for in the authorisation have been identified (see chapter 3.5.2.1). It is important to determine all the functions of a substance for each use, so that possible alternatives that may deliver or replace the equivalent function can be identified. The determination of a specific function and use conditions allows clearer communication and consultation within and outside the supply chain as it describes exactly what is required. Suppliers of alternative substances and alternative technologies can then try to match the function performed with possible alternatives.

3.5.2. Identifying and gathering information on possible alternatives

As described above the understanding of the exact tasks the Annex XIV substance performs and the conditions under which it has to be able to perform these tasks is the starting point for the identification of alternative substances or technologies.

On the basis of the substance function it is useful to identify possible alternatives and at the same time gather the information needed to establish their technical and economical feasibility, capability to reduce the overall risk and availability. Recommendations and considerations for identifying alternatives and gathering information are given in the sections below. Further guidance on gathering information on hazards and risks to health and environment is given in section 3.7. The applicant is advised to consider what he will need to consider in his SEA at the stage where he is gathering and analysing information for the analysis of alternatives.

[13] The Chemical Safety Report (CSR) is a mandatory part of an authorisation application. The CSR must assess the exposure scenarios for those uses that are applied for. Authorisations may be granted for uses within the conditions specified in such exposure scenarios as amended by the conditions of the authorisation decision if any. The exposure scenarios for authorisation applications therefore need to be sufficiently specific and precise. Guidance for the preparation of the CSR contains advices on the development of the CSR including the specific circumstances for authorisation.

It is advisable to also list possible alternatives which are easily shown not to be suitable. This is to document that the applicant has considered the possible alternatives broadly. However, the information gathering and analysis of such clearly non-suitable alternatives can be kept limited as long as it meets its purpose of showing whether they are suitable or not.

3.5.2.1. Communication within the supply chain

Consultation with the supply chain with regard to the uses of the Annex XIV substance to be applied for will be important at an early stage. This will help to ensure that consideration has been given to the exact use of the substance and for supply of information on alternatives that may possibly fulfil an equivalent function to the uses applied for. Consultation may also address any necessary changes in equipment, the form of the substance and the waste and re-use of the substance (these may also have economic consequences). The aim of communication with the supply chain is to identify for each use, what the possible alternatives are, and to understand how they perform in relation to the required equivalent function.

Possible sources for the applicant to initially find possible alternatives within the supply chain include (the list is not exhaustive):

- Applicant's own knowledge (including industry employees/in-house knowledge)
- Downstream users
- Suppliers
- Trade/sector organisations

Communication with the supply chain will help to:

- Gain precise knowledge of specific function;
- Identify possible alternatives (substances and technologies);
- Provide an understanding of the technical and economic feasibility, safety and availability of alternatives;
- Identify information on existing, on-going and planned future research and development on alternatives; and
- Identify possible responses of the supply chain to not being able to use the Annex XIV substance (for the uses applied for).

Alternatives can be identified that seem feasible for a particular use; but there may be some factors that could make the transfer to such alternatives difficult. For example, a downstream user relying on their supplier's (e.g. M/I) authorisation[14] may have the use of a particular substance imposed on

[14] Note that an applicant can be a manufacturer/importer or a downstream user, or a joint application may be made in involving a number of legal entities.

them through the use of operating procedures that are set out by legislation or their customers (sometimes in countries outside the EU) and therefore substitution can only be made with prior consent. In some cases this may lead to loss of contract work, which may have economic consequences (economic feasibility of alternatives is considered in section 3.8).

On the last bullet point above, this information will be useful to gather for applicants preparing application under the SEA route. Information in the SEA on what downstream users may do if they cannot use the Annex XIV substance (i.e. if an authorisation was refused), may be needed to analyse if the socio-economic benefits of continued use of the Annex XIV substance (for the uses applied for) outweigh the risks to human health and the environment. Gathering this information from the supply chain at the same time as information on alternatives will optimize the applicant's data gathering and give a better understanding of what possible alternatives might be used. Guidance on Socio Economic Analysis – Authorisation is set out in a separate guidance document (this includes guidance on developing a consultation plan in Appendix A of the guidance).

Supply chain communication is an interactive process and can involve all relevant parts of the supply chain from downstream users to suppliers, involving the appropriate experts. This is important for identifying possible alternatives for all uses applied for. Suppliers may have identified a possible alternative that the downstream users are unaware of and *vice versa*. Downstream users usually have a clear understanding of the functions required by a substance/product/process, whilst suppliers, manufacturers and importers may have a more informed view on possible alternatives. Contact with trade associations could also prove useful in this regard.

Consultation with the supply chain is an interactive process, so when possible alternatives have been identified, the supply chain may have to be consulted further on technical and economic feasibility; environmental and human health hazards and risks; as well as availability of alternatives. Guidance for Downstream Users sets out guidance on aspects of communication with the supply chain from the DU's point of view. Example 2 illustrates the process of supply chain communication for a substance.

Example 2. Illustration of supply chain communication

Substance B is used as a coolant and a lubricant for metal-working. When coolants/lubricants containing substance B are used, the substance has potential emissions and risks for the environment. Workers are potentially exposed to the substance through skin contact or inhalation of dust or mist and there are risks for workers through use of the substance.

The initial view of the supplier (here M/I as applicant) was that it would be difficult to find a suitable substitute. The supplier had contacted relevant downstream users in order to gather information to develop the CSR for substance B. During this process information on possible alternatives and process changes required to accommodate possible alternatives were gathered.

As a result of the collected information, the supplier contacted users, to identify possible alternative for the substance in the metal working fluid.

Possible alternatives identified through communication with the supply chain DUs were:

Possible alternative	**Identified problems**	**Possible solutions**	**Comments**
Sulphur based oils	Production of SO_2 during use and risk to workers also problem for waste and disposal of substance after use – environmental risk and	Control of sulphur release and emission.	Expensive to fit and require very large investment in equipment disproportional to benefits

	cost implications.		
Animal fat oil	Problems with use at high temperature – inadequate cooling.	Addition of additives to increase high temperature resistant properties	No such additives available
Vegetable fat oil	As above	As above	As above
Zinc-based compound	Increase of environmental risk	Control of metal in waste – emissions treatment.	Very difficult to remove metal component from waste stream.
Process optimisation	Requires different formulations to be used according to the material (i.e. type of metal) that is being processed.	Testing required to identify possible reformulation of products in order to reduce and eliminate use.	Requires drawing on R&D and possible technical testing programme. Business risks as programme has costs and may not be possible at busy times.

For the options above the details of the relevant R&D may be appropriate to set out in the analysis of alternatives, in particular where the supplier and user identified that testing would be required in order to understand better if the alternative was a technically and economically feasible option (consideration of R&D is in section 3.9).

This process of collecting information from the supply chain was repeated for each use that is to be applied for by the applicant. Information on alternatives can be summarised as in the table above.

It may also be useful for the applicant to consider the possible barriers to information gathering on the substance and possible alternatives. For example, effective communication within the supply chain may be hindered by aspects of confidential business information (CBI), which may prevent some parts of the supply chain giving full and precise information on specific uses and possibly on possible alternatives. In this case, the downstream user would need to consider the possibility to supply that information under a confidentiality agreement with his supplier or to make his own application for the authorisation of that use. Box 2 sets out CBI and competition law in this context.

Box 2. Competition Law and confidential business information (CBI)

Competition Law

EU Competition law is not intended to inhibit legitimate activities of companies. Its objective is to protect competition in the market as a means of enhancing consumer welfare. Therefore, agreements between companies or decisions by associations or concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market are prohibited (Article 81 of the EC Treaty).

The EU competition rules also apply in the context of REACH-related activities. Although none of the obligations under REACH require exchanging information or other actions that are in breach of the competition rules, when preparing a joint application for an authorisation, applicants need to be aware of the competition rules. While a single exchange of information about the use of a substance will not generally give rise to antitrust concerns, competitors should abstain from organising periodic exchanges of information or from exchanging information on markets, prices, or customers. Also, certain decisions between competitors as to whether an alternative is or is not suitable could be seen as unlawful collusion. Therefore, the use of an independent third party could be considered by competitors making a joint analysis of alternatives or a joint substitution plan (particularly if they have large market shares). Exchanges of information on uses and on whether an alternative is suitable between manufacturers/importers and their downstream users will generally

not give rise to antitrust concerns.

Further information and considerations can be found in the Guidance on data sharing.

Confidential business information (CBI)

Some information or data may be considered by companies to be confidential business information (CBI) that they consider important to protect. Whether certain information is CBI, needs to be determined on a case-by-case basis. CBI issues must not be confused with competition law which refers to situations where the sharing of information is likely to lead to distortion of competition (see above). The Guidance on data sharing is also considering CBI in detail, including useful options identified to circumvent problems with CBI (e.g. using third party experts to assess information which companies do not want to exchange).

3.5.2.2.Communication outside the supply chain

For information on possible alternatives, it may be useful to contact other manufacturers, research organisations, environmental or consumer groups, academic institutions, industry experts or other third parties. This is particularly important when a possible alternative is not produced by manufacturers/suppliers within the supply chain.

It will be possible to search within the REACH IT system i.e. IUCLID 5, for substances within the same broad category of use, and this may act as a starting point for identifying possible alternative substances. There may be difficulties associated with this approach, for example where possible alternatives are not part of the applicant's portfolio of products or where another company holds a patent on an alternative technology.

External sources to be consulted will vary depending on the substance under consideration. It may prove useful to consult:

- Key suppliers/manufacturer/importers not within the substance supply chain
- Key process/technology developers/producers not within the substance supply chain
- Leading academic and research institutions on chemicals and processes
- Publicly available tools and databases

Possible sources for the applicant to initially find possible alternatives outside the supply chain include (the list is not exhaustive):

- Academic/trade journals
- Trade/labour unions
- EU and non-EU programmes on chemical safety
- REACH-IT system
- Non-confidential Annex XV dossier information; comments from public consultation and response to comment
- Patents databases

3.6. How to determine the technical feasibility of alternatives

Technical feasibility of an alternative is based on the alternative fulfilling or replacing the function of the Annex XIV substance. It is therefore closely linked to the function that the Annex XIV substance performs, i.e. the specific task that the Annex XIV substance performs and under what conditions the function must be performed as discussed in Section 3.5.1. Therefore, the function of the Annex XIV substance in the uses applied for must be clearly defined before considering the technical performance and feasibility of the alternative(s).

In principle, the assessment of technical feasibility may be straight forward as it may be a case of selecting an alternative that meets specific functional requirements in order to replace the Annex XIV substance. However, the process changes that may be needed in order to accommodate the alternative have to be considered in all cases. On the other hand, the determination of technical feasibility may require a more detailed analysis and may include research in order to identify whether the alternative can perform or replace the function of the Annex XIV substance as well as possible trials to verify performance.

3.6.1. Technical feasibility criteria

It may be possible to develop technical feasibility criteria (i.e. a list of technical requirements on function that must be fulfilled for an alternative to be technically feasible, see Box 3). A good understanding of the substance function is the basis for the development of these criteria. This list of criteria may include the tolerances of these requirements (i.e. an acceptable range) and may also include consideration of the constraints on functionality. For example, for replacing one substance with another the criteria may include a criterion on the minimum purity required or minimum physical or chemical properties that must be imparted to the end product. For the process changes needed to allow the use of an alternative, criteria may include the range of conditions that can be achieved with available technology and evaluation of whether these enable the alternative to be used for the desired function.

Box 3. Technical feasibility criteria and performance analysis

The development of criteria for evaluating technical feasibility could include a series of steps, as set out below (a screen-printing ink cleaner is used as the example*):

1) Review the functional requirements of the use. For example, for a printing ink cleaner a minimal amount of residual ink on the screen after cleaning may be a specified requirement. A performance criterion may be that the screen must be cleaned until no visible ink residue remains on the screen surface.

2) Identify relevant performance characteristics that could be qualitatively or quantitatively evaluated. For example these might include the ease of use (e.g. the physical effort required to clean the screens), the time required to accomplish the desired function (e.g. cleaning), the effectiveness of the alternative in achieving the function, or the effect of the alternative on the quality of the finished product (e.g. will use of the cleaner reduce the life of the screen).

3) Establish a performance scale for each of the performance measures to facilitate evaluation of the alternative/s. The scale should consider both subjective and objective characteristics. (For example, visual inspection could be used to assign a high, medium or low level of cleanliness. A quantitative test, such as light transmission through cleaned screens, could be used to quantitatively measure the amount of residual ink left on a screen after cleaning). Some objective characteristics can be evaluated using standard product specifications, such as military specifications.

The technical criteria against which possible alternatives can be appraised for feasibility will depend upon the

consideration of the function as well as other concerns such as customer requirements. The approach to technical feasibility set out here relies upon setting a basis for technical feasibility that is determined by the functioning of the Annex XIV substance (the assumption here is that the Annex XIV substance performs the function adequately, otherwise the applicant would not be considering applying for continued use of the substance). However, this does not disregard the possibility that an alternative may out-perform the original substance in terms of technical functionality.

Evaluation against technical criteria measures how well an alternative performs to meet the functional requirements of the use. Technical performance data can be collected for both current use and the alternative processes and used as a basis for an evaluation. The effort required to perform a useful assessment of technical feasibility may vary depending on the thoroughness of the study and the specific nature of the process under consideration. In the first instance the evaluation would rely on the compiling of performance information from literature sources and from consultation rather than the design of an actual operating trial. The focus for the user will be on the:

- Design of accurate and reliable performance measures.
- Collection of required data from suppliers.
- Evaluation of relative performance of the alternative.

** Based on the US EPA document: US Environmental Protection Agency: Cleaner Technologies Substitutes Assessment - Office of Pollution Prevention and Toxics Washington, DC 20460 EPA Grant X821-543*

3.6.2. Consideration of process adaptation and changes

The selection of possible alternatives to the Annex XIV substance can be done based on consideration of the replacement of substance function with another substance or with a technical alternative or perhaps by eliminating the need for the Annex XIV substance through process change or changing the end-product. How to use substance function to identify possible alternatives is considered in the previous section (section 3.5). The determination of what process adaptations or changes may be needed to replace or remove the need for the Annex XIV substance and whether these are technically feasible are considered below.

The technical feasibility of an alternative will be highly dependent on the possibility of the process adaptations and changes that may need to be put in place in order for the alternative to perform the desired function. Therefore, the consideration of the questions below for each type of alternative is recommended in order to address the technical feasibility of a possible alternative (i.e. substance or, technical alternative or process redundancy) [15]:

1. Is it possible to replace the Annex XIV substance with an alternative substance?
    a. If yes, what adaptations to the process are needed?
    b. Are these adaptations technically feasible for the applicant?
2. Is it possible to replace the Annex XIV substance with an alternative technology?

[15] Considerations on the economic feasibility of replacement of the Annex XIV substances are set out in section 3.8. Considerations for the documenting past or future R&D are set out in section 3.9.

   a. If yes, what adaptations to the process are needed in addition to applying the technology for replacing the substance?
   b. Are these adaptations technically feasible for the applicant?
3. Is it possible to make redundant the process or a part of the process in which the Annex XIV substance is used?
   a. If so, what changes are needed?
   b. Are these changes technically feasible for the applicant?

Consideration of process conditions influencing the functional requirements have also been given in section 3.5.1 The alternative may not need to be used under the same process conditions as the Annex XIV substance in order to fulfil the same function. For example, it may be possible that the constraints imposed by the use of other chemicals or processes could be adapted or changed to accommodate an alternative. However, the constraint may be imposed by the conditions under which the function must be performed.

Process change is normally required to accommodate an alternative and technical feasibility should not be discounted on the basis that an alternative cannot be simply substituted without any process change. For example:

- Changing one chlorinated solvent for another with a higher boiling point in vapour degreasing baths may mean increased use of energy to produce the necessary vapour.
- The design and use of spraying nozzles for the use of biodegradable mould releases; the nozzles for the current substance in use are not effective with the alternative substance. Adaptation of the design of the nozzles allows the alternative to be used.
- In offset printing, certain rubber mixtures for the rollers could not be used, as they tended to swell with alternative substance. Using different material for the rollers allowed the use of the alternatives. This however required tests to determine the technical feasibility of the new roller types (with time implications).

An alternative substance or technology may also require investment in equipment for it to become technically feasible. Therefore, what process changes and investments in equipment and training are required should be identified and described. These may include:

- Determining what equipment and worker training will be needed for changes in the process required in order to accommodate the use of an alternative substance or technique.
- Assessing the requirements associated with installation of equipment e.g. space (housing) considerations, health and safety requirements (for installation and operations of equipment) and maintenance and repair of equipment.
- Calculating the cost of equipment and training requirements[16].

Based on consideration of the constraints, an assessment can be made of whether it is possible for the applicant to replace the Annex XIV substance through changes and adaptation to accommodate the alternative or remove the need for the Annex XIV substance function altogether. However, the technical feasibility of these adaptation or changes will also be dependent on further factors.

[16] The analysis of economical feasibility is addressed in section 3.8.

Therefore the assessment will also comprise consideration of requirements which may include one or more of the following:

- Legal requirements: for example relating to product safety.
- Customer requirements: for example changes that require customer approval.
- Testing or research requirements: for example the process change may need to be tested to ensure that it is compatible (this may have fit in alongside normal production processes), or research may be needed to analyse the effects of the process change.

The outcome of the assessment of the technical feasibility of process adaptation or change has to be documented in the application. The assessment of technical feasibility of alternatives may clarify actions needed to make an alternative technically feasible or reveal need for research and development to develop or ensure the technical feasibility of an alternative. In such case relevant action, together with a timetable, and/or R&D should be documented in the application. How to do this is set out in further sections of this guidance:

- Circumstances that might prompt the inclusion of R&D in the analysis of alternatives is considered in section 3.9.1; and
- The listing and documentation of the actions that are needed in order to make an alternative suitable and available are set out in section 3.11.

Example 3 is intended to give an illustration of the consideration of the technical feasibility of alternatives.

Example 3. Considerations for technical feasibility

Substance C is used in plating of metals and plastics; it is used to lower the surface tension of metal plating solutions to prevent the formation of mists containing potentially harmful components from the baths. The substance is used specifically in this application for hard metal and plastic plating and decorative metal plating.

The importance of the substance for metal plating is that it is stable in 'hostile' environments, such as hot metal acid, where it can form a foam blanket on the surface of the treatment bath, thereby preventing the release of acid mists by acting as a barrier. The substance is considered to be vital to operations of this type ensuring the health and safety of workers and reducing the risks of health impacts (including lung cancer and metal exposure ulcers) associated with metal plating. Prior to the introduction of the substance, control of metal ion emissions was by local extraction – substance C is considered to have made the control of mists more efficient and a considerable help to meet Workplace Exposure Limits.

Suppliers purchase aqueous solutions of the substance C, which they may dilute further and then sell to their customers. Typically 10% solutions are used.

R&D suggests that the substitution of the metal ion with a less hazardous ion of the same metal in some plating applications (use 1) would eliminate the need to use any substance for prevention of mist formation. This option is not available for use 2 – alternatives for this use are subject to industry research.

Difficulties with technical feasibility

<u>Substance alternatives</u>

There are currently no known alternative chemical mist suppressants to the substance for metal and plastic plating. Testing* has shown that substitute mist suppressants, such as substances D and E are not technically feasible because of excessive pitting of coatings and rapid breakdown during the process (electrolysis). [*Reference to relevant R&D reports or findings supports this]

Possible technically feasible alternatives

Technical alternatives

A number of options for mechanical mist suppression and improved ventilation have been identified.

For use 2, the longer time periods of immersion in the electrolyte required to obtain the necessary thickness of coating provides the opportunity for greater tank enclosure (compared with use 1 where immersion times are measured in minutes rather than hours/days). Whilst causing some interruption to the process of immersing and taking out articles, this would eliminate the need for chemical mist suppression to meet occupational exposure level when combined with suitably adjusted ventilation extraction (the use of the metal ion is already limited in the automotive electric and electronics industries).

For use 2 applications the use of greater physical tank enclosures presents some operational disadvantages over the use of chemical mist suppressants. These include the need to remove and replace the enclosure between operations; the advantage of chemical mist suppressants being that they effectively provide a floating chemical enclosure through which articles can be raised and lowered. Such disadvantages do not occur with the use of improved ventilation extraction alone. However, while these may present operational disadvantages over chemical mist suppressants there are no technical disadvantages from the perspective of product quality /production standards.

Process changes making the Annex XIV substance function redundant

For use 1, the indication from R&D is that the use of the less toxic ion of the metal would eliminate the need for substance C (or any other substance for the prevention of mist formation) in this use and would not result in any significant technical difficulties and may have a number of technical advantages including:

- production of fewer rejects and freedom from burning
- better metal distribution and good covering resulting in better corrosion production
- easier draining because of the lower viscosity and lower chemical concentration of metal ion electrolytes resulting in less staining of the work.
- uniform coverage without build up on high current density areas
- maintained plating and deposit appearance over a very wide current density range

3.6.3. Uncertainties in determining technical feasibility

It is important to clearly set out what the uncertainties are in the documentation of the analysis of alternatives and determine how they may affect the outcome of the assessment of the analysis. Setting out the actions required to make an alternative suitable and available (see section 3.11) will therefore be a critical part of the analysis of alternatives and this will include the consideration of what needs to be done to make an alternative technically feasible. The uncertainties, for example the possible outcome of research, product safety[17] and technical test-trials will need to be part of the documentation.

[17] Product safety referred to here relates to the possible legal requirements, such as for fire safety as distinct from the analysis of safety of chemical within REACH (i.e. in the CSA).

3.7. How to compare the risks of the alternative and the Annex XIV substance

3.7.1. General considerations on assessing and comparing the risks

The use of a suitable alternative must lead to a reduction in overall risks to human health and the environment compared to the Annex XIV substance. Therefore, in the analysis of alternatives it is essential to compare the potential risks of possible alternatives to the Annex XIV substance for the uses that are being applied for. This should also include the consideration of the appropriateness and effectiveness of risk management measures that control risks.

Note that for substances included in Annex XIV and following the SEA route to authorisation (based on the provisions in Article 60(4), see section 1.5.5. for further details on applicability), an SEA report, which may include an assessment of health and environment impacts made according to the Guidance on Socio-Economic Analysis - Authorisation will be available. This assessment could be used to support the decision making on whether the possible alternatives will lead to a reduction in overall risks or not.

The assessment of risks related to the alternatives has a comparative nature. It should document whether or not the transfer to the alternative would result in reduced overall risks to human health and the environment. It is therefore important not only to consider the risks that resulted in the requirement for authorisation (based on the substance properties listed in art. 57), but also all other possible risks resulting from the Annex XIV substance and the alternative. The aim is to assess the effects of the transferral to the alternative in reducing the identified risk of the Annex XIV substance while not causing other risks that cannot be controlled.

For example, in relation to alternative substances, the work involved may include:

- collecting data on the properties of alternative substances from manufacturers and importers or other sources (e.g. registration dossiers on alternatives when these have been registered, or from other sources when registration has not yet taken place);
- examining the hazard profiles of the alternative substances and comparing them to the hazard profile of the Annex XIV substance to assess whether it is possible to determine with sufficient certainty that the alternative would result in a lower level of risk;
- examining the exposure levels of the alternative substance, e.g.,
    - examining information on emissions to the environment and/or environmental concentrations of the alternatives and data on current levels of exposure of workers or consumers from publicly available sources or impacts associated with alternative options;
    - using exposure modelling
- where necessary, combining the hazard and exposure data for alternatives to determine whether they would result in a lower level of risk
- if appropriate, quantifying and valuing the change in risk following the approach set out for the Annex XIV substance.

The applicant is not required to generate new hazard data or provide a chemical safety assessment for each of the alternatives. Nor is it required that the risks associated with alternative substances or

technologies are assessed in the same detail as the risks associated with the Annex XIV substance. The level of effort that needs to be put into this assessment above the documentation of available information will be a matter of judgment for the applicant. For example, the comparison of hazard profiles may indicate that the alternatives present a clearly lower level of risk. In these cases, no additional assessment may be necessary. When a comparison of hazard profiles or a lack of data raises concern, then there may be a need for more detailed assessment of any changes in risk following as appropriate the approaches described in the guidance on preparing chemical safety assessment.

For the purpose of the analysis of alternatives, when the applicant can show that an alternative that could be assumed to entail lower risks is not technically or economically feasible for him, it would not be necessary to continue with further assessment of the risks of the alternative. However, if the applicant considers inclusion of a SEA in his application, it may be useful for the applicant to provide information comparing the risks of alternatives to those of his application (even if the alternatives are not feasible for the applicant) to be used as a basis for the assessment of health and environment impacts within his SEA.

3.7.2. Collecting hazard and risk information on alternatives

This section addresses primarily how to collect information on alternatives that are substances, but to some extent also provide information relevant for alternative technologies (e.g. see box 4).

As already mentioned it should be noted that the applicant is not required to generate new hazard data or perform and submit a chemical safety assessment in order to determine the safety of possible alternatives. However, the applicant should use all information available for him, including public information generated by possible registrants of the alternative substances.

The guidance for preparing the CSA will be useful for collecting and generating easily available information on hazards and risk and control of risks in order to compare the safety of the alternatives with the Annex XIV substance. For example, the applicant can use the same basic information strategies in assessing the risks of alternative substances as set out in the Guidance on information requirements and CSA. These approaches consider what the applicant might do in cases where information on hazard and exposure of the alternative substance is scarce or are not available, for example because the alternative substance is not registered under REACH[18]. Where there is insufficient information on hazards for the purpose of concluding whether the overall risks are reduced by a transfer to an alternative substance, the applicant may for example use methods like quantitative structure activity relationships ((Q)SARS) and 'read-across' from similar substances.

The CSA guidance also includes detailed information on data search strategies and databases for collection of available data using publicly available data sources to assist with gathering information on possible alternatives. Box 4 gives some further examples of internet based information tools that have been developed to assist with comparing safety of alternatives. The

[18] Availability of data via REACH-IT will be dependent on whether substances have been registered (above 1 tonne per annum). Note that the registration timetable depends on the tonnage band therefore this will determine whether and when information is available on possible substance alternatives within the REACH system. It should also be noted that the whole registration dossier is not publicly available.

examples in Box 4 are only examples of the type of information that is freely available and are not recommendations. Note that none of the databases is designed specifically for REACH.

Box 4. Examples of databases and tools to assist with hazard and exposure information on possible alternatives

There are a number of publicly available databases that have been set up aimed at assisting the substitution of dangerous substances. Some allow hazardous properties of substances to be searched, while others provide examples of how hazardous substances have been substituted (i.e. case studies). Some of these databases are listed and commented upon below (these are examples and there are other databases available):

Examples of alternative comparison tools:

Tool: P2Oasys Tool to Compare Materials

Developed by: TURI - Toxics Use Reduction Institute (University of Massachusetts Lowell USA)

Web reference: http://www.turi.org/

Description/comments: The aim of P2OASys is to allow companies to assess the potential environmental, worker, and public health impacts of alternative technologies aimed at reducing 'toxics' use. The tool is supposed to assist companies in two ways: 1) Examine the potential environmental and worker impacts of 'TUR' options in a comprehensive manner, examining the total impacts of process changes, rather than simply those of chemical changes. 2) To compare TUR options with the company's current process based on quantitative and qualitative factors.

Input of data can be quantitative and/or qualitative data on the chemical toxicity, ecological effects, physical properties, and changes in work organisation as a result of the proposed option.

Tool: Column Model

Developed by: Berufsgenossenschaftliches Institut für Arbeitsschutz - BGIA

Web reference: http://www.hvbg.de/e/bia/

Description/comments: Various types of hazard (health, environmental, fire and explosion, potential emission and procedural) are grouped in columns and the attributes of a possible alternative could be compared (with the Annex XIV substance) within a group/column. This allows the user to focus on the hazards and exposure potential that is most significant for the use of the alternative.

Because of data uncertainties, data quality and the mix of quantitative, semi-empirical and qualitative data used to complete the matrix; a risk index of this type can be subjective.

Example of hazardous substances database:

Database: PRIO

Developed by: KEMI (Swedish Chemicals Agency)

Web reference: http://www.kemi.se/

Description/comments: The aim of PRIO is to facilitate in the assessment of health and environmental risks of chemicals so that environmental managers, purchasers and product developers can identify the need for risk reduction. To achieve this PRIO provides a guide for decision-making that can be used in setting risk reduction priorities.

The PRIO database is most useful for users identifying the hazardous properties of the substances they use in order to help them in priority setting for action on the substance, rather than identify possible ('safer') alternatives to a substance. Listing of alternatives is not currently available, but may be considered in the future.

Example of substitution experience database:

Database: CatSub

Developed by: European Agency of Occupational Safety and Health, Danish Working Environment Authority

and Danish Environmental Protection Agency

Web reference: http://www.catsub.dk

Description/comments: Catsub is a database of examples of the substitution of hazardous substances. The data base is populated with some 200 examples which can be viewed. The process of substitution difficulties and how these were overcome is provided in the commentary from industry and authorities.

The database does not provide information 'look-up' on hazardous properties of substances or have possible alternatives for dangerous substances other than those in the database examples. The examples are in the Danish language (apart from eight examples in English). There are plans to develop Catsub into an international tool for substitution.

It should be noted that the information on the comparison on the risks of the Annex XIV substance and alternative(s) may be of use in an SEA, if such an analysis is to be performed for the application. As noted in sections 3.2 and 3.4.2, key information collected and analysed in the analysis of alternatives may be used in the SEA. Conversely, the assessment of health and environment impacts that may be carried out as part of the SEA could be used in the analysis of alternatives to support the decision making on whether the possible alternatives will lead to a reduction in overall risks or not. Box 5 sets out the links between the comparison of risks in the analysis of alternatives and the assessment of impacts in the SEA.

Box 5. Comparison of risks: links to the SEA

The aim of the SEA as part of an authorisation application is to assess whether the socio-economic benefits of the use of the Annex XIV substance (for the uses applied for) outweigh the risks to human health and the environment (see Guidance on Socio-Economic Analysis - Authorisation). To do this two scenarios are compared:

1. The use of the Annex XIV substance for the uses applied for (this is called the 'applied-for use' scenario); and

2. Not using the Annex XIV substance for the uses applied for (this includes what the response to the 'non-use' (i.e. removal) of the Annex XIV substance would be – this is called the 'non-use scenario'.

In order to compare the two scenarios, there is a need to understand what the impacts of the two scenarios are, and to assess what the difference is (i.e. the net impact). When assessing the health and environmental impacts, a stepwise approach is proposed, whereby the assessment focuses on those impacts that are considered to be significant outcomes of the authorisation, with the level of detail and quantification applied determined by the extent to which further information will be needed in presenting a robust SEA. Throughout the process, judgements will need to be made on what impacts are likely to be significant and how these can best be assessed.

The basis for the identification and assessment of health and environmental impacts is a proper understanding of the changes that granting or not granting an authorisation causes on step 1-3 below:

1. The use of the Annex XIV substance or the use of any alternative substance or technology.

2. The resulting emissions and exposures,

3. The subsequent impacts to health and environment,

4. If possible, valuation of these changes in impacts can be applied as a last step.

The stepwise assessment of changes induced needs to be done for the Annex XIV substance as the 'applied-for use' scenario and any alternative substance or technology identified for under the 'non-use scenario'. Respectively, any other affected process upstream or downstream in relation to the Annex XIV substance or to alternative(s) will be analysed.

The above outline is used as the conceptual framework for identifying, assessing and, if possible, quantifying, and ultimately valuating health and environmental impacts in the SEA.

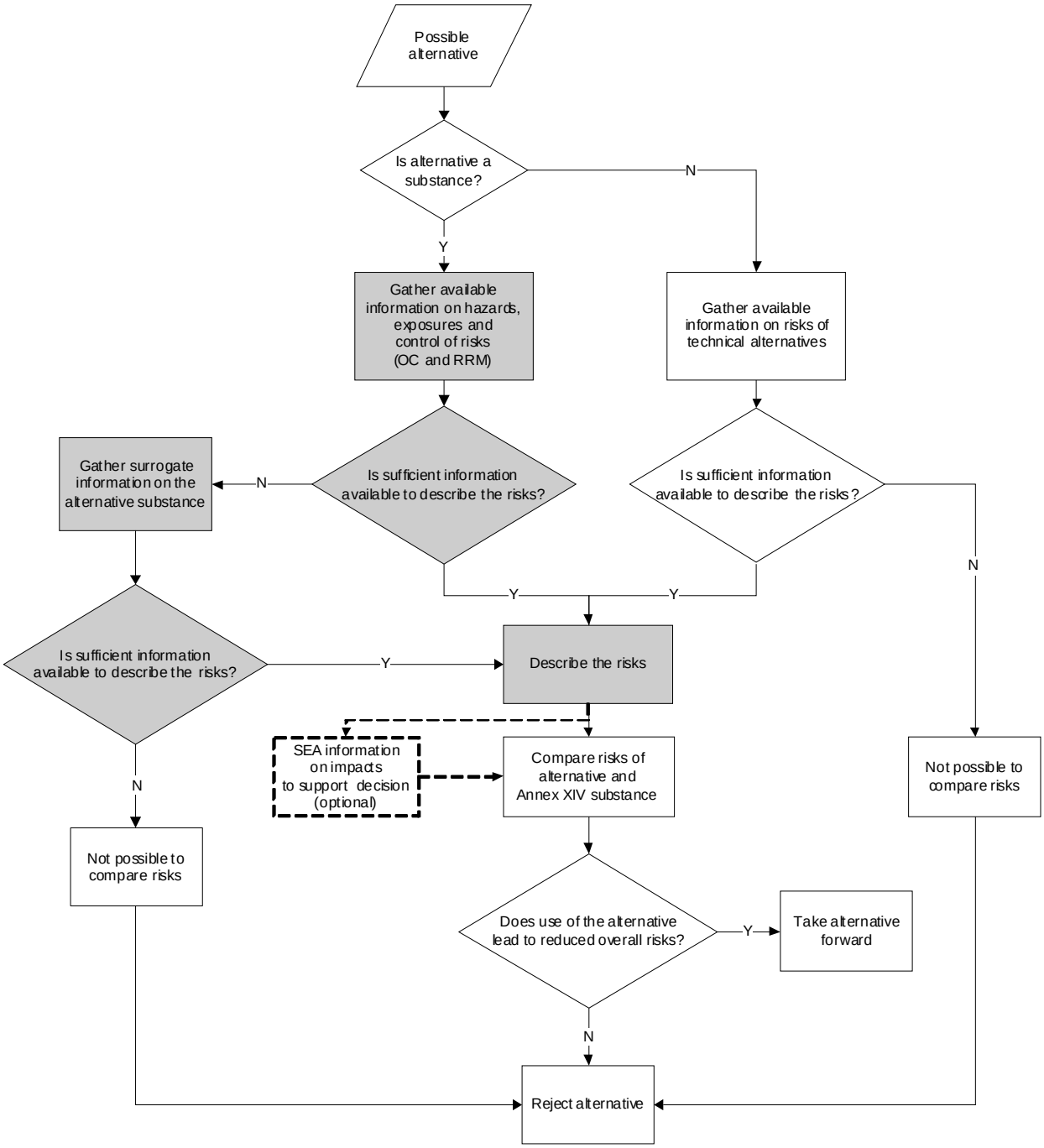
The analysis of alternatives may have considered replacement or adaptation of the end product that would lead to removal of the need for the Annex XIV substance altogether. However, the extent/scope of the analysis of alternatives may not have covered the extent of the non-use scenario in the SEA (e.g. use of a non-suitable alternative which may be applied in case the Annex XIV substance is not granted authorisation). This may require the gathering of further information for the impact assessment of the SEA as mentioned in sections 3.3 and 3.5.2 above.

3.7.3. Assessing and comparing with the risks of possible alternative substances

In principle the assessment of human health and environmental risks for an alternative substance can be conducted using the same approaches as for the Annex XIV substance for which a CSR is developed as a part of the application. However, the Guidance on information requirements and CSA does not consider the comparison of risks between substances (i.e. comparing the risk of the alternative with the Annex XIV substance).

In order to be able to compare the risks arising from the available alternatives one needs to take a flexible approach towards the assessment of such alternatives, as well as the Annex XIV substance. Ideally the assessment should address all possible risks throughout the entire lifecycle of the substances including all relevant compartments and populations, even those not originally associated with the identified risk. The reason for this is that, while an alternative may reduce the specific identified risks of the Annex XIV substance, it may pose other risks at different points in its lifecycle or may shift the risks to other compartments/populations when it replaces the substance of concern. In other cases, the use of alternatives may have secondary adverse effects that may not be immediately recognisable, for example, an increase in the production of hazardous waste at the end of the lifecycle or increased energy consumption.

It is recommended that the assessment of the risks of possible alternatives is approached in a step-wise manner, considering whether there is sufficient information on hazard, exposure, risk and risk control in order to make an assessment of the risks of the alternative and compare this to the Annex XIV substance. Figure 9 illustrates in a general flow diagram how one might address the risks of alternatives.



Note: Solid grey boxes indicate where guidance on gathering hazard and exposure information and chemical safety assessment of substances is set out in Guidance on information requirements and CSA (including where surrogate information on hazards may be derived such as (Q)SAR and read-across); the dashed box indicates a link to Guidance on Socio-Economic Analysis - Authorisation.

Figure 9 Flow diagram for the assessment of and comparison to risks of alternatives

The assessment of alternatives should be based primarily on risk rather than hazard. However, risk-based replacement of the original substance or process may not always be simple or indeed feasible. Therefore, assessing the risks of alternatives substances may be conducted using a tiered approach starting from a comparison of the hazardous properties and, if necessary, possibly ending in a full assessment of the risks arising from the alternatives.

A detailed tiered approach is described in Box 6. Each tier increases the level of data required and complexity of the assessment. However, the complexity of the assessment is highly dependent on the properties of the alternative substance or technology. For example, if a clearly less hazardous substance is available then a comparison of the hazardous properties could be enough, or in the case where an alternative technique results in the elimination of emissions of the substance of concern, then a description of the resulting emissions could be suitable. Nevertheless, care should be taken to assess other possible secondary effects of the alternative, such as possible increases in the production of hazardous waste or increased energy consumption.

Box 6. A tiered approach for assessing the risks of alternative substances

For alternative substances the tiered approach set out below may be appropriate. Such an approach may include the following levels of increasing complexity:

- **Tier 1:** Comparison of the hazards of the alternative substance to those of the substance of concern.

  Part A: Collection of available hazard information for the alternatives. Where registration dossiers and other REACH-related information (Articles 31 and 32) are available, these may be reviewed. If such sources are not available, other sources should be considered (see section 3.5). Where vital information is missing, consideration may be given to generating this, for example, by use of (Q)SARs. Uncertainty on the validity of such results should be acknowledged and documented in the analysis.

  Part B: Comparison of the hazard information of alternatives to that of the Annex XIV substance. This assessment should be used as a screening process to rank alternatives based on their hazard profile in order to help on whether to consider such alternatives as potentially suitable. This comparison should first look at those hazard properties of highest concern such as PBT/vPvB, and CMR characteristics. If both the Annex XIV substance and the alternative substances have similar properties of concern or when all potential alternatives have PBT/vPvB/CMR properties, the applicant should take into consideration information on the potential exposure and any possibilities to better control the exposure[19]. Furthermore, for applications via the SEA route a health and environment impacts assessment may form part of an SEA. This assessment can provide further information for the decision on whether the alternative would lead to a reduction in overall risks or not. The same principles apply when comparing less severe hazard properties. If the alternatives have been registered and have been assessed for risks, PNEC and DNEL values for them may be available and these may be compared to those for the Annex XIV substance. Also, the collection and comparison of information on physico-chemical properties of the alternatives may be pursued if it is of particular relevance to the identified risks.

- **Tier 2:** This would involve the use of information on the alternative substance (properties and hazards) within the Chemical Safety Assessment for the Annex XIV substance to perform a quick revised exposure assessment and risk characterisation for the alternative for the applications associated with the identified

[19] If an alternative substance is already on Annex XIV, it will normally not make sense to transfer to it. If the substance is on the candidate list, then a very close consideration on the overall risks should be given before transferring to it. If the alternative substance seems to fulfil article 57 criteria but it is not yet on the candidate list or registry of intentions, the applicant should document his reasons for suspecting the substance to be a SVHC and such hazard profile could be seen as an argument that the transfer to this substance may not reduce the overall risks.

risk; there may be three possible situations of increasing complexity:

1) If the exposure assessment for the Annex XIV substance shows that the release estimates do not depend on the substance properties, then the existing emission estimates for the original substance may be used.

1a) When the alternative has similar physico-chemical and environmental fate properties to the Annex XIV substance, it may be sufficient to use the existing PEC values for the comparison of the PNEC or DNEL values of the substance of concern and the alternative; or

1b) When the alternative does not have similar physico-chemical and environmental fate properties to the Annex XIV substance, the emission estimates may be used in conjunction with environmental fate data on the alternative to calculate its PEC values. These should then be used to revise the risk characterisation.

2) If the emission estimates in the chemical safety assessment depend on the substance properties, it may be possible to estimate whether the alternative would have lower or higher emissions than the Annex XIV substance by simple consideration of the properties. However, it is possible that emissions to one compartment may increase while those to another decrease, and it will be difficult to make a simple judgement on how this would affect the PECs (for regional concentrations at least). In such cases, it may be necessary to estimate the emissions of the alternative substance and then carry out similar calculations as those for the substance of concern to generate PEC values. It may also be necessary to consider the effect of replacing the substance with the alternative in terms of the tonnage of the alternative that would be required. For example, the registration dossier for the alternative will be based on the current tonnage and uses and is unlikely to consider an increase in use or a new use as a result of replacement (see also Appendix 5 on 'risk profiling' for environmental risks of substance alternatives).

- **Tier 3:** use of exposure scenarios specific to the alternative substance (rather than those for the Annex XIV substance) to perform an assessment of risks for the alternative for the applied for uses across all compartments/populations at risk. This will effectively be similar to Tier 2 only that the Exposure Scenarios will be specific to the alternative substance for the applications associated with the identified risk, if available for example from an annex to the SDS or from a registration dossier for the alternative.

  Note: This approach has been adapted from an approach set out in Guidance for the preparation of an Annex XV dossier for restrictions

It may also be the case that the Annex XIV substance would have to be replaced not by a single substance but rather a combination of substances or a complete reformulation of products containing the substance or even by alternative substances used within an alternative processes. In such cases, the combined effects of such changes may be difficult to assess. Therefore, the analysis may include an assessment of the potential effects of each alternative used in isolation and some discussion of the envisaged implications of combined effects may be provided.

For hazard data, the key health and environmental effects of alternatives should be identified where this is possible. For alternative substances particular attention should be focussed on carcinogenic, mutagenic or reproductive effects and PBT and vPvB properties. These comparisons of similar properties and effects between substances are not necessarily straightforward or simple. The classification and labelling of possible alternative substances can be consulted in the list of harmonised classifications (Part 3 of Annex VI to Regulation (EC) No 1272/2008 (if available[20])

[20] The Classification and Labelling Inventory (database) is available at the ECHA website.

and the hazard statements applied to substances may be useful in the assessment of the comparative hazard[21].

The comparison of different hazards and their magnitudes may require value judgments about the acceptability of different risks to different endpoints. For example, such judgements may involve comparing different types of health impacts (e.g. liver toxicity versus neurological effects) or different effects to the environment. Simultaneously ranking health, safety and environmental risk may require the applicant to be involved in trade-offs which are not always straightforward. Risks of the alternative may also be difficult to compare to those of the Annex XIV substance because they may be of a radically different nature. For example, a substance of low toxicity could have an adverse effect on the earth's ozone layer. Alternatives may be more benign with regard to such effects but they could be, for instance, flammable, toxic or may pose other hazards to the environment. In these cases, the applicant should assess the relative importance, gravity, imminence and implications of the different types of risk and decide whether the risks introduced by the alternatives are acceptable and why.

The applicant may also need to consider the wider implications of the risk and impacts in order to further inform and support the decision on whether the use of the alternative would represent a reduction in risk. This may include addressing risks of various other substances from other processes, i.e. upstream or downstream processes related to the manufacture or use of the Annex XIV substance and alternative substances. This may also include external impacts or substances created unintentionally, e.g. emissions from energy generation as well as consumption/production of other things such as waste production and water use.

It may not, however, be necessary to conduct a full comparison of risks on all possible alternatives. This could be very resource intensive, especially if new information needed to be collected on a number of possible alternatives in order to compare risks. For alternative substances it may be possible to conduct an initial comparison of risks by focusing on the specific use pattern, tonnage used and predicted emissions. With key (but limited) information on the physico-chemical, eco-toxicological and biodegradation properties, alternatives may be compared in terms of their predicted risk. Such a process of so-called risk profiling[22] may enable short listing of alternatives that may be of lower environmental risk.

3.7.4. Assessing and comparing with the risks of possible alternative technologies

There are difficulties in comparing the risks of a substance and the risks of a technical alternative. For example, there may be risks associated with alternative technologies but these may not be of the same nature that the Annex XIV substance risks present to human health and the environment However, for it to be suitable, the alternative must represent a reduction in the overall risks to human health and the environment as compared to the Annex XIV substance. Therefore, a comparison of risks must be conducted and the applicant will need to consider how these different

[21] For example the COSHH Essentials published by the UK HSE provides a scheme by which substances can be grouped by relative hazard on the basis on risk phrases.

[22] An approach developed by the Environment Agency of England and Wales for compiling generic risk assessment from detailed knowledge of likely release patterns and the influence of key environmental properties of those substances used in a particular industry. A brief description is presented in Appendix 4.

risks might be compared in terms of risks to human health and the environment. Note that the introduction of an alternative technology to replace the Annex XIV substance may also involve a change in the use of other substances in the relevant processes. Possible risks of these substances will also need to be considered in the assessment following, as far as possible, Guidance on information requirements and CSA and section 3.7.3.

The comparison with technological alternatives can normally not be fully quantitative (i.e. with directly comparable numeric values) as the risks will not be expressed in similar terms, but will in most cases be qualitative or semi-quantitative. Nevertheless, a clear and transparent description can give a good basis for the applicant to conclude whether overall risks are reduced (and for the Agency Committee to give its opinion on that).

Especially in the case where the analysis requires the comparison of the risks of technical or process alternatives with the Annex XIV substance[23] the applicant may also need to consider the wider implications of the risk and impacts in order to further inform and support the decision on whether the use of the alternative would represent a reduction in risk. For alternative technologies consideration should for example be given to environmental controls, working practices and legislation controlling other risks (e.g., fire and explosion, confined spaces and extreme temperature and pressure). Care should be taken to assess other possible secondary effects of the alternative, such as possible increases in the production of hazardous waste or increased energy consumption (see also Box 7).

There are systems that have been developed for the qualitative, semi-quantitative and quantitative comparison of risks. These range from simple comparisons of hazard information such as the 'column model' from Germany's Berufsgenossenschaftliches Institut für Arbeitsschutz – BGIA (see also Box 4), to more complex systems that consider more far-reaching impacts from the whole life cycle of products such a life cycle analysis (LCA) and related methodologies. With LCA methodologies, however, it may be difficult to focus only on the impacts from the alternative since the LCA is concerned with all impacts from the final end product. These methodologies are designed more for selection of the sustainable manufacture and use of products than selecting lower risk alternatives for hazardous chemicals for particular uses. But the same basic methods and approaches used in LCA to describe the effects could be used.

Some consideration of the possible difficulties in comparing substances risks and risks from technical alternatives is given in the example in Box 7.

Box 7. Comparing risks from substances and technical alternatives

Cleaning of facades – halogenated solvents vs. high pressurised water

The cleaning of building facades can use a number of hazardous chemicals. In this example the focus is on the use of a chlorinated solvent (that is assumed to be the Annex XIV substance). An alternative cleaning method (i.e. technical alternative) for this use is high pressure water systems. The alternative technique has risks associated with its use but these are not toxic risks but are due to the physical working environment, waste and energy use created by the use of the alternative. The risks of the solvent and the use of high-pressure water are summarised below:

[23] The socio-economic impacts of the possible wider risks of the use of alternatives may be one of the aspects considered within an SEA (see Guidance on Socio-Economic Analysis - Authorisation).

Risks of halogenated solvents:

- Exposure of workers with a toxic or carcinogenic substance (risk to workers health)
- Contaminated soil (risk to environment)
- Dangerous waste (risk to health and environment)

The identification of risks takes into account risk management measures and operational conditions related to the control of exposures. It is of importance to consider the actual effectiveness of the measures. For the purposes of this example, it is assumed that the effectiveness of risk management measures to control emission to soil is limited due to problems in putting them in place as the work moves from site to site. Similarly, occupational controls are not fully implemented in practise because the use is not in one place and some items of personal equipment (e.g. respirator) are found to be physically restrictive for the operator when using the substance in particular situations.

Risks of high pressure water:

- Accident risk due to high pressure (risk to workers' health), also for pedestrians (risk to public health)
- Noise and vibration (risk to workers' health)
- Technical Risks: Risk of damages of the façade: mechanical, wetness, oxidation, freezing (technical risk)
- Waste water (risk to health and environment)
- Energy consumption (risk to environment)

As for the substance, the risks are considered with possible risk controls in place. As with the use of the substance, some measures are not fully implemented because of the non-stationary nature of the use scenario. When assessing these (non-toxic) risks any obligations under other Community legislation setting requirement on the implementation of RMMs and OC has to be taken into account. As above, the actual effectiveness and the possibilities to implement these requirements have to be considered.

3.7.4.1. Comparing with risks of alternative technologies: Human Health

Physical hazards to human health arising from the use of alternative technologies such as potential exposure to extreme temperatures, raised levels of noise and vibration or increased risk of fire and explosion are likely to be particularly relevant in the workplace. Comparison of the risks associated with use of the Annex XIV substance and those associated with other possible alternatives should include these physical risks. However, comparing different types of risks (i.e. toxic with non-toxic) is also difficult (see Box 7).

Although the guidance on the evaluation of human health risks within the Guidance on information requirements and CSA is not directly applicable to the consideration of alternative technologies and does not address all the different kinds of physical hazards that could be posed by technologies, it provides a framework for an assessment that may be applied to the assessment of these risks (i.e. comparing hazards with exposure).

Where hazards have threshold effects; no-effect 'safe' levels could be determined. These levels can be compared to the predicted worker exposure level. The implementation of control measures to mitigate risk should be included in the assessment. The safety of an alternative technique may be assessed by comparing residual exposure (i.e. after the implementation of control measures) to effect levels.

Member State Competent Authorities for the protection of worker health will often have information available on the assessment and control of non-toxic hazards. It is recommended that

such guidance is consulted to determine the relevant risks (and control measures) from alternative techniques.

3.7.4.2.Comparing with risks of alternative technologies: Environment

The comparison with risks to the environment from alternative technologies replacing the Annex XIV substance will probably in many cases primarily address changes in the use of other substances in the relevant processes caused by the introduction of the alternative technology. The risks of these substances will need to be included in the assessment and should as far as possible be assessed following the Guidance on information requirements and CSA and section 3.7.3.

A potential difficulty with comparing environmental risks of alternative technologies to those of the Annex XIV substance is that the risk of toxicity and or risk of persistence in the environment may need to be compared with other kinds of risks. For example such as the risk presented by the generation of greenhouse gases from increased use of energy or risks by increased production of waste etc. However, it should be noted that these risks could also be caused by the release of chemical substances and this difficulty is not confined to comparison of substances and technologies.

Some guidance on determining best available techniques (BAT) has been developed in the framework of Integrated Pollution Prevention and Control directive (see Box 8). This offers a methodology to allow a comparison of different options in terms of their potential environmental effects considering seven broadly defined so called environmental themes. The concept takes into account the likely cost and benefits of measures as well as aiming to protect the environment taken as a whole to avoid creating a new and more serious environmental problem when solving another.

Box 8 Alternative techniques and comparing environmental risks: 'cross media effects' guidance from IPPC

Choosing between different options for the control of emissions to the environment has been considered under Integrated Pollution Prevention and Control (IPPC). A Reference Document ('BREF') on Economics and Cross-Media Effects has been developed and published[1].

In the BREF document the term 'cross-media effects' is used to describe the environmental effects of the options under consideration. Choosing between alternative options might require a choice to be made between releasing different pollutants in the same environmental medium (e.g. different technology options might release different air pollutants). In other cases, the choice might be between releasing to different media (e.g. using water to scrub an air emission thereby producing waste water or filtering a water discharge to produce a solid waste). The BREF also provides guidance on comparing the costs of different abatement measures (including investment costs, operating and maintenance costs, revenues and avoided costs) the possible use of this methodology is considered later in section 3.8 on economic feasibility.

The BREF is focused comparing alternative options for determining what represents the best available technology (BAT) for controlling emissions from industrial processes in order to achieve a high level of protection for the environment as a whole. It is not specifically intended to allow a comparison between the specific use of a substance and a possible alternative. The BREF does however offer a methodology to allow a comparison of different options in terms of their potential environmental impact, taking into account different environmental media, different environmental impacts and the costs of each option.

The cross-media methodology consists of four steps. However, the first two steps (called 'guidelines' in the BREF) describe the process for identification of abatement technology and compiling an inventory of emissions for each option. Whilst this is not so relevant for identification of alternatives under the REACH authorisation process, it presents a framework for the selection of techniques that may be helpful. Steps (guidelines) 3 and 4 in which the possible effects and risks from different techniques are compared and interpreted are of more direct

use. The BREF also describes how the economic viability of different options can be evaluated.

Where the BREF may be helpful is where it considers effects other than toxic effects on humans and the environment (such as ozone depletion, climate change, eutrophication and acidification etc.). The BREF does set out assessing toxic effects, but the methodology is based on toxicity factors that have been derived from a number of air pollutants for human health and the derivation of PNECs (based on the TGD for new and existing substances). For assessing the risks of the Annex XIV substance and alternative substances the guidance within REACH, i.e. Guidance on information requirements and CSA should be used where relevant.

The BREF guidelines are summarised below:

Guideline 1 - Scope and identify the alternative options: the initial step in the process is to scope and identify the alternative options that are available and that could be implemented. The boundaries of the assessment need to be set at this stage, with the normal expectation being that the assessment will be restricted to the boundary of the IPPC process.

If at this stage there is sufficient justification to come to a conclusion, the user should stop and set out the justification for the decision.

Guideline 2 - Inventory of emissions: this step requires the user to establish an inventory of emissions for each of the alternative options under consideration.

If at this stage there is sufficient justification to come to a conclusion, the user should stop and set out the justification for the decision.

Guideline 3 - Calculate the cross-media effects: this step allows the user to express the potential environmental effects anticipated from each of the pollutants within seven environmental themes (e.g. human toxicity, global warming, aquatic toxicity, etc.). This is so that a wide range of pollutants can either be compared directly or aggregated and expressed as a total effect.

Two approaches are described which allow the mass emissions of an individual pollutant to be expressed as an equivalent effect (e.g. the Global Warming Potential of a wide range of greenhouse gases can be expressed as kg of CO2 equivalents). These allow individual pollutants to be summed and expressed as a total potential effect within each of the seven environmental themes2. The user may then be able to compare the alternatives to estimate which option has the lowest potential effect in each theme.

If at this stage there is sufficient justification to come to a conclusion, the user should stop and set out the justification for the decision.

Guideline 4 - Interpret the cross-media effects: this final step in the cross-media guidelines discusses how the user can interpret which of the alternative options offers the highest level of protection for the environment. Different approaches for comparing the result of the cross-media assessment are discussed.

The degree of uncertainty in the basic data collected for Guidelines 1 and 2 is relatively low compared to the uncertainty after subsequent manipulation when guidelines 3 and 4 are applied.

[1] *European Commission (July 2006) Integrated Pollution Prevention and Control Reference Document on Economics and Cross-Media Effects*

[2] *Environmental themes/cross media effects are: human toxicity, global warming, aquatic toxicity, acidification, eutrophication, ozone depletion and photochemical ozone creation.*

3.7.5. Uncertainties in evaluating risks

The uncertainties in determining chemical safety are set out in the Guidance on information requirements and CSA. However, that guidance does not consider the uncertainties associated with determining risks that are wider than toxicity or physico/chemical effects when considering substances and in particular technical alternatives.

The quality of the data that is used to assess the risks of alternatives is important. This is because a decision on the relative risks of the alternative (i.e. as compared to the Annex XIV substance) may be based on these data. The applicant may need to evaluate the quality of the data available and to compare data from different sources where necessary. There may be quantitative measures available regarding the uncertainty that can be attributed to data. For example, reported output of emissions may be measured or estimated based on a range (e.g. ± 5 %). Using such data it may be possible to consider the upper and lower ranges to allow a sensitivity analysis.

It may also be possible to give a qualitative indication of the data reliability using a rating score. This may help to give a guide to the confidence the applicant has in the data and may help to indicate the depth of a sensitivity analysis. See the Guidance on information requirements and CSA for further guidance on evaluating data quality and reliability.

It is important that data of 'inferior' quality are not suppressed nor excluded from the assessment by considering only data of highest quality. Otherwise, if less reliable data are excluded, then applying the methodology might become a barrier to considering alternatives. New and innovative alternative techniques will often not have as much data available as established techniques. If only data of inferior quality are available, then conclusions should be drawn cautiously. However, conclusions can still be drawn and can form the basis for further discussion or to identify where more reliable data needs to be obtained.

Uncertainties will apply to the risk assessments for the Annex XIV substance and to the alternatives, but may not apply equally. This needs to be considered in drawing the conclusions.

3.8. How to determine the economic feasibility of alternatives

The economic feasibility of an alternative is to be addressed within the analysis of alternatives and is focused on the economic viability of the use of the alternative in the uses applied for. It focuses on the changes in applicant's costs and revenues including possible pass-through of cost to customers if he was to transfer to an alternative substance or technique.The assessment will not regard the wider impact on society or the wider economy.

The assessment may consider the economic impacts of the transferral to an alternative and the use of an alternative within the supply chain. The assessment may include:

- The investment and recurrent costs of the alternative substance or technology including how they may change over time.
- Other costs of transferral to the alternative – including equipment, training, energy use, regulatory costs, potential down-time and handling to the extent these are not covered under recurrent costs.
- The cost of R&D – including trials[24].
- The time spent and other costs by downstream users in re-specifying alternative products.
- Potential market distortions: For example if an alternative is produced by only a single company (monopoly) or a very limited number of companies (oligopoly). However, one

[24] This should be documented along other aspects of R&D, see section 3.9 on research and development.

should note that if a producer of an alternative would abuse its dominant market position, competition authorities of Member States should be notified.

One criterion for an alternative to be economically feasible is whether the net present value of the revenues minus costs is positive. In other words, the issue is that using the alternative should result in generating gross profit.

Box 9. Economic feasibility: links to socio-economic analysis

While the assessment of economic feasibility focuses on the economic viability of the possible alternative for the applicant; SEA addresses the wider social and economic benefits of the continued use of the Annex XIV substance (granted authorisation) and compares this to possible the social and economic impacts of the withdrawal of the Annex XIV substance from the market (refused authorisation).

Applications for authorisation for Annex XIV substances that cannot be adequately controlled can only be granted if it is shown that the socio-economic benefits outweigh the risks to human health and the environment and there are no suitable alternatives to the Annex XIV substance. The way to assess the socio-economic benefits is by conducting a socio-economic analysis (SEA) and guidance on how to conduct and document an SEA supporting an authorisation application is in a separate Guidance on Socio-Economic Analysis – Authorisation. The entry point to the SEA is that the analysis of alternatives has concluded that there are no suitable alternatives. (SEA may also be used to support authorisation application for Annex XIV substances which can be adequately controlled.)

Some of the same techniques that are used and explained in the guidance for SEA may be used in the assessment of economic feasibility and where relevant reference is made to the separate Guidance on Socio-Economic Analysis – Authorisation, including:

- Consistency in cost analysis;
- Discounting;
- Relevant product/substance life-times

These techniques are set out and explained in the technical guidance for SEA because that guidance includes the consideration of economic methodologies and is a good reference if the applicant chooses to use and apply such techniques to his assessment of economic feasibility. Since applications under the SEA route will have to include documentation of an SEA, the applicant will need to refer to that guidance in this case anyway.

The basis of determining the economic feasibility of alternatives can be called a cost analysis. This identifies the costs associated with the Annex XIV substance and compares this to possible alternatives, calculating the comparative costs between them. The analysis should also include possible changes in revenues due to substitution. Such revenues would be deducted from the costs.

The costs and revenues identified should reflect only the uses applied for and take account of economic consequences of any related changes in the production volume. It is recommended that, as a minimum, the cost analysis identifies and compares the direct and indirect costs and revenues

of the use of the Annex XIV substance and the use of alternative(s). Data may also be collected on future liability costs[25] and indirect benefits[26] that occur due to the transferral to an alternative.

Appendix I of the Guidance on Socio-Economic Analysis – Authorisation provides practical information and further guidance on how to estimate economic feasibility in the analysis of alternatives. The appendix builds on this section as well as Chapters 3.4 (Economic impacts), to some extent 3.5 (Social impacts) and Appendices B, C, D, E and F of the Guidance on Socio-Economic Analysis - Authorisation.

The process can be summarised as:

- Categorise and determine the costs and revenues that are incurred by producing or using the Annex XIV substance and the alternative(s).
- Identify possible liability issues and less-tangible benefits that can result from the transferral to the alternative.
- Perform a comparative cost analysis of current use of the Annex XIV substance versus the alternative/s.

A stepwise process for considerations in determining economic feasibility is set out below[27]:

1) Determine the data requirements for the cost analysis, including data showing if the revenues of the applicant would be affected as a result of producing or using the alternative substance or technology. It is advisable that these data are collected at the same time as data on the technical feasibility of alternatives (see section 3.5.2). Data should be collected on a "per unit production basis", or some other basis that allows a comparative evaluation of the trade-off issues (for example human health and environmental risks and energy use). Obtain these data and additional relevant cost-related data for example on energy use, risk management measures, regulatory status, process safety and market information. Determine whether resource consumption rates, waste generation rates, and worker activities data for the Annex XIV substance and alternatives are consistent. If the data are not consistent, it may be necessary to have knowledgeable industry personnel review and resolve any inconsistencies[28].
2) Estimate the direct costs associated with the operation of the Annex XIV substance and the alternatives using the data gathered in and checked in Step 1. Direct costs include capital expenditure, operating costs, and maintenance costs. Waste management costs are also examples of direct costs (but many businesses allocate these costs to overhead). The costs

[25] It can be difficult to quantify costs that are incurred as a consequence of uncertain future liability for clean-up of hazardous substance releases or for liabilities from personal injury claims stemming from environmental releases or product use.

[26] These are benefits that may occur but cannot be readily quantified (e.g. reduced health maintenance costs because of a safer work environment, or increased product sales as a result of better product performance).

[27] Based on US Environmental Protection Agency: Cleaner Technologies Substitutes Assessment - Office of Pollution Prevention and Toxics Washington, DC 20460 EPA Grant X821-543

[28] To ensure that the cost analyses for alternatives are comparable, these data should be used in actual cost calculations only if the data are available for all of the alternatives being evaluated. There may not be sufficient data contain on new or novel alternatives that are not widely used.

relating to the application procedure (fees, personal costs for drafting and updating authorization dossier) should also be included. Estimate the revenues from the sales of the Annex XIV substance (or the product using the substance) as well as the revenues for the alternative.

3) Estimate possible indirect costs, indirect benefits and possible liability issues for the Annex XIV substance and alternatives:
    a. If there is a reasonable indication of possible liability in connection with the use of the Annex XIV substance or the alternatives, this should be considered. In most instances, the estimation of future liability cost is subject to a high degree of uncertainty. Therefore, the need to quantify the future liability may be less important than assessing how likely it is that the risk of liability could materialise in future.
    b. If possible, identify any less-tangible benefits that could result from the transferral to an alternative. The benefits of a cleaner product, process, or technology can be substantial and should not be overlooked when performing a cost analysis.
4) Perform cost analysis of the Annex XIV substance and alternative(s) using the data on costs and revenues collected in Step 1 and possibly in Step 3. (Further guidance on how to ensure the consistency of the cost analysis can be found in Appendix I and Chapter 3 of the Guidance on Socio-Economic Analysis – Authorisation. This provides guidance on dealing with; exchange rates, inflation, double counting and discounting. These are crucial aspects to any robust cost analysis.)

The above points present a generic approach for considerations to asses the economic feasibility of alternatives. In addition, it may be possible to support the cost analysis using financial ratios that may be available as these are the figures that are routinely reported for financial performance of companies (such as for reporting to shareholders or for internal financial reporting). However, in many cases these financial ratios are company wide figures rather than product specific, and furthermore, such figures are not available for the future. Therefore their use is likely to be limited. (Possible financial ratios which can be used for assessing economic feasibility are set out in chapter 3 of the Guidance on Socio-Economic Analysis – Authorisation.)

Apart from analysing if the net present value of the revenues minus costs is positive aplicants may use other methods to document whether an alternative is economically feasible for them, but it is recommended that any such explanation is sufficiently detailed, particularly if the applicant concludes that the alternative is not economically feasible for them. A simple conclusion that the alternative is not economically feasible for the applicant that is not supported by sufficient justification could be considered insufficient by the Agency, particularly if other applicants have identified that alternative as being suitable for them.

The example presented in Box 10 illustrates simple supporting arguments for non-feasibility of an alternative on an economic basis (based on the example above). Note that these are descriptive examples and use in an application would have to be supported by evidence (i.e. data) and/or references.

Box 10. Simple example of supporting information

If the alternative had a negative NPV it could be argued that the alternative was not economically feasible. This may be based on the assumption that the price of the product is unchanged. A qualitative assessment of the market provides some supporting evidence for this assumption that the price will not increase (although references and data where possible should be used for an actual authorisation application).

Current market synopsis of the applicant's product:

- The market for the product produced with the use of Annex XIV substance is price driven by a highly competitive international market (i.e. the use can take place either within or outside EU where no authorisation is needed). There are approximately 60 producing companies, with no single producer having a dominant share of the market. Any increase in the price of the product will mean a substantial loss in demand for the applicant's product. This is because the costs of transporting rival imported products accounts for only a very small fraction of the product price. The threat of imports and competition from rival products ensures the applicant product price does not increase (in order to some on pass on some of the capital costs required to use the alternative) with the overall price remaining sufficiently low to make competing products less attractive than the applicant's product.
- Due to low product prices combined with low entry costs for new entrants to the market, current profitability is kept low by market forces. If sufficient profits were made in the industry then new entrants would have the incentive to enter the market (i.e. enter the market with a lower price to gain market share at the cost of a small reduction in profitability). Therefore if it is not possible to pass on some of the capital costs of the alternative, it is not economically feasible to invest and raise the capital required to use the alternative, even though there will be some savings in operating costs.

The qualitative analysis above only considers the implications of using the alternative to the applicant. Impacts such as unemployment and health benefits are not included because they are not part of the economic feasibility analysis. Guidance on Socio-Economic Analysis – Authorisation is provided in separate document and chapter 3 of that guidance provides further details on how to analyse the market for a substance.

3.8.1. Uncertainties in determining economic feasibility

The evaluation of economic feasibility may be based on the average cost of a substitute at a "typical" or "model" facility. Neither the cost analysis nor the assessment of technical performance are intended to give absolute cost or performance information, but they may result in comparative information on the relative cost or performance of the Annex XIV substance and alternatives. This analysis together with the information on the impact of the substitution costs on the operating margin and on their possible pass over of the costs, would give the basis upon which the applicant can demonstrate whether an alternative is economically feasible for him. However, the uncertainties in the assessment of economic feasibility should be clearly stated in the documentation of the analysis of alternatives. Chapter 4 of the Guidance on Socio-Economic Analysis – Authorisation can be used for guidance on how to carry out uncertainty analysis and Appendix F of the SEA guidance contains several uncertainty techniques which may be relevant when determining if an alternative is economically feasible.

3.9. Research and development that is relevant and appropriate

Article 62(4)(e) states that the application shall include: *an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate, information about any relevant research and development activities by the applicant*;

This means that the applicant should document in the analysis of alternatives of his application any relevant information on research and development that is considered appropriate for the understanding of the Agency and the Commission of the present or future availability of suitable alternatives to the Annex XIV substance. Although not mandatory, it is noted that it is strongly advisable to provide this information if available, in order to strengthen his analysis of alternatives, particularly when it is concluded that there are no suitable alternatives available. Also, the applicant may plan to initiate new R&D and may decide to document this in the application. These plans will play a critical role in fixing the review period. This may be appropriate when no suitable alternatives have been identified. The Commission, when deciding on the duration of the time-limited review, would take this information into account.

This section addresses the consideration of R&D in the analysis of alternatives, it includes consideration of:

- Under what circumstances it would be appropriate to report (document) R&D that the applicant considers to be relevant to the analysis of alternatives;
    - Examples of relevant types of R&D and what they may involve;
    - The costs of R&D; and
- Documenting R&D in the application (see also section 3.12).

3.9.1. Circumstances that might prompt the inclusion of R&D in the analysis of alternatives

The applicant should consider that past, current (on-going) or planned research and development activities are appropriate for inclusion in the analysis of alternatives for example in the following situations:

- The results of past or current R&D activities can be used to support the documentation that sufficient analysis of identified possible alternatives has been made. This is particularly relevant when suitable alternatives have not been identified or have been identified on the market but are not available for the applicant for an immediate substitution..
- R&D related to generating information on risks, economic or technical feasibility of the identified possible alternatives, in order to support the arguments made in the analysis of alternatives.
- When R&D is needed because transferring to the alternative would require major changes in the production processes or in the supply chain; or because the transfer include fulfilling legal product safety or other requirements that may take many years. This may include test trials by the applicant, his suppliers or downstream users, that are necessary to ensure functioning and acceptability of the alternative. While R&D is not mandatory, it should be noted that the finding that no suitable alternatives exist and no plans for R&D are indicated will lead to short review periods. It may also undermine the credibility of the applicant,

particularly if third parties have submitted information about alternatives or other operators in the sector have transferred to an alternative.

- The lack of any possible alternatives may prompt the initiation of R&D on novel substances and/or techniques. Although there is no obligation for the applicant to initiate such research and development, it may be very valuable to show such research has, is being, or is planned to be conducted to support the analysis of alternatives.

In summary, as mentioned above information from any relevant research and development activities by the applicant should be considered appropriate to include in the analysis of alternatives whenever this information can be used to increase the understanding of the Agency and the Commission regarding the reasons for present alternatives being non-suitable and prospects for future availability of suitable alternatives in the uses applied for. The information on research and development will also be taken into account by the Commission when deciding on the duration of the time limited review period.

Below some **examples** are given showing different reasons for presenting R&D on the basis of past, current and future activities:

- Past R&D may be demonstrating why a certain alternative is not technically feasible, or that processes are unable to be adapted to accommodate an alternative. This R&D may take the form of test trails for example. Test trials may also be related to the manufacturing of the alternative. For example, where the R&D has focused on the possibility to achieve the required purity of an alternative substance. Test trials with end products may have focused on the quality of the end product manufactured using the alternative. (For example, in the production of paper, by investigating the possibility of coating drying cylinders without using the Annex XIV substance or with an alternative and testing the quality of paper produced against customer quality requirements.) Past R&D may also demonstrate that possible alternatives are not technically feasible on the basis that they have not been demonstrated to meet legal standards for product safety.
- Ongoing R&D may be able to show that there are efforts being made to search for alternatives, or that currently technically unfeasible or unavailable alternatives are being subject to research on what would be required to make them feasible. For example, what needs to be done to make an alternative available and/or feasible? This may relate to sourcing or production of the alternative or industry and legal requirements that must be satisfied before products can be accepted. This R&D may have addressed what testing must be done and what criteria need to be satisfied before an alternative can be used for a particular function. It should also clearly set out the timing for such product testing and research. In some industry sectors the timing for such product safety development and testing can take many years.
- Future (planned) R&D will have a similar role to ongoing R&D and may be able to show a planned commitment to continued investigation of alternatives that have been shown to be currently not technical feasible or available and investigating what will be needed to make them suitable. R&D could also focus on the continued search for replacements for the Annex XIV substance such as molecular or product design. It may address known, possible or anticipated changes in product design and consumer need. For example, there could be indications of further technological changes that reduce the need for the Annex XIV substance or will make use of the substance redundancy due to trends in industry design or new technology in the longer term.

The applicant may also identify research and development undertaken by suppliers, industry, regulators, universities, research institutes and others by using in-house information, publicly available information and/or by communicating within and outside the supply chain.

The costs of R&D can be considerable and vary widely from sector to sector. Expenditure on R&D may also be the subject of commercial confidentiality. However, the cost of R&D should be considered and may help to show, in cases where there are no suitable and available alternatives, a commitment to replace the Annex XIV substance when that becomes a possibility. The cost of further R&D needed should also be considered within the assessment of the economic feasibility of an alternative.

3.9.2. Documenting R&D in the application

The applicant may wish to consider supporting an application by including details of:

- Results of past relevant research and development activities;
- The current status of relevant research and development activities regarding alternative(s) for the applicant and for other users;
- Planned future relevant research and development for identification of possible alternatives to the Annex XIV substance.

Further recommendations on what to consider in documenting relevant research and development activities is given in section 3.12.

3.10. Concluding on the suitability and availability of alternatives

The analysis of alternatives is the process of determining the suitability of the alternative and consideration of its availability. There are three main aspects that the applicant should assess in relation to the suitability of the alternative for each use applied for:

- reduction of overall risks to the environment and to human health (taking into account the appropriateness and effectiveness of risk management measures);
- technical feasibility for the applicant (based on the alternative fulfilling the specific function); and
- economic feasibility for the applicant (based on the assessment of the economic consequences of transferral to the alternative).

The guidance here is intended to show how the applicant can draw together his analysis and conclude on the suitability and the availability of alternatives. This process focuses on the three main aspects mentioned above. However, it should be borne in mind that according to Article 60(5) not only these but all relevant aspects shall be taken into account by the Commission in assessing whether an alternative is suitable and available. Consequently, the applicant may also decide to include other relevant aspects in his assessment.

The flow diagram in Figure 8 illustrates a process for the analysis of alternatives that may be considered to be step-wise, considering different aspects of an alternative's feasibility, risks and availability separately and bringing these together in a final decision. However, in reality although this may be possible, it is more likely that all these aspects will be considered simultaneously.

Further to this, consultation within and outside the supply chain on alternatives will not be a single process in advance of selecting possible alternatives for further investigation; but rather it will be iterative, with continued consultation and information gathering at each stage of the process.

The alternative must represent a reduction in risk compared to the Annex XIV substance. The alternative must also be technically and economically feasible. For risk, the evaluation is one of comparing the alternative with the Annex XIV substance. In terms of technical and economic feasibility, the evaluations are whether the alternative is viable for the applicant, including if relevant his downstream users in the uses applied for. The applicant can refer to any of these aspects or combination thereof when demonstrating that an alternative is not suitable.

The applicant should show and document analysis of these aspects, but the extent of the different parts of the justifications that should be provided by the applicant will depend on the specific circumstances of the case. If the applicant concludes that there are no suitable alternatives, then the analysis of alternatives should clearly document the reason why no such alternatives exist. For example, the applicant should document in as much detail as possible why identified alternatives resulting in an overall reduction of risks were not technically or economically viable for him. In addition, in this case the applicant is encouraged to provide information on planned or ongoing R&D activities concerning potential alternative substances or technologies. In these cases it is not necessary to explain in full length the examination of the risks of such potential alternatives.

The level of detail will of course depend on the relative importance of each aspect in determining the alternative as not suitable. For example, it may be clear to the applicant that all technically feasible alternatives do not represent a reduction in risk as compared to the Annex XIV substance. In this case there would of course be little merit in detailed analysis of the economic feasibility of those alternatives that are not suitable on the basis of the risks.

The focus of the analysis will be the compilation of the information from the assessments of the various aspects of the alternatives and weighing them together and considering any possible trade-offs between them in order to draw a conclusion on the suitability and availability:

- Compilation of the results of the assessments of technical feasibility, economic feasibility and risk; comparing the Annex XIV substance and the alternatives;
- Compilation of information on the uncertainties in the data that should be considered in the decision-making process;
- Identification of the possible ‘trade-offs’ between technical feasibility, economic feasibility and risk; comparing the original substance and possible alternatives. For example, some reduction in end product performance resulting from the use of an alternative could be acceptable (subject to, for example, product safety approval) on the basis of the reduction in risk and the decreased costs in exposure control; and
- Consideration of the availability of suitable alternatives: e.g. whether there is enough of the alternative available at a certain point in time and if it is accessible to the applicant.

Alternative techniques can be regarded as available when they are developed enough to allow implementation in the relevant industrial sector and they are reasonably accessible without undue delay to the operator. Alternative substances can be regarded as available when they are reasonably accessible without undue delay to the operator in the required quantity (i.e. the global production capacity should not be severely constrained due to the new demand). To be considered available, both techniques and substances have to fulfil the relevant legal requirements (e.g. a substance may need to be registered in accordance with REACH before it can be manufactured, imported, placed

on the market or used; or the change of the substance used in production may require approval under other legislation; a major change to the production facility may require a permit in accordance with the IPPC-directive.)

An important issue in identifying the availability of alternatives is also timing: alternative substances may not be available immediately or they may not be available in the required tonnages but could become available in the market at some point in the future. To assess this, knowledge of the quantities, relevant markets and the current trends and research within them would be useful. On alternative techniques the same basic consideration applies: is the necessary equipment or technology already available in the market in sufficient quantities? The time needed to invest, install and make alternative techniques operational should be considered. This applies also to alternative substances that need changes in processes or equipment. In both cases fulfilling the legal requirements may require time.

When assessing the time constrains the applicant will have to consider the sunset date, i.e. the date from which the placing on the market and the use of the substance is prohibited unless an authorisation is granted. The sunset date will take into account, where appropriate, the production cycle specified for that use (Article 58.1(c)(i)) and will be at least 18 months after the deadline for receiving the authorisation applications (Article 58.1(c)(ii)). Should the substitution be possible before the sunset date, the alternative will be considered available from this perspective.

For the reviews of authorisations the holder of an authorisation will have to submit an update of the analysis of alternatives taking into account any new possible substitutes. He should verify the grounds for concluding on availability (or non-availability) of suitable alternatives referring also to the list of recommended actions to make possible alternatives suitable and available (see section 3.11), contained in his original application. It should be noted that under the SEA route authorisations will have to be withdrawn when suitable alternatives exist for the holder of the authorisation, having due regard to the proportionality principle.

Box 11 sets out some considerations on suitability and availability of alternatives for different types of applicants and for a third party.

Box 11. Availability of suitable alternatives for different actors

The consideration of whether an alternative is *available* will depend upon the perspective of different actors in the authorisation process. For example:

Manufacturer/importer (M/I) as the applicant: The M/I should not *a priori* take the view that any alternative that is not or cannot be part of his product portfolio is not an alternative that is *available* to him. He will need to consider what alternatives may be *suitable* on the basis of technical and economic feasibility, considering possible alternatives from outside of his portfolio and even from outside of his sector (for example, possible alternatives for one or more uses that he may be applying for may be a change in process or a technical alternative rather than a substance). He may also wish to consider the suitability of the alternative for other parts of the supply chain.

Downstream user (DU) as applicant or contributor to an application: The DU, who is in perhaps the best position to understand his use most fully, may not be familiar with the supplier's portfolio, and be only aware of what alternative(s) is(are) technically and economically feasible for his use(s).

Third party, contributing information on alternatives: The third party may have less resource for investing in research to understand all the possible alternatives but may have experience of what may be suitable or available for broad uses. Note, however, that third parties could be suppliers of alternatives. In this case they may have the full technical knowledge of the alternative. However, they have to submit information on alternatives on the basis of 'broad information on uses' on the Annex XIV substance published on the Agency's website. Therefore, the information may not be able to be tailored to the specific uses that are the subject of the application.

As set out in Figure 8 in section 3.4, if the applicant's analysis of alternatives concludes that suitable alternatives are available, an authorisation cannot be granted in accordance with Article 60(4) ('socio-economic route').

3.11. Actions needed to make possible alternatives suitable and available

If the analysis of alternatives demonstrates that currently there are no alternatives or the possible alternative(s) is/are not suitable or available, the applicant should provide the following additional information:

- a list of actions that are needed to make a possible alternative(s) technically or economically feasible for the applicant and a timetable in which these actions can be implemented taking into account investment and operating costs required; and
- research and development activities needed, e.g.:
    - What research and development activities are needed and/or planned to develop an alternative substance(s) or technology(ies), or develop equipment or processes enabling the use of alternative(s); and
    - What testing must be done and what criteria need to be satisfied before an alternative can be used for a particular function – including clearly setting out the timing for such product testing and research.

The inclusion of the additional information listed above would support the applicant's assessment that the alternatives are not available for the applied-for uses within the given timetable. It will also be taken into account when fixing the review period of the authorisation. The actions needed for

making a non-suitable and/or non-available alternative into a substitute will most likely have been considered by the applicant in determining the various parts of the analysis of alternatives. For example, in the consideration of technical feasibility the applicant will have determined why the possible alternative is not technically feasible for him and on what basis. It may be that the alternative is not technically feasible because it has not yet satisfied the legal safety or performance criteria that are required for the end product. Here the list of actions would include what needs to be done for the alternative to be allowed to be used and the timetable necessary for these actions. Furthermore, the possible costs of such actions may well have been considered in the assessment of the economic feasibility of the alternative, or may be available in an SEA.

In the list below some examples are given of situations where the applicant should include information on actions needed to make the alternative suitable and available (this list is not exhaustive):

- The transfer to the alternative requires investments that take considerable time (time needed to plan the necessary changes, to purchase the equipment needed, to build any constructions, to install, to train the personnel, etc.);
- The transfer to an alternative substance requires regulatory approval (e.g. production of aircraft or medical equipment), or change to an alternative technique requires a review of a permit (e.g. under the IPPC Directive);
- The transfer to an alternative requires customer approval (e.g. for use in products that must be tested for technical performance over long time periods, or where the transfer to an alternative up in the supply chain may affect the quality of the end products and testing by several downstream user levels is required);
- An alternative substance is currently not produced in sufficient quantity ; and
- Costs related to investment in new equipment/techniques may depend on other planned investments, age of the current equipment, etc.

Example 4 illustrates, for a hypothetical substance and situation, how the applicant identified the actions that may be needed to make a possible alternative suitable and available.

Example 4. Actions needed to make a possible alternative suitable and available

Scenario description

Substance H (a vPvB substance) is an active ingredient in coatings that are used to prevent corrosion in commercial/industrial machinery. The coatings are used in production of the machinery and also for professional maintenance and repair of machines. Substance H is only used professionally by trained technicians and exposure of workers and the environment to substance H is well controlled both during machine manufacture and repair and maintenance. The CSR details the operational conditions and risk reduction measures in place. The applicant is the downstream user of the substance.

There are very prescriptive legal safety requirements that mean that any change in manufacture, maintenance or repair of the machines is subject to considerable safety criteria and legal requirements. Addressing the safety criteria and legal requirements takes a minimum of five years.

The machines have a long service life (30+ years, if well maintained). The continued use of the Annex XIV substance is required to maintain and repair machines during their service life. As there is no available alternative that is technically feasible, a refused application would mean that machines would be manufactured outside the EU and existing machines could not be repaired and maintained and therefore would not be available for use.

Alternative that is not technically feasible for the applicant

There is a possible substance alternative that may be used to replace the function of the Annex XIV substance. However this alternative has not been subject to any safety testing, so it is not yet shown to be technically feasible or available for the applicant (or anyone) to use for the desired function.

The identification of actions needed to transfer from the Annex XIV substance to the possible substance alternative

This includes what testing has currently been done on product safety and what further work is required for it to satisfy product safety legislation (noting that the alternative may fail to fulfil the product safety requirements). It also includes a description of the time required for product safety testing. To document this, the applicant sets out (in the analysis of alternatives report in the application):

- The safety requirements that must be met;
- What product safety testing has been done and what the results were for the possible alternative;
- What further testing needs to be completed for the legal requirements to be met; and
- The time-line for the completion of the testing programme for the possible alternative.

The task here is bringing together of all the aspects of the alternative that lead to it being concluded as not suitable and not available and assessing what would have to be done to make it a suitable and available substitute. The applicant will have concluded that these actions are not currently possible; otherwise he would not have concluded that there are no suitable and available alternatives. Therefore, for each aspect of the evaluation of alternatives (i.e. technical and economic feasibility, reduction in risk and availability of the alternatives) the applicant can consider the actions and timescale required to make the alternative suitable and available. Table 8 illustrates hypothetical examples of how the information may be summarised.

Table 8. Hypothetical examples of summaries of actions needed to address the suitability and availability of possible alternatives

Aspect of	Outcome of analysis of	Action to address suitability/availability

analysis	alternatives	
Technical feasibility	Not feasible on the basis that the required purity of the substance cannot be achieved (see: ref to reported R&D and assessment of technical feasibility).	R&D is addressing the possible methods that may be able to provide the required purity (99.9%) at the volumes needed. These include: • 'Method 1' • 'Method 2' • 'Method 3' The method that indicates that the required purity can be achieved will be subject to R&D to investigate the possibility to scale the production to deliver the required volume. Actions required with indicative timescales are: • Completion of lab scale R&D to determine which method can be used to deliver the required purity: x to y months. • Confirmation of lab scale results on purity: x to y months. • Planning of pilot plant for initial production: x to y months. • Pilot scale production on-line and conformation of purity: x to y months. • Product testing and customer approval: x to y months. • Commercial scale production initiation to x% of required tonnage: x to y months. • Scale up to full commercial production: x to y months. Total timescale required x to y months/years. Details of the proposed R&D programme are at (ref).
Economic feasibility	Not feasible because introduction of the technical alternative would mean that no currently used equipment could be used (i.e. this would mean that the current assets would be zero as sale value of equipment would be very limited). The replacement would mean re-housing and relocation of all users. The investment in capital and operational costs are too large to be borne by any users. This prevents the possibility of costs being passed onto the customer, because the economic barrier is the investment costs to accommodate the alternative. Phase out/phase in is not possible as the systems are so different (see economic feasibility analysis - ref)	The capital and operational costs could only be overcome by very large financial investment in the industry, which is currently not possible (as essentially this would mean firms changing the business they are in). This would require considerable financial assistance for phase out of the Annex XIV substance and phase in of the alternative over at least an x year period. Actions required (with indicative timescales) to overcome the financial barriers to substitution for each of estimated 200 users are: • Identify possibilities for re-housing/relocation possibilities required to house and operate new equipment (approx. cost to each user firm depending on location € x to y): Possible timescale: x to y months. • Investment in new equipment required to accommodate alternative (approx. cost to each user firm € x) – action to find funds or investor: Possible timescale: x to y months. • Set up and testing of equipment and facility (including, relocation, recruitment, training/retraining, detailing and documentation of new operating procedures, health and safety and other legal requirements). Approx. cost to each user firm depending on location € x to y). Timescale: x to y months. • Customer approval for use of alternative, including product testing. Approx. cost to each user firm € x. Timescale: x to y months. Estimated cost per user facility ranges from € x to y M per user firm (total estimated cost (i.e. for 200 firms) ranges from € x to y billion). Estimated timescale ranges from x to y years for each user.

		(Details of the financial analysis are presented in the analysis of alternatives under the assessment of economic feasibility)
Risks to human health and the environment	The alternative has not been demonstrated to represent an overall reduction in the risk to human health and the environment as compared to the Annex XIV substance. This is because the alternative is a nanoparticle for which the possible risks to human health and the environment have not yet been fully understood. There is evidence to suggest that release to the environment and exposure to workers could cause risks. However, the control of risks is still uncertain since the hazards are not well understood and the operational conditions and risk reduction measures are not yet developed (see consideration of risks of the alternative - ref)	Understanding of the hazards and exposure presented by the alternative is required before appropriate control measures can be developed to ensure that the possible risks from the alternative are adequately controlled. This is possible but is dependent on further research and development of appropriate tests to determine the hazards of such materials and development of appropriate exposure control measures. Actions required to determine the human health and environmental safety of the alternative are: • Completing of documentation of the test methodologies for determining the environmental hazard of nanoparticles. This is being completed by an international initiative. Timescale for completion of ring-test for aquatic toxicity testing: x year/s. • Publishing of test guidelines that can be used by industry: x years. • Development of test programme to determine the environmental (aquatic toxicity) hazard – x year/s. • Completion of test programme for human health hazard: x year/s*. • Development of risk reduction measures for the effective control of emissions to the environment: x years • Development of occupational control measures for workplace exposure: x year/s*. (*Human health testing programme and development of controls could be planned and conducted at the same time as the environmental testing.) Total time required to be able to assess the risks and develop effective control measures – x years.

Note: Entries in the table are summaries for different hypothetical alternatives and situations. Each aspect is considered individually. However, the total actions and time required to make a possible alternative suitable and available should include consideration of all the aspects that have been identified leading to the conclusion that the alternative is not suitable or available. Some actions may be conducted at the same time.

3.12. Considerations for documenting the analysis of alternatives

REACH does not specifically describe the minimum documentation required for the analysis of alternatives. However, Article 62(4)(e) sets out the information on alternatives that shall be part of the analysis. This includes consideration of the risks of alternatives and the technical and economic feasibility of substitution and, if appropriate, information on any relevant research and development activities by the applicant. Furthermore, the applicant should note that according to Article 60(5) the Agency's opinions and the Commission's assessment of the application with regard to the suitability and availability of alternatives is not limited to reduction in overall risks or technical and economic feasibility of the alternative, but will take all relevant aspects into account. This could for example include information on alternatives from interested third parties. Therefore, in order to demonstrate that adequate steps have been taken to identify possible alternatives or to demonstrate whether or not possible alternatives are suitable and available the applicant would be well advised to document a comprehensive analysis of all possible alternatives and take all relevant aspects into account.

It is important that the documentation is clear and transparent. This means that for each part of the analysis the applicant should try to present the information in a logical way that describes how they came to their conclusion on each aspect of the analysis. It should present the information used to come to decisions, including data/information gaps and assumptions made, as well as provide explanations and justifications for the conclusion made addressing the uncertainties, and reference the material that has been used. In this way the Agency can see what is being presented, what assumptions have been made, what conclusions are drawn and how those conclusions were drawn.

Information on appropriate research and development activities could be included under the most relevant heading for each separate case. For example it could be addressed under section 2 on the analysis of substance function or under section 4.1 on the assessment of technical feasibility of alternatives. The applicant may also consider adding a separate heading for research and development, e.g. under section 4 on the assessment of suitability and availability.

The guidance below is intended to be an indication of what could be documented for each aspect of the analysis of alternatives following the structure of the analysis of alternatives format published on the Agency's website. Under these headings the applicant should document the results of his analysis for each use applied for (noting that he may indicate which data he regards as confidential).

Summary of the analysis of alternatives

This section could present a summary of the findings and conclusions of the analysis regarding the identification of possible alternatives and the suitability and availability of alternatives for each use applied for. Furthermore, any findings on actions needed to make possible alternatives suitable and available and the timescales for these actions should also be included.

Introduction

The applicant could use this introduction to describe any appropriate background information for the analysis of alternatives.

Analysis of substance function

Detailed information should be presented on the precise functions or tasks performed by the Annex XIV substance for each of the uses applied for. This should also include a description and outcome of the process where the use is applied and under what process conditions the function must be performed. Examples of functional requirements to take into consideration may include: critical substance properties related to the desired equivalent function, quality criteria, process and performance constraints, customer requirements or legal requirements for technical acceptability.

For all functions the applicant may wish to report any obstacles or difficulties identified or expected in relation to finding possible alternatives and their consideration as substitutes.

Identification of possible alternatives

The possible alternatives identified for each use should be presented and described in detail in this section. For substance alternatives this would include the identity and a summary table of relevant properties. For technical alternatives a description should be given of the technology to be

introduced in order to achieve the same function as the Annex XIV substance, or to possibly remove the need for the Annex XIV substance function altogether by other changes to the process.

A description of the data searches and consultations that have been made should be included. In particular in cases where no possible alternatives have been identified this documentation needs to be detailed and thorough. In such cases also including information on research and development activities supporting the lack of possible alternatives would be appropriate.

Data searches

The extent and results of searches for data and information on possible alternatives should be detailed and in particular how these were incorporated into the analysis of alternatives.

Consultation

The applicant may wish to document consultation undertaken during the analysis. Such documentation should be transparent and auditable. When documenting the communication to support an application the applicant may wish to include:

- Details on which parts of the supply chain have been consulted;
- Details on other organisations that have been contacted;
- Details on the possible alternatives that have been identified through this process and evidence of (non)availability of (suitable) alternatives.

Technical feasibility

Technical feasibility is a key aspect for determining the suitability of alternatives. Here the applicant needs to present a transparent analysis of technical feasibility of alternatives in terms of the possible provision of equivalent function. There may be a number of alternatives for different uses, therefore the applicant must clearly document the consideration of the technical feasibility for each use that is being applied for and consider each alternative for that use in turn.

If an approach developing technical feasibility criteria has been taken (see Box 3 section 3.6), the applicant should clearly document how the criteria for equivalent function were applied to possible alternatives to determine technical feasibility. For example, which data were used (citing the sources) and how they were used including any assumptions made, i.e. what was the process by which criteria were developed and applied.

The applicant should also document the process changes required for possible transfer to the alternative as well as the requirements for equipment, risk management measures, energy, personnel changes and training needs (amongst others) and how these affect the technical feasibility of the alternatives.

The analysis will be different depending on who the applicant is. For example, the technical feasibility of an alternative may depend upon process changes, use of equipment or risk reduction measures that are available to the manufacturer but not to downstream users for technical or economic reasons. An important consideration will be the uncertainties in data evaluation and how these have been dealt with. The applicant should clearly indicate the effect that these uncertainties may have on the assessment of technical feasibility.

Reduction in overall risks to human health and the environment

An important consideration for documenting the assessment of the reduction of overall risks to human health and the environment by use of possible alternatives will be what data have been used to compare the risks of the Annex XIV substance and the alternative. For example as mentioned in section 3.7, there is likely to be less information available on alternatives than there is for the Annex XIV substance (but noting that if the alternative has been registered and a CSR has been carried out, there may actually be a similar amount of information on the risks as for the Annex XIV substance). Therefore, the documentation will need to set out how the assessments have been conducted, what data were used and what assumptions have been made (for example the use of assessment factors for hazard data and conservative emissions for exposure scenarios).

Further to this, how any comparison between risks of different types has been dealt with will need to be described and clearly documented. For example how have different health effects or different environmental effects been compared and weighed against each other? For alternative technologies, where the risks may be physical such as temperature or vibration, how have these risks been compared to toxic risks of the Annex XIV substance? The conclusions drawn on the possible reduction in risk to human health and the environment will need to be supported by the data used; highlighting the uncertainties within those data and how they have been addressed.

Economic feasibility

As with technical feasibility the evaluation of economic feasibility is from the applicant's perspective. It will be important, for each use, to set out how the analysis has been conducted detailing the data and the methodology used for analysis. It will also be important to set out the perspective of the analysis, as the economic feasibility of an alternative may be different for a downstream user compared to a supplier. For example, a downstream user may be able to easily consider the economic feasibility of an alternative (provided it is technically feasible and reasonably accessible) by assessment of the direct cost of possible transfer. However, for a supplier this could mean having to implement changes in production process and the loss of customers for the product related to the Annex XIV substance that cannot switch to the alternative and, as such, the analysis would be more complex. The analysis will therefore be different depending on who the applicant is. As such, the documentation of the assessment of economic feasibility will need to clearly set out the boundaries of the assessment and show the reasoning for the setting of these boundaries.

The documentation of the assessment of economic feasibility will need to set out the sources of data and importantly the uncertainties in the data sources used and how these have been dealt with (i.e. what the assumptions are).

Research and development activities

When documenting any relevant research and development activities, for example the following issues should be considered:

- What is the purpose of documenting the R&D?
    - Demonstrating that a possible alternative is not technically feasible for an applied use.
    - Demonstrating that the alternative does not satisfy product safety legislation or rules.

  - Demonstrating research and development on novel substances and/or techniques to show that such research has, is being, or is planned to be conducted to support the analysis of alternatives.
- Who did/does/will do the R&D, who was/is/will be participating/consulted (e.g., in house, trade organisation, commissioned or from literature only)?
- What was/is/will be done?
- What were the results/findings?
- What were the changes implemented and other follow-up actions taken?

The applicant should note that he may indicate parts of the application that are confidential {Art. 118 and 119}. This may be of particular importance with regard to research and development on possible alternatives, but also other confidential information that he considers would have a detrimental affect on his business, if they were to be made public (see Box 2).

Conclusions on suitability and availability of alternatives

The documentation of the steps taken to identify whether alternatives are suitable and available will need to set out that a sufficient analysis of alternatives has been conducted. Clear reasoning and transparent documentation will be essential to demonstrate that a proper consideration has been made of the technical and economic feasibility, reduction in overall risks and availability of alternatives.

This is especially important in cases where the conclusion is that no suitable alternatives are identified. In these cases the applicant should also provide information in the report on what actions and time scales are needed to make the alternative a suitable replacement for the Annex XIV substance in the uses applied for.

Actions needed to make a possible alternative suitable and available

This section should include a presentation of a list of actions that would be needed in order to make the alternative(s) technically and/or economically feasible, and available in the uses applied for, including the time frame required for these actions to be implemented as well as potential obstacles (see section 3.11 and Table 9). This should apply in particular in cases where the conclusion is that no suitable alternative is available for the applicant but there is a suitable alternative available on the market although not yet ready for an immediate substitution (i.e. within the "sunset date") or another operator in the same market is already or will switch in the short future to alternatives. This information will be considered for determining the review period of the authorisation decision.

3.13. Links to other parts of the application

3.13.1. Substitution plan

If an application under the adequate control route concludes in the analysis of alternatives that a suitable alternative(s) is available, then the applicant must prepare a substitution plan that sets out

his commitment to transfer to that substitute(s), setting out the timing and other considerations for transferral. Guidance for how to produce a substitution plan is set out in Chapter 4 of this guidance.

3.13.2. A socio-economic analysis (SEA)

An SEA is required for applications under the SEA route and can also be submitted in the case of applications under the adequate control route on a voluntary basis. Guidance for compiling an SEA in support of an authorisation application and submission of an SEA or input to one from a third party as part of the authorisation process is set out in the Guidance on Socio-Economic Analysis – Authorisation.

A key link between the analysis of alternatives and the SEA will be communication with the supply chain on the possible response to an authorisation not being granted. For example, this may lead to the use of alternatives that were found to be unsuitable. The SEA may have to consider the socio-economic impact of such a scenario. Another key area is the comparison of the safety of alternatives with the Annex XIV substance (see section 3.7, Box 5). While the analysis of alternatives is focused on the Annex XIV substance function and whether this can be replaced or made redundant; the SEA may need to consider a wider boundary. This may be considering the consequences of use of an unsuitable alternative or the wider consequences of removal of function in end-products. This would usually be beyond the scope of the analysis of alternatives. However, the SEA assessment of health and environmental impacts could be used in the analysis of alternatives to assist in the decision regarding comparison of risks for substances following the SEA route.

The applicant is advised to consider what he will need to consider in his SEA at the stage where he is gathering and analysing information for the analysis of alternatives. This will help to optimise data gathering and help the applicant to have a wider consideration of possible alternatives to the Annex XIV substance, especially where there are possibilities to make redundant the use of the substance by changes in end-product. Key phases of the analysis of alternatives where links to the SEA are particularly important are indicated in the guidance, especially in:

- section 3.3 on the focus and scope of the analysis of alternatives;
- section 3.5 on how to identify possible alternatives; and
- section 3.7 on comparing the risks of the alternative with the Annex XIV substance.

3.14. Presenting the documentation of the analysis of alternatives to the Agency

Applications should be made via the Agency's website. Applications can be prepared as indicated in the user manual(s) made available on the ECHA's website. Supporting documents such as the analysis of alternatives and an SEA should be appended to the application.

4. PLANNING FOR SUBSTITUTION: GUIDANCE ON SUBSTITUTION PLANS

4.1. Introduction

If the applicant has found a suitable and available alternative to the Annex XIV substance for a use(s) for which he is applying for an authorisation under the adequate control route, he must provide a substitution plan. A substitution plan is **a commitment to take the actions needed to substitute the Annex XIV substance with a suitable alternative substance or technology within a specified timetable.**

The information contained within a substitution plan will be used by the Agency Committees when forming their opinion and by the Commission when considering granting an authorisation and it will be taken into account when determining the duration of the time-limited review period of an authorisation decision[29].

This section of the guidance addresses the preparation of a substitution plan in accordance with {Art. 62(4)(f)}. It encompasses guidance on the following elements:

- Scope and contents of a substitution plan
- How to prepare and document a substitution plan:
    - Identifying the actions required for substitution.
    - Defining a timetable for those actions.
    - Documenting the plan for submission with the application.

Figure 10 illustrates the overall proposed process of developing a substitution plan; including consulting with downstream users/the supply chain, where relevant, to get necessary information and to ensure that it is workable; documenting the plan; and submitting it with the application. The figure also includes later stages (i.e. post granting of an authorisation) relating to initiating the introduction of the substitute and updating the plan as a result of authorisation conditions and for the authorisation review process. However, the guidance set out here focuses on the preparation and documentation of the substitution plan that is presented as part of the application.

[29] Various other factors are taken into account in determining the duration, as set out in Article 60(8), see Section 1.5.5. Note that the holder of an authorisation has to comply with any conditions of the authorisation. This may require him to take different actions than he had presented in his substitution plan included in the authorisation application. However, once an authorisation is granted there is no obligation to re-submit an up-date of the substitution plan, until the authorisation is due for review.

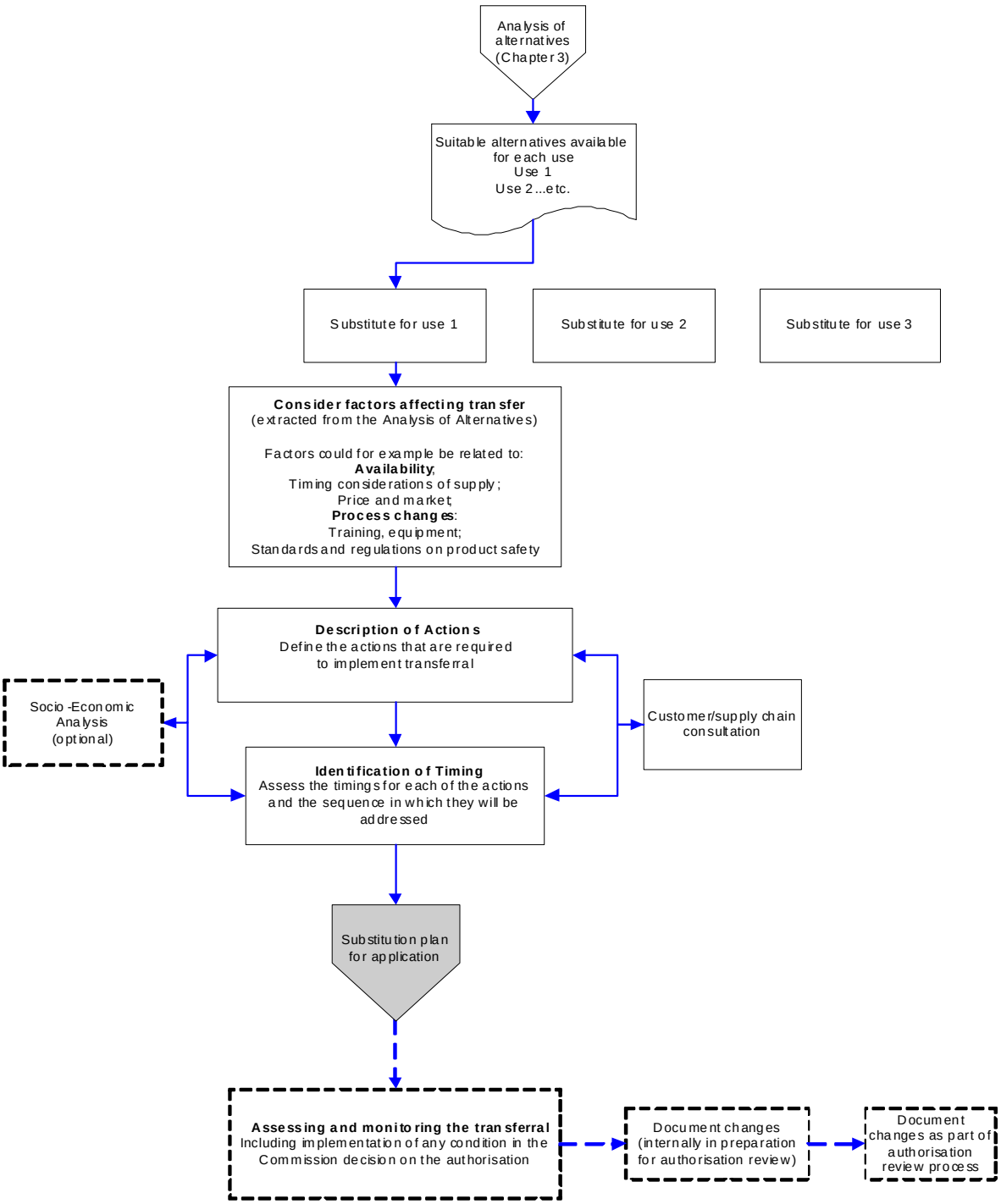


Figure 10 Flow diagram for preparing and implementing a substitution plan

4.2. Scope and contents of a substitution plan

A substitution plan can only be developed for those uses for which a suitable alternative is available to the applicant. It should be noted that different alternatives may be suitable for different uses applied for, so a number of substitution plans may need to be developed and included in the authorisation application. The overall process of preparing and submitting a substitution plan is expected to be similar amongst different types of applicants (e.g. M/I or DU).

The key elements of the substitution plan are the list of actions required for transferral to the substitute and the timing for those actions. The substitution plan therefore needs to include:

- A description of proposed actions and justifications why those actions are required;
- Who will conduct the proposed actions;
- A timetable for proposed actions that will lead to transferral to the substitute and justification why the actions require the time allocated; and
- What the uncertainties are in achieving the actions within the timescale and what possible mitigation is to be considered.

4.3. Preparing a substitution plan

The preparation of the substitution plan involves a number of activities summarised in the bullet list given below. It should be noted that the order of the bullets do not imply that they should be carried out following that sequence. Especially supply chain consultation will have been an important part already in the analysis of alternatives and will be crucial also in detailing the actions for the substitution plan.

- Identifying the factors affecting the transfer to the substitute(s);
- Determining the actions required for transferring to the substitute;
- Determining what time is needed for each of those actions;
- Consultation with the supply chain on actions and timings;
- Planning the management of the actions including consideration of uncertainties and mitigation; and
- Identifying how to follow up the progress of the plan.

Each of these aspects is considered in the sub-sections below. In Appendix 6 a possible check-list for a substitution plan is presented. This list is intended to assist the applicant in planning how to develop a substitution plan and identifying the essential issues to be considered.

4.3.1. Factors affecting the transfer to the substitute(s)

The main factors that affect the suitability and availability of the alternative will have been addressed in the analysis of alternatives. Therefore, the substitution plan should be based on the considerations of these factors for the alternative and especially on how these different factors may

influence the actions needed and the timing for the transfer to the substitute. Some examples are given below:

- Availability (considered in the assessment of availability in the analysis of alternatives): How soon can the substitution be made based on current markets? The substitution plan will need to take account of the ability of the market to supply the substitute and within which timetable. The transferral will be dependent on continuing supply of the substitute. The possibility of the substitute being phased in could also be taken into consideration.
- Price and the market (considered in the assessment of economic feasibility in the analysis of alternatives): For example how potential changes in the market for the alternatives may change the availability of the substitute (perhaps not considered in the analysis of alternatives in the wider context of the supply chain). This may also have links to a supporting SEA that considered the wider impacts of transferral in terms of socio-economic impact and may consider more complex analysis of a justification for the timing of transferral.
- Process change (considered in the assessment of technical feasibility in the analysis of alternatives): Changes in equipment and production processes (including training and health and safety considerations) may be required to accommodate the use of the alternative. In some cases this may take considerable time and resource.
- Process change (considered in the assessment of technical feasibility in the analysis of alternatives): Regulations, standards and customer requirements may require testing and changing of operating procedures as well as product safety requirements. These factors require actions that have a considerable influence on the timing of the plan (for example legal product safety requirements can often take substantial time to complete).

The appraisal of these factors will enable actions to be defined on how these factors can be addressed so that the substitute can be transferred to, in a way that is achievable and manageable for the applicant. This appraisal can then be used for the derivation of the justification required for each action and/or the time needed for the action in the documentation of the substitution plan.

4.3.2. Defining the actions

The actions are defined as individual tasks or sets of tasks that address distinct aspects of the transferral process. It is recommended that the list of actions should contain the following elements:

- A series of actions proposed by the applicant (though not necessarily always for the applicant to undertake) to carry out the substitution.
- A proposed timescale/date for the completion of each action (see section 4.3.4 below).
- A justification statement to present the rationale behind each action/timescale proposed by the applicant.
- Detail of uncertainties associated with actions and possible problems that may affect the actions or the timing of actions. This should include consideration of measures that can be put in place to mitigate any problems that may arise.

- A process for reviewing progress against the proposed timetable for the actions. This assists with investigating reasons for lack of progress and with planning and initiating corrective actions when the plan is in progress.

4.3.3. Identifying and setting progress markers

The identification of critical actions or groups of actions that must be completed in order to ensure that the substitution can be carried out in practice will facilitate the development of the substitution plan and later support its implementation. Progress markers ('milestones') essentially represent the completion of key stages (e.g. groups of actions) in the plan and allow progress to be measured and assessed against the timetable of the substitution plan. It is useful to document these milestones in the substitution plan as this will help the Committees in assessing the effectiveness and practicality of the substitution plan.

It is important to bear in mind when setting milestones that, whatever milestones are chosen, they must be relevant to the analysis conducted earlier in the development of the substitution plan (i.e. to those elements to which the most significant uncertainty or highest level of risk are attached or on which the success of the overall substitution plan depends).

The next stage is determining what review criteria will be used. This can be as simple as assessing whether or not a milestone target has been achieved in line with the proposed timetable. In more complex substitutions, a broader set of review criteria may be warranted such as:

- Is the project on target with the proposed timetable?
- Are all outstanding actions from the last review complete?
- Have all high risks (to the substitution plan) been mitigated? If not how many remain?
- Are all interdependencies currently being managed?

Such criteria as given above are illustrative only and should be set in discussion with supply chain stakeholders in the substitution plan. Documenting in the substitution plan how the applicant plans to follow up and document the progress against the plan increases the credibility of the plan and will facilitate in the update of the plan for the review of the application (if and when appropriate).

4.3.4. Defining the timing of the plan

The timetable for actions can be drafted using a number of methods. At its simplest it could be a short list of key actions and associated timescales.

The key element of the substitution plan timetable is the start and end dates for the identified actions. Both are critical and must be made with full and appropriate consideration of the factors affecting the transfer to the substitutes and the uncertainties that should be identified in the preparatory work to produce the substitution plan. The setting of an end date (i.e. the date at which completion of the substitution plan is made) should be guided by the development of the list or series of actions and individual dates for completion of each of these actions.

For each action that has been identified, it is required that the substitution plan contains a justification made by the applicant as to why such an action is required and a justification for the time allowed for it to be implemented. In many cases this may be obvious (for instance, the supply

of sufficient quantities of the alternative(s) may take a certain amount of time). In other cases, the justification may be more complex and draw upon information from a wide range of sources.

When setting the timetable it may be important to consider issues such as (list is not exhaustive):

- Periods of stakeholder consultation and/or information dissemination;
- Potential delays from other parties, particularly where information is being supplied by another company or person outside of direct programme/project control;
- Customer approval timescales (for example industry standards); and
- Other legislation (e.g. that affects the final product).

4.3.5. Communication with the supply chain and customers

In developing a substitution plan, good communication with key stakeholders in the supply chain is in many cases important to ensure that the plan will be practical and implementable. Supply chain communication will also be important for gathering information to identify the actions needed for substitution and timings for those actions and to understand the conditions necessary for these actions to succeed.

It will be important for all relevant parts of the supply chain to be aware of the need to replace the substance and input to the development of the plan. An applicant that is a manufacturer of the Annex XIV substance may, for example, benefit by taking into account his customers' or suppliers' needs in developing the substitution plan.

The presentation of information on communication could be used in the justifications for actions needed, where appropriate, to demonstrate that the substitution plan, and especially the timetable, has a practical basis and takes into account implications for the supply chain and end users. It can also be used to show how the applicant and downstream users intends to carry out the substitution in the uses applied for in accordance with the timetable set out.

4.4. Documenting the plan

The format of the substitution plan is not set out in the REACH Regulation. Due to the nature of the substitution plan the structure must be flexible to meet the requirements of the application. For the five part outline suggested below (and illustrated in a format published on the Agency's website), the applicant is prompted by questions to set out the detail of each aspect of the plan, so that a full documentation of the plan may be presented to the Agency/Commission in the authorisation application.

- Part 1) Use and substitute;
- Part 2) Analysis of factors affecting transferral;
- Part 3) Actions required for transferral with a time-plan;

- Part 4) Links to other parts of the application[30]; and
- Part 5) Internal monitoring

It may be helpful to document a summary of the justification for actions to be taken and the actions themselves in the plan. In many cases, a simple table of issues referenced to justification statements may be sufficient to demonstrate a considered approach with suitable transparency. In others, a more complex approach may be required. An example is provided in Box 12.

[30] Especially links to the analysis of alternatives, but there may be links to other parts of the application. For instance, there may be links to a voluntarily submitted SEA, as some of the reasons why the transfer to an alternative requires time may be of a complex socio-economic nature.

Box 12 Summarising actions of the substitution plan and their justifications

Table A Example of an action list summary table

Ref.	Factor affecting transferral	Proposed Action	Resource	Review	Timescale
	Keep this brief and if necessary, refer back to other documents or parts of the substitution plan	*When proposing actions, focus on succinct statements including the following:* *Indication of any uncertainty/how this will be managed.* *Links to any proposed mitigation measures.*	*Who is responsible for completing the action.* *Availability of staff resources*	*Who is responsible for reviewing the action*	*This may be a date or a timeframe (e.g. within 6 months)*
A1.1	Sufficient supply of alternative substance	Agree contracts in principle with supplier to allow sufficient quantities to be developed. Monitor progress through regular meetings.	Suppliers in place and staff availability for undertaking work confirmed	Manager/skilled person in place to review decisions	12 months
A1.2					
A1.3					

Table B Example of an action list justification statement summary table

Ref.	Rationale/Justification	Additional Reference
	When writing the justification try to consider the following elements: *Why the action is required?* *What additional information supports the action?* *Are there any constraints relating to the action (e.g. resources).* *The rationale behind setting any dates for completion?* *Estimation/quantification of the level of risk associated with completing the action.* *Whether the action is on the critical path.*	*It is important that links to supporting information be made, for example arguments made within the socio-economic analysis report should be referenced.*
A 1.1	Substance Y (the replacement for substance X) has only recently become available commercially. Current production is only 25% of that needed for full replacement of substance X in this use. Detailed discussions have been undertaken with the supplier of substance Y and 12 months is considered the most realistic estimate of the time required to reach the desired level of supply. This is critical to achieving full substitution. If there is not full replacement of X with Y, it will no longer be possible to produce the required number of medical devices, etc.	Contact details for supplier of substance Y.
A 1.2		
A1.3		

Summarising the actions against timescales and their justifications are intended as a presentation of considerations of the applicant based on a wide range of factors. Some of which are likely to be presented in further detail in other documents, such as the analysis of alternatives and the socio-economic analysis.

The actions should be set out against a timeline for achieving these actions with progress markers and key stages indicated. This can be described simply against a timescale and illustrated in a table or using a timeline illustration or project management graphic tool such as a Gantt chart. How this is done is dependent upon the complexity of the plan. A possible illustration is set out below.

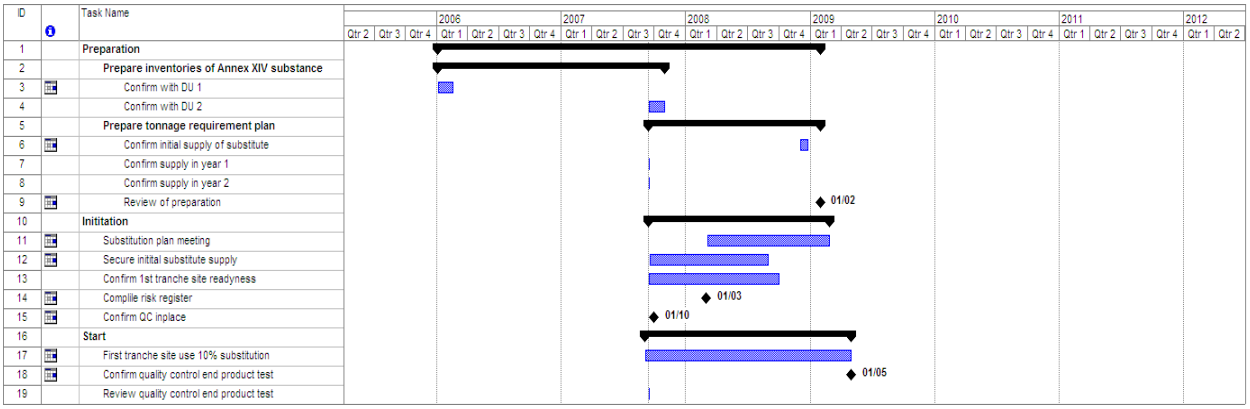


Figure 11 Illustration of timeline for substitution plan

In order to demonstrate transparency within the substitution plan, the sources of information used by the applicant should be clearly referenced. The most appropriate method of this may be inclusion of an appendix or a referencing system to other documents submitted as part of the authorisation application (or available elsewhere).

4.4.1. Presenting the documentation of the substitution plan to the Agency

The substitution plan should be submitted as part of the application for authorisation as indicated in the user manual(s) made available on the Agency's website.

5. GUIDANCE FOR THIRD PARTIES ON SUBMITTING INFORMATION ON ALTERNATIVE SUBSTANCES OR TECHNOLOGIES

The guidance in this chapter has been drafted to assist third parties in their submission of information about alternative substances and technologies to the substance for which authorisation is sought or reviewed. The aim is to assist third parties in making effective submissions to the Agency. Further detailed guidance on how to perform an analysis of alternatives primarily directed to the applicant for authorisation is given in chapter 3. Interested third parties may find the guidance in that chapter useful in order to submit a well documented information on alternatives.

It should be noted that interested parties also have an opportunity to contribute further evidence to support the decision making process on the Annex XIV substance on the basis of its technical performance, on economic grounds or its environmental/human health impacts through contribution to the SEA process (guidance on this process is given in Guidance on Socio-Economic Analysis – Authorisation).

This chapter describes the overall context within which third parties may wish to provide information and the interactions between the applicant, downstream users, the Agency and third parties. The guidance chapter is intended to assist all third parties: any organisation, individual, authority or company other than the applicant or the Agency/Commission with a potential interest in submitting information on alternatives including:

- The suppliers of alternative substances or technologies;
- Academics/innovators who have developed or have knowledge of an alternative substance or technology;
- NGOs and Trade Unions;
- Governmental and intergovernmental agencies; and
- Downstream users.

Submissions from third parties may be extremely important to the Agency's Committees' considerations on authorisation applications. The applicant may not be aware of the alternative substance or technology proposed by the third party and the Agency may only become aware of the existence of alternatives through the submissions made by third parties. In addition, technical, economic and safety information provided by third parties on alternative substances or processes may influence the Committees' assessment of suitability.

The extent to which information submitted by third parties can influence the decision process will depend on the quality and clarity of information submitted and the extent to which third parties are able to help to demonstrate the technical and economic feasibility of using an alternative substance or technology as well as assessment of its capability to reduce the overall risk. In accordance with Article 64(3) any information submitted by third parties will be taken into account by the Agency when preparing an opinion. In this regard, it should be noted that, in deciding whether an alternative is suitable for the applicant, the Agency will have to consider the economic and technical feasibility for the applicant.

Third parties do not have access to the detailed information within the application for authorisation and must base their submissions on the information provided by the Agency on its website about the broad use of a substance for which authorisation is sought or being reviewed. Third parties

should pay special attention on when describing what function the alternative fulfils, for which uses their alternative is suitable and under which conditions is can be used. For example, a lubricant that is specially designed for extreme temperatures and/or use with specific material; should not be described simply as a lubricant without any accompanying information about the conditions of use.

Information must be submitted within a specified time period (see below), if it is to be considered by the Agency. It may be appropriate to submit information even before technical feasibility for a specific use has been fully established. For instance, a convincing case may be presented that the innovation is sufficiently promising to warrant further research, further research is planned and the innovation would be likely to have a major benefit for human health or the environment. This information may inform the specification of a review period for the authorisation by the Agency.

The Agency is not required to respond to submissions made by third parties but may choose to request further information.

5.1. Circumstances leading to third party submission of information

Third parties may wish to submit information about potentially suitable alternatives that are technically feasible and safer for human health and/or the environment. They may have a particular interest in indicating how the use of a chemical could be entirely avoided by use of an alternative technology or by optimizing the process such that the chemical is no longer required or very much less is used.

5.2. Timing of third party submissions

Third parties are specifically invited to submit information on alternatives when the Agency publishes information on its website about uses for which applications have been received or when the Agency indicates on its website that an authorisation is subject to review (Art. 64(2)). The Agency will indicate a deadline for the submission of information which will be within the 10-month period that the Agency's Committees for Risk Assessment and Socio Economic Analysis have to prepare a draft opinion. Article 64(3) indicates that third parties may also be invited by the Committee for Socio-economic Analysis to provide additional information on possible alternative technologies and substances.

The sunset dates[31] given in the Annex XIV list provide an indication of the likely timing of applications for authorisation. Applications for authorisation should be made before the deadline specified in the Annex XIV entry, which will be at least 18 months before the sunset date, in order that use of the substance shall be allowed after the sunset date if a decision has not been taken by that time. Once an application is submitted, the Agency's Committees for Risk Assessment and Socio Economic Analysis must issue a draft opinion within a 10-month period.

Submissions on proposed alternatives are likely to be most effective in influencing the decision process if submitted during the consultation period defined under Article 64(2) that is specifically tailored for the consideration of alternatives. There are however two earlier periods of consultation during which interested parties may wish to comment:

[31] Date from which the placing the market and use of the substance shall be prohibited unless an authorisation is granted

- Following the preparation of an Annex XV dossier[32] by the Agency/Member State, the Agency is required by Article 59(4) to place a notice on its website inviting comment from interested parties. Details of this process are provided in the Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern and Guidance on inclusion of substances in Annex XIV.
- Once the Agency has considered the Annex XV dossier, Article 58(4) requires the Agency to publish its recommendations on priority substances and uses to be included on Annex XIV on its website and to invite comments, in particular on uses which should be exempted from the authorisation requirement, from 'all interested parties'.

These earlier phases of the procedure provide an early indication of substances that may become subject to authorisation. In addition, these phases provide information about why substances have been placed on Annex XIV. This may assist third parties in the preparation of a submission that can demonstrate a suitable alternative when a certain use(s) is applied for. It should be noted that the inclusion in the candidate list does not set any presumption when the substance would be subject to authorisation.

As well as the formal opportunities for input of information and commenting, some third parties (for example users of a substance for which an application for authorisation is being made) may wish to maintain a two-way dialogue with the applicant for the authorisation to ensure that information on the actual uses, and what is and is not being covered by the application is clear to both parties, and the best available information is used to generate the application. Communication within the supply chain is addressed in more detail in Chapter 3.

Following the granting of an authorisation, third parties may still submit relevant information to the Agency. All authorisations will include a time limited review period and the holders of authorisations are required to submit a review report at least 18 months before the expiry of this period. In addition, Article 61 (2) indicates that the Agency may review authorisations at any time if circumstances change so as to affect the risk to human health or the environment or the socio-economic impact, or if new information on possible substitutes becomes available. The review process will include an invitation for third parties to submit further information within a specified time period following the publication of broad information on uses on the Agency's website.

The time line below summarises the opportunities available to third parties to comment on Annex XIV substances. The guidance in this chapter relates to the specifically to the stages after placement of a substance on Annex XIV including the granting of authorisation and the subsequent review of authorisations.

[32] Annex XV dossier proposing the identification of substances of high concern. For further information see Guidance on inclusion of substances in Annex XIV).

A time line illustrating the opportunities for third parties contribution is shown below:

Agency actions	Third party actions
Notice that Annex XV dossier has been prepared placed on Agency website (Article 59(4))	
	Comments invited from interested parties within specified time period (Article 59(4))
Substance placed on candidate list, recommendations for priority substances published on Agency's website (Article 59(10))	
	Comments invited from interested parties, in particular on uses that should be exempted within 3 month time period (Article 58(4))
Substance placed on Annex XIV, applicant applies for authorisation, Agency publishes information on broad uses on website (Article 64(2))	
	Information on alternatives invited from third parties within a specified time period (Article 64(2))
Agency may request further information from third parties (Article 64(3))	
Granting of authorisation (Article 60)	
	Interested parties may still provide information on alternatives to the Agency (Article 61(2))
Review of authorisation (Article 61)	
	Comments invited from interested parties (Article 61, 64(2))

5.3. Preparation of a third party submission

All information submitted by third parties must be taken into account by the Agency, but submissions are most likely to be effective if information is presented in an organised logical fashion that will enable the Agency to take proper account of the arguments and information presented. Third parties may wish to state their interests in respect to the outcome of the authorisation process.

Third party submissions should be based on the information provided by the Agency on use and, if possible, include sufficient technical detail to enable the Agency to assess the availability and suitability of the proposed alternative. If possible, the extent to which the alternative can deliver an equivalent function to that provided by the substance in relation to the use(s) specified by the Agency should be clearly described.

A single alternative may not be suitable for all different processes or uses for which the original substance was suitable, thus the original substances could be substituted by more than one suitable alternative. Third parties may submit information relevant to a limited number of uses or describing several alternatives for different uses. Third parties may submit information about alternatives that are still under development, where technical feasibility and reduced risks to human health and/or the environment have still to be fully established. Although it would not be possible to immediately introduce the alternative, the Agency will take such information into account when setting of a review period for the authorisation.

Third parties may wish to take account of the information requirements placed on the applicant (Chapter 2), in setting out their submissions. The guidance provided for applicants on the analysis of alternatives may be of particular relevance (Chapter 3). Ideally, submissions would include a good description of the proposed alternative and indicate its relevance within the context of the authorisation process. A suggested format for third party submissions is provided on the Agency's website.

In making an assessment of the suitability and availability of proposed alternatives, third parties may wish to take account of the information provided by Agency on the inclusion of the substance on Annex XIV that led to the application for authorisation and on the uses for which authorisation is sought.

To the extent that it is possible (which is likely to be limited by the information available about use), third parties should provide any information that is relevant to the application and seek to demonstrate that the proposed alternative(s):

- Meet(s) technical performance specifications relevant to the uses described by the Agency;
- Are/is safer for human health and/or the environment, and/or
- Are/is economically feasible including reasonably accessible in sufficient quantities to meet the probable annual volume required for the use of interest.

An alternative should have adequate technical performance that is fit for purpose. Third parties may wish to consult with the supply chain in order to inform their submission. Although it is unlikely to be possible to fully demonstrate technical and economic feasibility for the applicant, combined with reduced risks for health/environment, third parties should include any information that is relevant to the assessment of suitability. A statement that alternative X can be used should be supported by data and information demonstrating for which use(s) and under which use conditions it is a plausible substitute.

When providing information on an alternative substance, third parties may wish to consider what data are available that can be used to demonstrate lowered risks and to provide a description of these data in their submission. For substances already registered under REACH, information may be available from within REACH IT to demonstrate lowered risks to human health or the environment. When providing information on alternative technologies third parties would ideally seek to demonstrate that their use would lead to a reduction in human or environmental risks.

Where alternative substances or technologies are readily available, it would be helpful to describe the predicted costs, if known, associated with using an alternative in relation to those associated with the substance subject to authorisation. Where alternatives are not currently readily available, the costs of making them available and predicted costs of use would be useful.

In as far as it is possible, third parties should describe as clearly as possible the extent to which an alternative is better or worse than the subject of the authorisation application for each of the three criteria: technical and economic feasibility and reduction of overall risks. When assessing whether suitable alternatives are available the Agency is required to take into account all relevant aspects concerning the alternative(s), as stated in Article 60 (5) including whether:

- the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures; and
- be technically and economically feasible for the applicant.

In considering risks to human health and the environment, a life cycle analysis approach may be taken for the specified use of the substance. Some examples of hypothetical situations are given in Box 13.

Box 13. Examples of third party consideration of alternative substances

Substance: carcinogenic organic solvent **Specified use**: solvent used for extraction during laboratory analysis **Proposed alternative**: organic solvent with similar chemical and physical properties but not known to be carcinogenic, mutagenic or toxic to reproduction; similar potential to persist in the environment or bioaccummulate as the original solvent. **Functionality:** Alternative solvent is unlikely to provide same range of functionality as current solvent, but for many analytical protocols, the performance of the alternative is adequate. **Technical feasibility**: suitably as a laboratory solvent demonstrated for 4 widely used analytical protocols. Although alternative solvent is more flammable than the original solvent and therefore may not be suitable for larger scale applications; suitability of alternative solvent not demonstrated for all potential uses and its suitability would need to be validated for each analytical protocol. **Economic feasibility:** alternative solvent is more expensive, but as only small quantities are used, the calculated overall cost to laboratories of substitution is extremely small in comparison to the overall costs of maintaining laboratory facilities. **Risk reduction**: levels of human exposure similar for both solvents, but alternative not associated with cancer risk; environmental risks similar for both solvents
Substance: carcinogenic organic solvent **Specified use**: solvent used for cleaning of reaction vessels used in polymer production **Proposed alternative**: treatment with water heated to 90°C followed by treatment with an alternative organic solvent with similar intrinsic properties, including environmental hazards, but no proven potential to cause cancer **Functionality:** the hot water was not capable of removing congealed fragments of part formed polymer from the reaction vessel, but the two stage process was demonstrably effective and resulting in a lower use of the alternative solvent than would have been required if the hot water step had been omitted. The water requires treatment before discharge to the environment and the use of hot water presents safety issues. **Technical feasibility:** Alternative process was adequate for the intended purpose but introduced a requirement for facilities for wastewater treatment that had not previously existed. **Economic feasibility**: An analysis of the cost of heating and subsequently treating the water indicated that these represent substantial additional process costs. The alternative solvent is currently more expensive than the original solvent but this is likely to change as the demand for alternative solvents increases. **Risk reduction:** levels of human exposure lower for alternative solvent which is not associated with cancer risk, giving

rise to an overall reduction in health risks; reduced quantities of solvent use associated with small reduction in environmental risks; introduction of new hazard in form of hot water
Substance: carcinogenic organic solvent **Specified use:** solvent used for cleaning of nozzles used in polymer extrusion **Proposed alternative:** organic solvent with similar chemical and physical properties, poses similar risks to environment but not known to be carcinogenic **Functionality:** Solvent was demonstrated to be effective in use provided a longer washing time was allowed. **Technical feasibility:** Although the alternative solvent provided an equivalent function, the longer washing time had an adverse impact on the overall production schedule. **Economic feasibility:** The cost of the alternative solvent is similar to that of the original solvent. The longer washing time means that operators may need to have an increased number of spare nozzles available as the longer turnaround time means than individual nozzles are used less frequently. Over a ten year period, the calculated additional costs were small in relation to total operational costs. **Risk reduction:** levels of human exposure similar for both solvents, but alternative not associated with cancer risk; environmental risks similar for both solvents
Substance: carcinogenic metal **Specified use:** used with other metals in high strength alloy **Proposed alternative:** reformulated alloy excluding metal carcinogens **Functionality:** reformulated alloy is more brittle than original alloy and not suitable for all applications **Technical feasibility:** The reformulated alloy can be produced using existing production facilities **Economic feasibility:** Market demand for reformulated alloy is likely to be smaller than for the original formulation because of its lower technical performance. It is estimated that future demand will fall to 50% of current levels. **Risk reduction:** Reduction in human exposure to the metal carcinogen
Substance: carcinogenic solvent **Specified use:** dry degreasing of surfaces such as plate glass **Proposed alternative:** specialist textile which eliminates need for solvent use **Functionality:** the textile is highly effective in removing grease from smooth surfaces, but less effective on rough surfaces; textile becomes progressively less effective as it becomes saturated with grease but can be regenerated by treatment with an environmentally friendly detergent **Technical feasibility:** The textile can provide a similar quality of cleansing for smooth surfaces as the solvent but requires manual cleaning to be undertaken whereas the solvent can be used within automated process **Economic feasibility:** For small scale processes employing manual cleaning, there is a small long term saving in cost through discontinuation of use of the solvent, although initial investment in the textile is required. For processes that are currently automated, the transition to manual cleaning is likely to greatly increase labour costs and process time and the replacement of a solvent based process by a manual process employing the textile is likely to give rise to unacceptably high additional costs. **Risk reduction:** Use of the textile eliminates the need for human exposure to the carcinogenic solvent

5.4. Confidentiality

Third parties wishing to submit information on alternatives should take account of the right of access to documents of the Community institutions. Under Art. 2(1) of Regulation 1049/2001, any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, has a right of access to documents of the Community institutions, except for a defined number of reasons including where disclosure would undermine the protection of:

(a) the public interest as regards:

— public security,

— defence and military matters,

— international relations,

— the financial, monetary or economic policy of the Community or a Member State;

(b) privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data.

or where disclosure would undermine the protection of:

— commercial interests of a natural or legal person, including intellectual property,

— court proceedings and legal advice, and

— the purpose of inspections, investigations and audits, unless there is an overriding public interest in disclosure.

Similarly, the institutions may grant access to documents to any natural or legal person not residing or not having its registered office in a Member State (Art. 2(2)).

In case of a request for a third party document, according to Article 4(4) of Regulation 1049/2001, "[the Agency] shall consult [the provider of the comments] with a view to assessing whether an exception in paragraph 1 or 2 is applicable, unless it is clear that the document shall or shall not be disclosed."

Under Article 118 of REACH disclosure of information on the full composition of a mixture; on the precise use, function or application of a substance or mixture; on the precise tonnage as well as on links between a manufacturer or importer and his distributor or downstream user normally will be deemed to undermine the protection of the commercial interests of the concerned person. Thus, an exception according to Article 4(2) in the right of access of Regulation 1049/2001 will normally apply.

Third parties should clearly indicate within their submissions the information that they wish to remain confidential and the reasons for not disclosing submitted information. The Agency may grant access to documents, unless any of the above reasons applies. Therefore, if clear reasons for not disclosing information are not provided, the Agency reserves its right to decide that access can be given to your comments.

Third parties who have requested that information remains confidential may still decide to make available:

- certain parts of the document to anyone requesting access to it or
- certain parts or all of the document to a restricted number of actors requesting access to it.

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repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal L 396, 30.12.2006, p1-849.

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Appendix 1 Considerations for grouping of substances

An application for a group of substances is only possible if it is for a group in accordance with Article 62 (3). A description of the reasons for considering the substances as a group is required. It should be submitted as part of the application, in accordance with specific instructions in user manual(s) made available on the Agency's website. It should outline the argumentation for the grouping, based for example on similarity of physicochemical, toxicological and ecotoxicological properties, or where these follow a regular pattern as a result of structural similarity.

The group or category is most likely to have already been created as part of the registration process or for the Annex XV dossier which lead to inclusion on Annex XIV. In such cases, the argumentation for considering the substances as a group will already have been prepared, and the benefits of an application for a group should be relatively easy to determine. The majority of the guidance in this section relates to the situation where the applicant wishes to form a new group for the application. However, some of these considerations may be useful in deciding whether to apply for an authorisation for all members of an existing group.

The definition of a group of substances is given in Section 1.5 of Annex XI of the Regulation, and according to this definition, grouping of substances can be made only on the basis of similarity of physicochemical, toxicological and ecotoxicological properties, or where these follow a regular pattern as a result of structural similarity. Similarities may be based on:

- a common functional group;
- the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals; or
- a constant pattern in the changing potency of the properties across the category.

It is important to note that this definition precludes grouping of substances based on similarity of use alone. Further guidance on grouping of substances is given in the Guidance on information requirements and CSA.

A1.1 Reasons for grouping substances

The main reason for grouping of substances for an application for authorisation is that savings in time and effort can be made in some situations, particularly where common information can be used for the application. Possible situations that are envisaged with a group of substances are outlined below. For each situation, although there is nothing to stop an applicant from submitting a single application covering the group of substances, there may be some cases where the complexity of the situation will outweigh any benefit from reduction of information and effort needed. Therefore, it is advisable that the applicant assesses the benefits from grouping on a case-by-case basis.

a) All members of the group have the same uses, and the application for authorisation is made for all of the uses of the group. Here, as the same uses are considered for all substances, the information needed for the application for all substances may be similar, or could involve consultation with the same users or industry sectors, and so could then be collected at the same time.

b) All members of the group have the same uses, but the application for authorisation is made for only some specific uses of each substance within the group. Similar to above, if the specific uses considered are common to more than one of the substances in the group, then the necessary information could be collected at the same time. If, on the other hand, the specific uses are all different for each substance in the group, there would appear to be little advantage in treating the substances as a group, as the information for each substance would probably need to be collected separately, and the application would be complex and may lack transparency and clarity.

c) Members of the group have different uses, and the application for authorisation is made for different uses for each substance. Here there would appear to be little advantage in grouping the substances.

Another consideration when grouping substances is the basis that will be used for the application, i.e., whether the "adequate control route" or the "socio-economic analysis route" can be used. Different documentation may be needed for applications by these two routes and so there would appear to be little advantage in grouping substances where different routes will be used for individual substances.

When deciding whether or not to submit an application for a group of substances, a key consideration is maintaining clarity in the applications. In complex cases, it may be preferable to submit separate applications for each member of the group. In this case it may still be possible to use some of the same supporting information for each application if this information was collected for the group as a whole.

A1.2 Argumentation for grouping substances for authorisation

Several possibilities could be envisaged as a basis for describing the arguments for the grouping of substances. Examples are given below.

a) The substances were treated as members of a group or category in the context of registration (*i.e.* for the purpose of the CSR or use of read-across for the purpose of preparing the registration dossier). In this case an argumentation for considering the substances as a group/category would already exist in the registration dossier and the same reasons could be used as a basis for considering the substances as a group/category for authorisation, if compliant with Section 1.5 of Annex XI.

b) The Annex XV dossier(s) for inclusion of the substance in the Candidate List treated the substances as a group or category or used a read-across approach for the substances. Here, reference to the Annex XV dossier in the application for authorisations would be sufficient for considering the substances as a group/category for authorisation.

c) Grouping based on a common impurity or degradation product, or constituent of multi-constituent substance, if the impurity/degradation product/constituent is the reason why the substances were listed on Annex XIV. Again the Annex XV dossier for the substances should provide the necessary background for considering the substances as a group/category for authorisation.

d) The substances are considered as a group or category based on structural similarity. The arguments that could be used here could be structured around common structural features and/or functional groups or a constant and predictable pattern in the properties of relevance across the category. The properties of relevance here would be the properties outlined in the Annex XV dossier that lead to the substance being identified as a substance of very high concern, and so subsequently listed in Annex XIV. In this case the Guidance on information requirements and CSA (Chapter R6.2) should be used to develop the argumentation. If necessary, it is possible to draw on substances not listed in Annex XIV to strengthen the argumentation, although such substances themselves cannot be the subject of the application for authorisation.

For a review report, the argumentation for the grouping should be reconsidered in light of any new data that has become available.

Appendix 2 Applications by several legal entities

A2.1 Reasons for joint applications

Possible advantages for joint applications:

- Sharing of costs needed to put together the necessary documentation required.
- Broader range of experience and expertise.
- Ensuring the specific conditions of use of downstream users are covered.

Possible disadvantages for joint applications:

- Commercial and confidentiality issues relating to the use(s) of the substance.
- Not all uses of the substance may be relevant to each legal entity.
- Disagreements over the information.

Applicants who want to submit a joint application should refrain from exchanging commercial sensitive information prohibited under the competition rules (*e.g.* information about prices or customers). Exchanging information about substance identity or substance properties is permissible under the competition rules. However, exchanging detailed information about alternatives could give raise to concerns, particularly if there is a concerted action as to whether, when, and how companies switch to an alternative. Therefore, when preparing the analysis of alternatives, parties may consider the use of an independent third party.

A2.2 Approach for joint applications by groups of applicants

The basic approach for an application by a group of applicants[33] would be to firstly identify the manufacturer(s), importers and downstream users that are involved in the supply chain for the substance.

If a SIEF has been created for the substance, the interested members of the SIEF could form a useful basis for the formation of group for the application. SIEFs have no legal status in relation to applications for authorisations, but they may be a useful platform in cases where the substance has been (pre-)registered by more than one company. However an application for an authorisation from a group of applicants need not be limited to the group of, or a subgroup of, the members of a SIEF (*e.g.* manufacturers and importers of substances that have been identified as suitable for read-across).

[33] The REACH Regulation does not specify what form of co-operation should be used for applications from more that one applicant. This could include formal consortia or other forms of cooperation. The term group of applicants is used here to cover all forms of possible cooperation between manufacturer(s); importer(s) and/or downstream user(s) acting as applicants for authorisation.

It may also be beneficial to include downstream users in the group of applicants if they are not already members of the SIEF. Such downstream users could be identified, for example, based on the known customers of the members of the SIEF etc., or through relevant trade associations etc.

The Guidance on data sharing gives detailed guidance on how to put together SIEFs and other forms of collaboration, and how to deal with issues in relation to Confidential Business Information (CBI) and competition laws. This guidance could also be useful in the case of applications for authorisations by a group of applicants, however, it will be up to the applicants themselves to decide how they share information and prepare the joint application.

Possible situations that could be envisaged when considering an application for authorisation from a group of applicants are outlined below.

- The potential group of applicants consists of actors in one supply chain (manufacturer or importer and downstream user(s)). The different actors will have knowledge on different aspects required for the application and can effectively contribute to a joint application. For example, a downstream user has detailed knowledge on actual conditions under which he uses the substance contributing to an accurate exposure scenario while the manufacture or importer may have better knowledge on how to perform an exposure assessment and develop the CSR on the basis of that exposure scenario. The downstream users have good understanding on the requirements for an suitable alternative, knowledge of all actors is relevant for a SEA, etc.

- The potential group of applicants consists of manufacturer(s) and/or importer(s), all supply the substance for the same uses, and the application is for all uses of the substance. In this case there would appear to be an advantage in developing a group for the application as the information needed for the application would be common to all members of the group.

- The potential group of applicants consists of manufacturer(s) and/or importer(s) and/or downstream user(s), and the application is for only some of the uses. Here the advantages of developing a group for the application would need to be considered on a case-by-case basis as not all information that will be needed for the application may be relevant to all members of the group.

- The potential group of applicants consists of manufacturer(s) and/or importer(s) and/or downstream user(s) that each supply the substance for different uses, and the application is for all uses of the substance. Here it could be questioned whether there is any benefit derived in developing a group for the application.

The same situations could also arise where the application is for a group/category of substances. However here, as discussed at length in the Guidance on information requirements and CSA, the formation of a group/category may also be dependent on which chemicals are of interest to the companies sponsoring the category.

Subsequent applications {Art. 63}, whereby a second legal entity wishes to make an application for authorisation when an application has already been submitted by another applicant or an authorisation has already been granted to another legal entity, are discussed in Section 2.2.5 of this guidance.

A2.3 Completing the application

For groups of applicants the following points should be taken into account when completing the application.

- The application should identify the members of the group of applicants and also the main contact point.
- The application must have CSR(s) covering all the uses applied for by the group of applicants. In some cases it may be possible to use the existing CSRs of the group members (if available) but it is also possible that a single, consolidated CSR covering the uses for which authorisation is applied for, may need to be generated. The Guidance on information requirements and CSA should be followed in this case.
- An analysis of alternatives and where included in the application, an SEA and/or a substitution plan have to cover all uses applied for and can be submitted jointly.
- There may be issues in relation to Confidential Business Information (CBI) and competition laws in relation to an application for a group of applicants. The Guidance on data sharing gives more detailed guidance on these aspects but, if in doubt, legal advice should be sought.

How a single application from multiple applicants will be created in practice will be elaborated in a separate user manual.

Appendix 3 Checklist for analysis of alternatives

Analysis of Alternatives Checklist

The following checklist can be used by the applicant for cross-referencing the key components of an analysis of alternatives against their own preparatory work.

The analysis of alternatives includes the following information:	Yes ✓	No ✘
1. Identification of Annex XIV substance function for the uses applied for		
2. Identification of possible alternatives(s) – substances and/or technologies for the uses applied for		
3. The assessment of risks to human health and the environment of the alternatives and whether the transfer to alternatives would result in reduced overall risks;		
4. The assessment of the technical feasibility of the alternative(s) for substitution;		
5. The assessment of the economic feasibility of the alternative(s) for substitution;		
6. The assessment of availability of the alternative(s).		
7. List of actions required, as well as the time-lines, to switch to an alternative substance/technology. *In particular in cases where there is a suitable alternative available on the market but not yet ready for an immediate substitution (i.e. within the "sunset date") or another operator in the same market is already or will switch in the short future to alternatives.*		
8. A justification for the conclusion of the analysis of alternatives if it concludes that there are no suitable alternatives available. a. Reference to an SEA (if the application is for an Annex XIV substance which cannot be adequately controlled; i.e. for an application under the socio-economic route)		
9. A justification for selection of the alternative (for an application under the adequate control route) a. Reference to a substitution plan (if the application is for a substance for which adequate control can be demonstrated and there is a suitable alternative available).		
10. Relevant R&D is documented and explained where appropriate		
11. References to all information sources cited		
12. Confidential data is clearly indicated as such.		

Appendix 4 Checklist for Annex XIV Substance Function

The following checklist can be used to assist in determining the functional requirements of possible alternatives based on functional aspects of the Annex XIV substance (it is not exhaustive).

Functional aspect[1]	Explanation
1. Task performed by Annex XIV substance	What is the task that must be performed by the substance? Consider in detail what is required of the specific task that must be performed by the Annex XIV substance and why and how this must be performed. Sources of information: Exposure scenarios in CSA/R – this will detail the operational conditions (Guidance on information requirements and CSA). Supply chain: More specific information detailing exact use, quality criteria and specific product requirements will need to be gathered from downstream users (if they are not the applicant) – (see Guidance on information requirements and CSA). Note: the exact description of the function may be considered to be confidential information by the user – i.e. they may not wish to impart details of the exact process for manufacture. In that case the DU can consider providing the information under a confidentiality agreement. Alternatively he can consider making his own application for that use.
2. What critical properties and quality criteria must the substance fulfil?	This should include the tolerance range for acceptability, i.e. what is the acceptable range for performance (for example maximum drying time for a solvent or coating, or temperature tolerance).
3. Function conditions What is the frequency of performing the task (continuous or batch process)? How much of the substance is used/consumed in the process.	This will give an indication of the amount of substance that is required for the function and the speed and duration of the task.
4. Process and performance constraints What are the process constraints of the task? Does the task have to be performed under particular conditions?	For example these could be physical and chemical constraints as well as temporal and quality constraints. Consider the circumstances under which the task must be performed. How do these conditions determine the qualities of the Annex XIV substance i.e. what are the constraints? These could for example be physical (e.g. extreme pressure or temperature, or confined space), chemical (e.g. possible reaction with other chemicals in the process or pH), or biological (stability for biological systems e.g. microorganisms involved in the process e.g. a bioreactor) that may dictate how the task is performed.
5. Is the function associated with another process that could be altered so that the use of the substance is limited or eliminated?	For example the Annex XIV substance may be used to control emissions of another substance or produce another substance. If the need for control is removed or the end product is altered so that the second substance is no longer needed then the Annex XIV substance may be more easily substituted or not required at all.
6. What customer requirements affect the use of the substance in this use?	For example, customers may have particular operating procedures that must be followed and contractual arrangements that demand use for a certain length of time.
7. Are there particular industry sector	For example some substances are long lifetime products that must

requirements or legal requirements[2] for technical acceptability that must be met and that the function must deliver?	be tested for technical performance and acceptability for use over a long period. Also the function may need to deliver a function that meets particular standards (such as fire safety requirements, product safety or component worthiness).

Notes:

1. *Functional aspects suggested are not an exhaustive list, but an indication of the main considerations that may assist the applicant in determining function.*
2. *This is considered further in section 3.6 on technical feasibility.*

Appendix 5 Brief example of possible method for profiling environmental risk

'Risk profiling' may be used for comparing environmental risks of different substances used within the same specific industry sectors (using emission scenario information) and a similar technique may be adapted for human health. An outline of the technique is set out in Box A. The technique may be helpful for assessing the comparative risk of alternative substances and for indicating the potential risk of the alterative if used in the same use pattern (i.e. assuming the same emission scenarios).

Box A Risk profiling for environmental risks

Risk profiling[1] is a technique developed to allow the generic assessment of the environmental risks of substances that have similar function. It uses the same principles used in the risk assessment of chemicals for assessing the need to limit risks based on comparison of exposure with effects, but instead of focusing on a single substance, a range of possible substances used within a use pattern can be considered and the physical and chemical characteristics that lead to risks can be evaluated.

The prediction of emissions from the life cycle phases of substances can be determined based on the combination of the type of industry in which the substance is manufactured and uses to which the substance is put. These combinations determine the predicted emissions to environmental compartments based on the so-called A and B tables in the Guidance on information requirements and CSA and within the European Union System for the Evaluation of Substances (EUSES). Furthermore, more specific emissions from some industrial sectors have been documented in emission scenario documents. The emissions can be used to derive predicted environmental concentrations (PEC) for environmental compartments. However, certain key physico-chemical properties (biodegradability, octanol-water partition, and vapour pressure and water solubility) have the most influence on the environmental fate of a substance released into the environment. Therefore for substances with the same use pattern (i.e. releases to the environment) for the same tonnage use, risks will be determined by exposure (determined by key properties) and the toxicity of the substance (i.e. the predicted no-effect concentration - PNEC).

By using the calculations for determining the environmental fate of substances based on key properties and basic information on the aquatic toxicity of the substances, the combinations of these features and the tonnage used of substances that give rise risks can be investigated. Therefore for particular use patterns that define releases to the environment a theoretical 'profile' of the key physico-chemical properties, toxicity and tonnage use can be investigated. Combinations that lead to risks can be avoided and those that do not can be investigated further.

The utility for the analysis of alternatives is that for use patterns with known emission characteristics and for particular tonnage uses, the combinations of physico-chemical and toxicological characteristics substances that give rise to a risk can be compared to and between possible alternatives. This can be based on a small amount of information on the alternative substances (e.g. readily biodegradable, octanol-water partition and acute aquatic toxicity). The alternatives that indicate a potential risk can be avoided and those that do not can be selected for further investigation.

1. Environment Agency (2004) R&D Report: "Development and Assessment of Risk Profiles for Substances: Application to Specific Industry Sectors – Plastics Additives and Lubricant Additives

Appendix 6 checklist for substitution plan

Substitution Plan Checklist

The following checklist can be used by the applicant for cross-referencing the key components of a substitution plan against their own preparatory work.

Element	Yes ✓	No ✘
1. The substitution plan includes the following information • A list of actions detailing (as a minimum) the information presented in 2 (e-h). • A timetable for implementation of actions • The method used to communicate information to stakeholders and the supply chain • References to supporting information or reports (e.g. SEA)		
2. The list of actions includes: • A series of actions proposed by the applicant (though not always for the applicant to undertake) to facilitate or carry out the substitution. • A proposed timetable with a deadline for the completion of each action. • A justification to present the rationale behind each action/timetable proposed by the applicant. • A reviewing progress against proposed actions/timetable. (This may take the form of a progress chart so that progress can be tracked against the planned action (for example a Gantt chart).		
3. A substitution timetable should be presented within the plan that: • Contains a start-date for implementation of the substitution plan • Contains an end-date by which substitution is anticipated to be complete • Contains a timetable with a deadline for each action • Is realistic given the limitations identified in the substitution plan • Contains references to suitable justifications for proposed dates • Highlights the milestones set within the action plan • Highlights the internal progress review and internal progress reporting (i.e. by the applicant)		
4. Internal review of overall substitution position for the purpose of the review report, where relevant: • Are there any new/emerging alternatives that were not present before? • Is the substitution still the best available option?		

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Guidance for the preparation of an Annex XV dossier for restrictions

June 2007

Guidance for the implementation of REACH

LEGAL NOTICE

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

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PREFACE

This document describes how the authorities (Member States Competent Authorities or the Agency on request from the Commission) can prepare an Annex XV dossier to propose a restriction under REACH. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) lead by the European Commission services, involving all stakeholders: Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/reach_en.asp). Further guidance documents will be published on this website when they are finalised or updated.

The legal reference for the document is the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1]

1 Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006)

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1 INTRODUCTION

1.1 Overview

This document provides draft guidance to the Member States and the European Chemicals Agency in preparing an Annex XV dossier to propose and justify a restriction on the manufacturing, marketing and use under REACH (Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, concerning the registration, evaluation, authorisation and restriction of chemicals (the REACH Regulation)).

Annex XV of the REACH lays down general principles for preparing dossiers to propose and justify restrictions on the manufacture, placin on the market or use of substances within the Community. Agreement on proposed restrictions (Commission comitology decision) will lead to the addition of any agreed restrictions to Annex XVII. Any subsequent manufacture, placing on the market or use of the substance has to comply with the conditions of the restrictions.

This guidance is intended for use by those within the Member State competent authorities and the Agency responsible for the production of Annex XV dossiers to suggest a restriction. The guidance will also facilitate industry and other stakeholders interested in following up and contributing to the development of an Annex XV dossier.

The guidance lists and elaborates the different elements that should be considered when developing a restrictions dossier. The guidance is intended to assist Authorities developing a restrictions proposal to check which of the elements are relevant to the specific case and to provide relevant considerations when elaborating those elements in the proposal. The guidance thus assists in fulfilling the principles laid down in Annex XV of REACH.

In this document the term ‘Authority’ is used to refer to the Agency or any Member State authority undertaking work on substance evaluation or developing an Annex XV dossier.

1.2 Links to other REACH guidance and processes

This guidance is not intended to be used as stand alone guidance. Much of the guidance needed for carrying out hazard and exposure assessment and risk characterisation for the purpose of restriction proposal is covered in the CSA guidance being developed in RIP 3.2. The same approaches should be used in most cases and so these are not repeated here. Instead, this guidance indicates when to refer to the CSA guidance, and identifies areas where the approaches in that guidance need to be adapted for the purpose of the Annex XV dossier.

The compliance check under the dossier evaluation may also provide further information where this should have been provided in the registration(s). Substance evaluation is likely to be a part of the process of producing an Annex XV dossier in cases where further information is needed. As such there is a clear link between the two activities. Some of the guidance for Annex XV dossiers may be useful for carrying out parts of the substance evaluation, in terms of justifying a request for further information based on review of the available data and on risk assessment. Guidance for the evaluation procedures can be found in the Guidance on evaluation.

A restriction proposal needs to include available information on alternatives for the substance. The Guidance on Socio Economic Analysis and the Guidance on authorisation application will also contain guidance on gathering and analysing information on alternatives.

In producing a restrictions dossier under Annex XV, the Authority may carry out a socio-economic analysis (SEA). This is briefly described in section 5.6 of this guidance.

The relevant links to these other REACH guidance documents will be introduced when the documents are available. Where necessary overlapping parts are replaced by appropriate references.

1.3 Structure of this guidance

This introductory section contains background information. It first starts by explaining the legal basis of the procedure and what may prompt a Member State and/or the Agency (through the Commission's request) into taking action by developing an Annex XV dossier. The actual guidance sections provide an indication of what are the information sources which will serve as the basis for the Annex XV dossier, and then provide guidance on how to use such information in order to justify and formulate the most suitable restriction proposal (and on how to use the template for the Annex XV dossier). The document also provides guidance on how to decide whether a restriction it is the most suitable process to tackle the concern. Furthermore, guidance is given on how to proceed when, based on the preparatory work for the Annex XV dossier, it is concluded that an Annex XV dossier is not the appropriate way forward. It is also the aim of this guidance to provide information on the interconnections between the different processes deriving from REACH and the preparation of an Annex XV dossier. A part in the development of the restriction proposal is the use and documentation of the available information on alternatives and the voluntary evaluation of socio-economic implications of the restriction, and this is tackled further on in the text.

The appendices to this document provide the template of the Annex XV dossier and guidance required for the preparation of the dossier.

In addition to the main text of the guidance, the Annexes to this document contain more detailed information, and the purpose of this is to have broad guidance in the main text, and if there is the need for more detailed guidance the reader can decide to refer to the annexes.

2 LEGAL FRAMEWORK

The restrictions procedure is a safety net to address unacceptable risks to human health or the environment, arising from the manufacture, use or placing on the market of substances, which need to be addressed on a Community-wide basis. Restriction means any condition for or prohibition of the manufacture, use or placing on the market of substances. Any substance on its own, in a preparation or in an article may be subject, where justified, to restrictions.

All decisions on whether or not to restrict the manufacture, use or placing on the market of a substance are taken by the Commission in the regulatory comitology procedure with scrutiny. Any adopted restrictions will be included in Annex XVII to the REACH Regulation, and will thereby form part of the REACH Regulation.

There are a few exemptions from the restrictions in the REACH Regulation. They are for the manufacture, placing on the market or use of a substance (1) in scientific research and development, (2) in PPORD, if this as well as the exempted quantities are specified in the Annex, and (3) for the

use of substances in cosmetic products with regard to risks to human health within the scope of the Cosmetics Directive.

The Annex XV dossier for a restriction shall include information on hazards and risks, available information on alternatives and a justification for restrictions at Community level. In addition the Annex XV may include a socio-economic assessment. The Annex XV dossier will provide the ground for any decision taken by the Commission. If the Commission proposes restrictions to consumer use of a CMR substance on its own, in preparations or in articles, no Annex XV dossier is required, enabling a faster procedure.

An Annex XV dossier may be prepared either by a Member State or by the Agency, if the Commission asks it to do so or if the Agency considers that the use in articles of a substance subjected to the authorisation system poses unacceptable risks. Any Annex XV dossier for a restriction will be published (without prejudice to Articles 118 and 119 of the REACH Regulation) on the internet to invite interested parties' comments. The Agency's Committees for Risk Assessment and for Socio-Economic Analysis will both form an opinion on the suggested restrictions, taking into account the dossier and any interested parties' comments received.

To prevent duplication of work, any Member State is requested to notify the Agency that it proposes to prepare an Annex XV dossier for a restriction (Article 69 (4)). The Agency will maintain a list of Annex XV dossiers for restrictions that are planned or underway. For substances on this list, no other restrictions dossier shall be prepared (Article 69 (5)). The Member State that has notified the preparation of a dossier that is included on the list has to prepare the Annex XV dossier within 12 months of notification.

Therefore, when the Authority considers the need for developing an Annex XV dossier for a restriction, the first step is to check via REACH-IT the 'registry of intentions' whether another Member State or the Agency is already preparing such an Annex XV dossier on the same substance. The Agency's registry of intentions includes also information on the intentions of Authorities to prepare an Annex XV dossier for harmonised classification and labelling and for identification of SVHCs. It is recommended that the Authority checks also the stage of any such work on the same substance. If the Authority decides to proceed with the preparation of a restriction proposal although other Annex XV dossier for harmonised C&L or for the identification of SVHC is under preparation, it is recommended that he contacts the other Authorities working on the substance to ensure that work is not duplicated. The registry is accessible for the Agency, the Commission the Member States and interested parties.

Member States need also to consider carefully what the appropriate timing is for the notification of the intention to prepare a restrictions dossier under the restrictions procedure. It is recommended that a notification should only be made if there is sufficient confidence that an Annex XV dossier can be finalised within 12 months from notification and that it is likely that the dossier will conclude that a restriction is necessary to address unacceptable risks to human health or the environment at the Community level.

The main timeline of the restriction procedure is given in the figure below.

The main timeline of restriction procedure (a MS preparing the Annex XV dossier)

Durations indicated for the different tasks represent the max durations of the period within which the tasks have to be fulfilled.

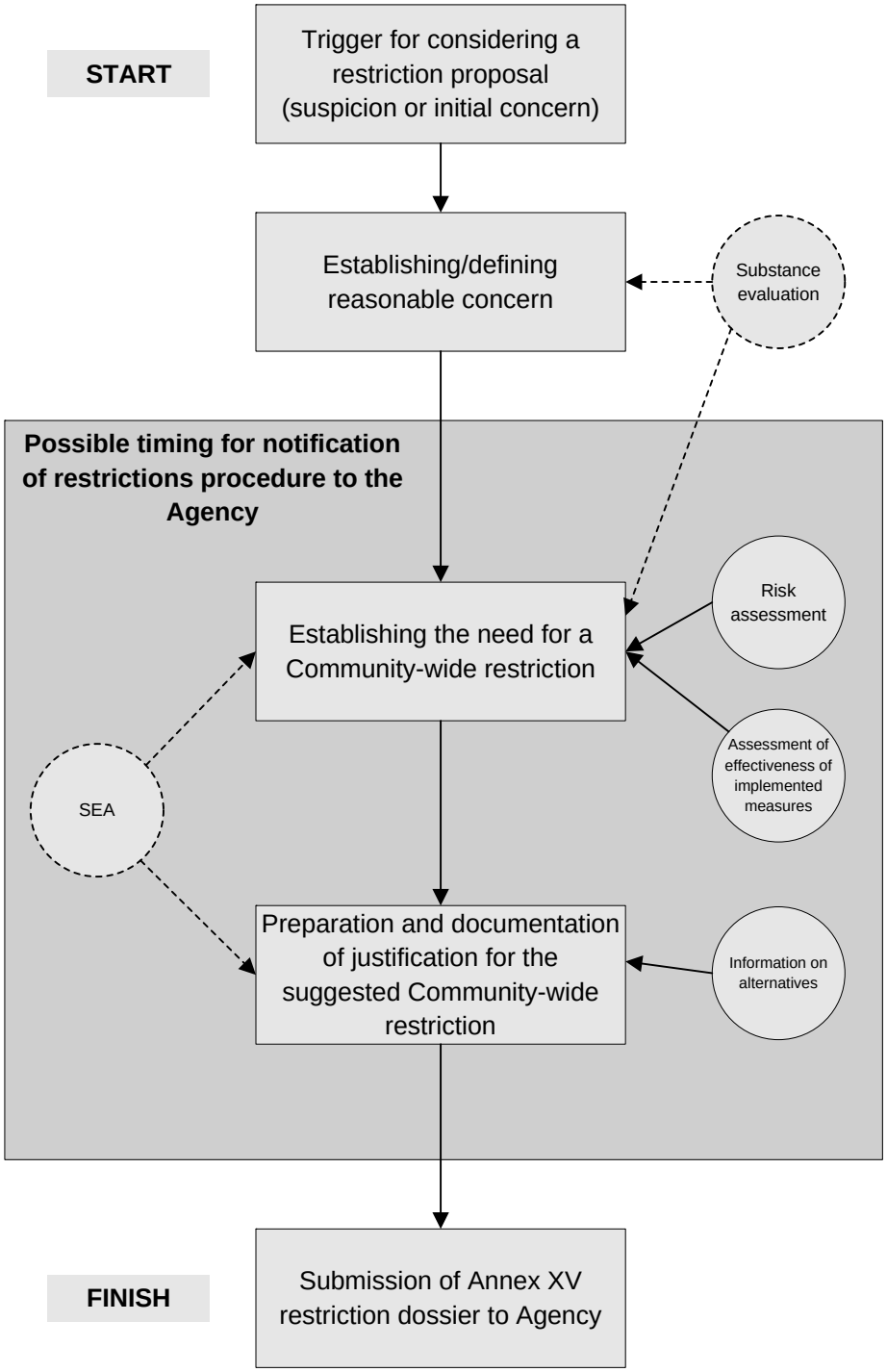
Interested Parties		Tasks										
Actions by MS[1]		MS starts work related to a restriction program	a	Period for preparing the Restrictions Dossier 12 months	b							
Actions by 3rd parties (Industry, NGOs, other MS)		Informal submission of information by 3rd parties				Comments on dossier and suggested restrictions; SEA or input to one 6 months		Comment on draft opinion of SEA 60 days				
Actions by the Agency		Maintain list of notified substances										
	RA Committee					Prepare an opinion based on the dossier prepared by the Agency/MS and take into account the comments submitted by interested parties 9 months			d			
	SEA Committee					Prepare an opinion based on consideration of the relevant parts of the dossier and on the socio-economic impact 12 months						
							c		d			
Actions by the Commission										Prepare a draft amendment to Annex XVII 3 months	f	at least 45 days	g

Key Deadlines

a	-	Notification to the agency
b	-	Submission and publication of the restriction proposal [2]
c	-	SEA publishes the draft opinion
d	-	Submit opinion of the Committee to the Commission and publish on the website
f	-	Draft amendment submitted to the Member States
g	-	Commission decision via Comitology procedure

An overview of the compilation of an Annex XV report proposing a restriction is described in chapter 5.1 and more detailed guidance is given in chapters 5.2 to 5.6. Figure 1 below shows the main tasks to be taken by Authorities when preparing a restriction proposal.

Figure 1 Overview of Authorities' actions throughout the preparation of a restriction proposal



Dotted shapes or lines represent non-compulsory actions or sources of information that may not always be available.

3 WHAT PROMPTS A RESTRICTION DOSSIER?

This section presents some examples of situations which may prompt a Member State or the Commission to consider a restrictions proposal.

Some of these triggers in the first group may lead a Member State to propose the substance for substance evaluation in order to request the data required for the restriction proposal. The Agency may then include such a substance on the Community rolling action plan for substance evaluation. The result of the substance evaluation may then trigger a restriction proposal.

The examples are not intended to be exhaustive since the motivation for initiating the restrictions process may depend on several different factors, including specific characteristics of the substance of concern.

Examples of triggers for initiating the restrictions process

- Where there are a number of available Chemical Safety Reports (CSRs) for one substance, even if each CSR demonstrates that the risks related to the activities covered by each registration are adequately controlled, the aggregation of the exposure related to all of the activities covered by the CSRs may lead to risks which may not be adequately controlled. For example, this could be through **multiple human exposures** from different sources including exposure via the environment, e.g. simultaneous exposure via inhalation of air, water intake, food consumption, handling of preparations and/or articles releasing the substance, where different components of the exposure arise from activities covered by different CSRs. Alternatively, it may be that the **total environmental exposure from aggregated sources** is considered likely to cause an unacceptable risk at regional level. This may be shown by combination of the largest regional concentrations from a single CSR with the local concentrations from others, or the sum of the individual regional PECs, for example.
- There may be combined exposure due to the formation of the substance of concern through degradation of another substance(s). Two examples where several/many substances were found to have the potential to break down to produce the same substance are presented in the box below.

Example 1 Examples of substances identified as posing a risk and produced by the breakdown of other substances

Nonylphenol - the ethoxylate derivatives of nonylphenol break down under some circumstances to form nonylphenol. Production of the ethoxylates is the production of another substance, or rather a range of substances, which might not be considered together as a group. These substances act as a further source of the original substance over and above what is released from direct use.

PFOS - a range of related substances could break down to give PFOS. In this case, most of the parent compounds are not made directly from PFOS itself, but involved several steps in-between. To produce an Annex XV dossier, one would need to identify (as far as possible) the possible parent compounds that could degrade into the substance. Where they exist, CSRs for the parent compounds could be used. Calculations would need to look at the contributions made by each product (or groups of products) to the overall emissions or levels of the substance of concern.

- A further situation could be where a registered substance (or substances) breaks down to give a product which is not produced or imported (and therefore is not subject to registration) or to a product which is not yet subject to registration (due to tonnage) and which may give rise to concern.
- When a single registration is available, there may still be cases where there is a need for a Community-wide restriction. However, in these cases the preliminary work before proceeding with preparing an Annex XV dossier is important to ensure that identified risks are addressed with an appropriate action.
- A restriction under REACH may be an appropriate measure in cases where the proper implementation and enforcement of risk management measures under other REACH processes or under other legislation is not possible to achieve. Such cases may include:
    - substances having a wide range of uses associated with multiple exposures;
    - substances which may be widely used by consumers in several applications and for which the conditions of safe use cannot be ensured.

It is possible that more than one of the above may be valid for any given substance.

Triggers resulting from enforcement

- Substance evaluation or a compliance check of dossiers by the Agency identifies unacceptable risks that may not be dealt with appropriately by proper implementation of other REACH requirements.
- Enforcement shows that the implemented risk management measures are insufficient and that better enforcement cannot reduce the risks to acceptable levels.
- Enforcement and monitoring of other legislation provides evidence that controls set at the Community level (for instance, environmental quality standards, emission limit values or occupational exposure limits) cannot adequately manage the risk and a change of these values would not be the right measure to achieve the aim.

Limits – when should an Annex XV dossier not be prepared?

An Annex XV dossier may not always be the right way to address the identified risks to human health or the environment. To be aware of the limits of the restrictions procedure under REACH can save a lot of time and resources.

There are limits set out in the REACH Regulation itself:

- A substance included in Annex XIV (the list of substances subject to authorisation) may not be subjected to new restrictions addressing risks related to the intrinsic properties specified in Annex XIV apart from the risks from the presence of the substance in article(s) (Article 58 (5) and (6)). Article 69 (2) requires the Agency to consider for each substance subjected to authorisation whether there are unacceptable risks from the use of the substance in articles after the sunset date set in Annex XIV.
- For the re-examinations of existing restrictions a decision whether this should be done will have to be taken by Comitology (advisory procedure) based on evidence presented by the Member State or the Agency (Article 69 (5)).

A restriction should not be considered to be the universal solution for solving enforcement problems, as all restrictions also need to be applied, monitored and enforced. What is relevant is that all persons who have to comply with any legal obligations are aware of these

obligations and know how to define risk management measures (RMMs) and operational conditions (OCs) required for fulfilling the obligations. The REACH Regulation provides tools to identify RMMs and OCs in the chemical safety reports and communicate these in the safety data sheets or other information to downstream users.

There may also be situations where it can be recognised already at an early stage that an identified risk may not directly require the introduction of Community-wide restrictions and other action, e.g. enforcement may be considered as well. Some examples could be the following:

- The CSRs produced by manufacturers, importers and downstream users may recommend different risk management measures for the same activity and some of these are not adequate.
- The modelling or calculation methods used to estimate exposure concentrations may prove to be not suitable for the substance, resulting in the under-estimation of exposure levels. This may arise when new data on substance properties or re-interpretation of existing data may lead to higher calculated concentrations which may be of concern.
- For effects, the trigger for the Authority's interest may be new data on effects (human health effects or environmental effects), or the re-interpretation of existing data. Where exposures have already been assessed (in CSRs for example) the new effect data would presumably indicate that the exposure levels were now expected to lead to an unacceptable risk.

It is recommended that such new data, or re-interpretation of existing results, are first discussed with registrants, who should, as appropriate, revise their CSRs. If such revision results in adequate management of the risks, the Authority would generally not need to initiate the restrictions procedure (although this may depend on the severity of the effects shown by the new data).

When the risk is relevant in just one Member State, there is no basis for it to be addressed on a Community wide basis. In this case the Member State might have to consider a case under Article 95 (5) of the Treaty. In cases where one Member State identifies a risk and there is no information whether this is the case only in this Member State, it is recommended that they should inform other Member States about this concern to find out whether the concern is shared.

4 INFORMATION FOR THE PREPARATION OF A RESTRICTION DOSSIER

4.1 Information sources

For the decision on whether there is a risk to human health or the environment, all available information on the hazards and risks of the substance should be gathered and evaluated. This information may stem from registrations and evaluations under REACH or from any other source.

Article 69 (4) requires the Agency or the Member State to refer to any dossier, chemical safety report or risk assessment submitted under the REACH Regulation as well as any relevant risk assessment submitted for the purposes of other Community Regulations or

Directives. Any Member State or the Agency may request such information from any Community body holding such information.

The main source of information on substances under REACH is the registration dossier(s). A registration dossier will be produced by each manufacturer or importer registering the substance. These will be stored within IUCLID in the REACH-IT system. The registration dossier consists of a technical dossier and, in some cases a Chemical Safety Report (CSR).

A technical dossier is submitted for all substances manufactured or imported in quantities of one tonne or more per year per manufacturer/importer. The technical dossier includes information on manufacture and identified uses and on uses the registrant advises against. The technical dossier also includes study summaries and robust study summaries. In the case of multiple registrants for one substance, most parts of the technical dossier will be submitted in a joint dossier including these summaries unless companies demonstrate that they have reasons to submit parts individually. The information required to be included in this technical dossier is all of the relevant physicochemical, toxicological and ecotoxicological information available to the registrant; the minimum required depends on the quantity manufactured or imported, with thresholds of 1, 10, 100 and 1,000 tonnes leading to increased data requirements. The time by which the registration is required to be submitted also depends, in the case of phase-in substances, on the quantity and the classification of the substance. Details of the information requirements are set out in Article 10 and Annexes VI to XI of the REACH and are included in the Guidance on registration, the Guidance on information requirements and the Guidance on the Chemical Safety Report.

For substances produced or imported in quantities of ten tonnes or more per year per manufacturer/importer, a CSA is required to accompany the technical dossier. This includes a hazard assessment (human health and environment) and a PBT/vPvB assessment for the substance. If this hazard assessment shows that the substance meets the criteria for classification according to Directive 67/548/EEC, or the substance is assessed as a PBT or vPvB, then an exposure assessment, including the relevant Exposure Scenarios (ES), and risk characterisation must also be carried out. ES include information on Operational Conditions (OCs) and Risk Management Measures (RMM) that the registrant implements and recommends for the actors down the supply chain to adequately control the risks. The results of the CSA are documented in the CSR. In addition, a Downstream User (DU) that uses a substance on its own or in preparation outside the conditions described in an ES communicated to him, needs to prepare a DU CSR, if he is not exempted in accordance with Art 37(4). DU reports to the Agency, where required, include brief descriptions of uses. More guidance can be found in the Guidance for Downstream Users

A further source of information under REACH is through dossier or substance evaluation. Under compliance check (part of the dossier evaluation) registrants may be required to submit any information needed to bring the registration(s) in compliance with the REACH requirements. Substance evaluation is the procedure by which further information (such as testing or exposure and use information) may be requested to clarify risks from substances. After the generation of any requested information, conclusions will be drawn and documented.

The amount of information available to an Authority when beginning the preparation of an Annex XV dossier will, therefore, depend on the status of the substance in REACH, and this may have an influence on the development of the dossier. Possible scenarios of data availability through REACH are:

- Substance is not registered;
- Substance has been registered but no CSR exists (i.e. the substance is produced at quantities <10 tonnes/year);
- Substance has been registered and a CSR exists;
- Substance has been registered and has undergone dossier or substance evaluation.

There could also be situations where more than one of these applies, in particular where some manufacturers or importers dealing with higher tonnages have registered the substance, but the timetable for other registrations at lower tonnages is still to be completed, or where an already registered substance is imported or manufactured by a new manufacturer/importer, resulting in a new registration.

Where a substance has not been registered, then there will be no information within the REACH-IT system at the time, apart from the possible classification and labelling inventory entries, and so other sources of information will then need to be considered. Reviews may have been produced by other fora such as the OECD, IPCS, IARC, national reviews by Member States etc., and if so it will be useful to use these to identify the information that is available. There may also be new studies published in the literature or new research reports. A more detailed search of the literature may help to identify relevant information where there are significant gaps in any available reviews, or where there are no reviews.

Given the possible importance of the outcome, it is recommended that the primary sources of data, for example the full study reports, where available to the Authority, should be reviewed for the Annex XV dossier, particularly for the key studies. Information from secondary sources should not generally be used as the basis for the proposal unless there is a high confidence in the robustness of the approach used to review the data for the secondary source (for example where it is documented that the secondary source had recently reviewed the original full study report against known and acceptable criteria).

Confidential data

A registrant may identify certain information in their registration as commercially sensitive. If the justification with regard to information listed in Article 119 (2) is accepted as valid by the Agency, then this information will be marked as commercially sensitive in REACH–IT. Such information can be used in the preparation of an Annex XV dossier for discussion with the Agency and Member States, as such discussions can be confidential. However, such information must not be included in any documents to be used for public consultation. The Authority therefore has to consider this when preparing an Annex XV dossier. It is recommended to include or mark confidential information in such a way (e.g. in separate annexes) that it can easily be left out when the Agency publishes an Annex XV dossier for commenting in accordance with Art 69(6).

Authorities need to pay attention also to information listed in Article 118 (2). Information to which access cannot be granted under Article 118 must not be published on the internet because the Agency would already have to deny access to such information on request in a single case on the basis of Regulation 1049/2001.

The general provisions on access to information are twofold:

- Some pieces of information will be made available over the internet in accordance with Article 119 (1).

- Access to other pieces of information will be granted by the Agency on request on a case by case basis in accordance with Regulation 1049/2001, as per Article 118 (1). Regulation 1049/2001 defines cases in which access to information has to be denied e.g. for reasons related to the protection of commercial interests which are further explained in Article 118 (2). It also requires the Agency to check with companies that have submitted information to it whether the company claims that the information asked for is confidential. The Agency then has to take a decision.

4.2 Obtaining further information

Any restriction of the manufacture, use or placing on the market of a substance to address unacceptable risks to human health or the environment on a Community wide basis will be adopted by the Commission if it is sufficiently justified. Logically, the Annex XV dossier for the restriction needs to contain sufficient information to support the proposal. Thus, if an Authority considers addressing an initial concern over an unacceptable risk, it will have to verify that sufficient information is available to support the restrictions proposal.

The first step should be to verify whether the **initial concern over the risk to human health or the environment can be substantiated**. Information for that purpose may be available from the Agency because it has been submitted in registration dossiers or as a result of dossier or substance evaluation or from any other source.

Generally, the restrictions procedure may be initiated with or without having completed any evaluation procedure. This depends merely on whether or not sufficient information is already available.

If more information is needed to decide whether an initial concern over the risk is justified, the evaluation mechanisms set out in REACH may be used to require registrants of the substance concerned to generate more information on its hazards and risks. Other parts of the Annex XV dossier will have to be developed by the Authority itself. The Guidance on evaluation describes the possibilities to obtain further information via these REACH procedures.

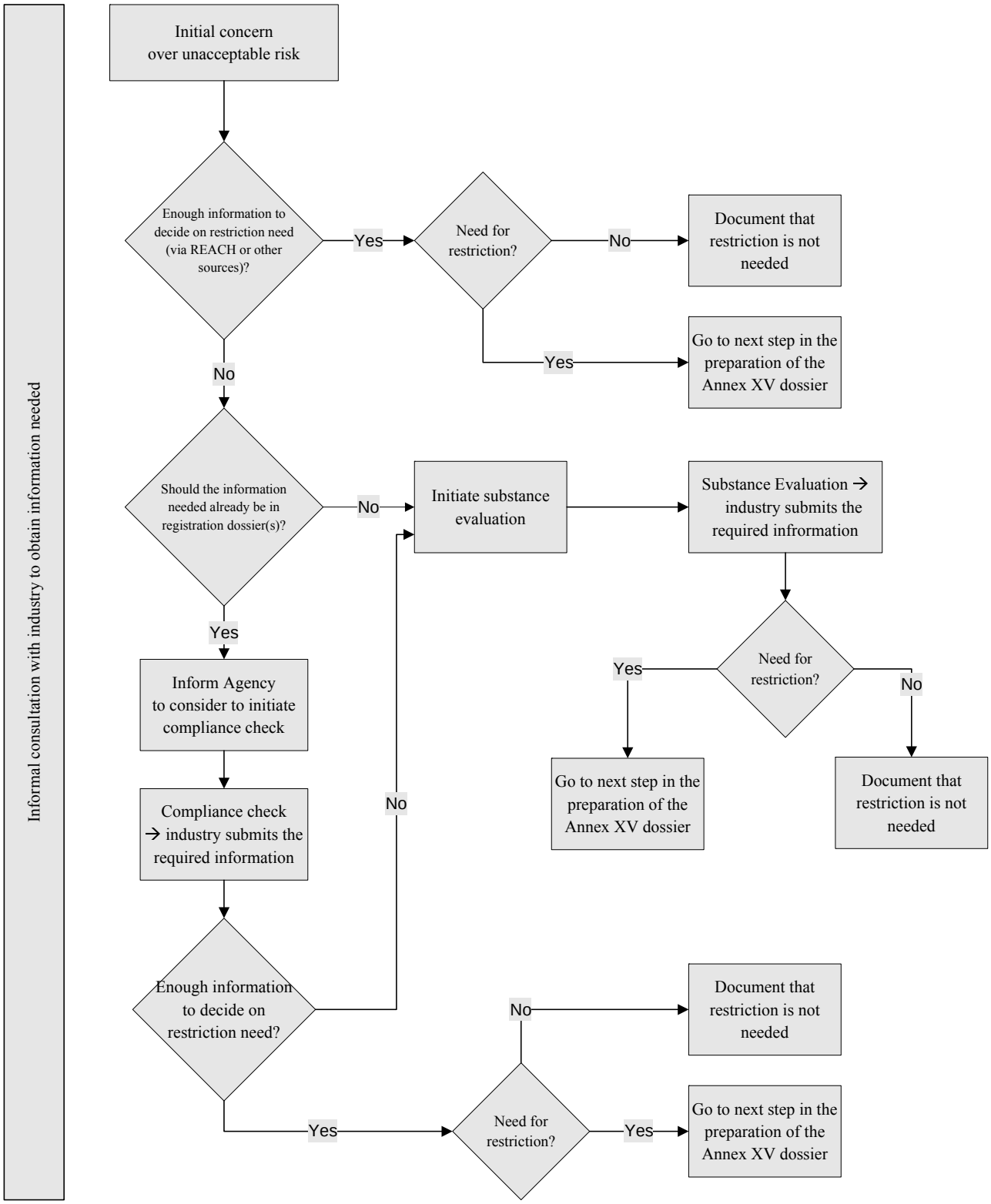
In addition to the formal way provided by the evaluation procedures to require information from registrants, the authority may decide to contact registrants or other relevant actors to request information needed. Even though it is not required, the consultation of stakeholders at this early stage is recommended. Any results from such consultation should also be included later in the Annex XV dossier.

Any examination of an initial concern over a risk – on the basis of sufficient information – will lead to one of the two conclusions:

1. The initial concern over the risk to human health or the environment is substantiated by the information. In this case the next steps for the preparation of the Annex XV dossier should be followed.
2. The initial concern over the risk cannot be substantiated. It is recommended to document the conclusion that restriction is not needed and to consider communicating it to the other Member States and to the Agency also in case this conclusion was made from the available information without an evaluation of the substance.

Figure 2 gives an overview of the possibilities to obtain the information needed for deciding which one of these two conclusions is relevant.

Figure 2 Possibilities to obtain information from substance evaluation to decide on the need for a restriction



4.2.1 Dossier and substance evaluation

Evaluation may provide information that is useful for developing restrictions proposals and the outcome of evaluation should be considered. This is summarised below, the Guidance on evaluation provides further details.

Dossier Evaluation

A first consideration may be whether the information should already have been submitted to the Agency in a registration dossier, i.e. whether there is a registrant who is not complying with the registration requirements.

With regard to hazard information the answer to this question depends on the quantity of the substance registered as the information requirements depend on tonnage bands, and on the justification for any waiving statements. If the missing information should have been submitted in a registration dossier, the compliance check under dossier evaluation could be the right tool to generate the missing information.

If the Agency is preparing an Annex XV dossier and considers that information is missing that should have been submitted under registration, it may decide to perform a compliance check of the dossier.. If a Member State considers that information is missing that should have been submitted under registration, it should inform the Agency which may decide to perform the compliance check.. The Member State may also make use of Article 45 (5), to notify the Agency at any stage of a substance that it suggests as a priority for substance evaluation. Substances included on the Community rolling action plan for substance evaluation are a priority for dossier evaluation. The Guidance on priority setting for evaluation provides further details on how substances are prioritised for dossier and substance evaluation.

Note that the Agency also keeps a list of all dossiers being checked for compliance. This list will be made available to the Member State competent authorities.

The Agency shall use the information obtained from the dossier evaluation for the purpose of setting priorities for substance evaluation. The competent authority of the Member State shall consider how to use the information obtained *inter alia* for the purpose of preparing any restrictions or suggesting a substance to be included as a priority for substance evaluation on the Community rolling action plan.

If the information generated under dossier evaluation is sufficient to decide whether there is a risk, one of the two numbered conclusions described under point 4.2 shall be drawn and documented.

Substance Evaluation

If the information included in a registration dossier(s) is not sufficient to decide whether there is a risk, substance evaluation may be considered. Substance evaluation is the tool to require from registrants further information that may be used to verify whether a substance constitutes a risk to human health or the environment where there are grounds to consider that such a risk exists.

Substances to be evaluated have to be included on the Community rolling action plan. Article 45 (5) allows any Member State at any time to suggest a substance to the Agency for

inclusion in the Community rolling action plan, if the Member State possesses information suggesting that the substance is a priority for evaluation. The Agency shall then decide about the inclusion on the basis of an opinion from the Member State Committee.

The competent authority of the Member State shall examine any information submitted, and consider how to use the information obtained for the purposes of, *inter alia*, the restrictions procedure. It has to inform the Agency, the Commission, the registrants and the other Member States of its conclusions.

4.2.2 Informal consultation in the preparation of an Annex XV dossier

Although Annex XV includes no specific requirement for Authorities to engage in consultation, stakeholder involvement in the process is important. Consultation of industry and other stakeholders may be an important way for the Authority to obtain additional information although stakeholders have no legal obligation to provide information for the development of an Annex XV dossier. It should be noted that the term consultation is used throughout this document to refer to contacts with stakeholders aiming at voluntary submission of information and should not be confused with the formal request for commenting and providing information which will follow the submission of a finalised dossier to the Agency (such as under Article 69(6) of the REACH).

The Authority preparing the dossier should decide upon the need for consultation and the resources and time to be allocated to consultation activities. However, Authorities are encouraged to engage stakeholders and other interested parties in the development of the dossier as early in the process as possible. This will facilitate the timely collection of the necessary information and will contribute to the transparency and representativeness of the restrictions dossier. At the very least, the Authority should consider informing the identified interested parties that work related to a possible restrictions dossier has been initiated (this is not the formal notification to the Agency of the intention to produce a restrictions dossier).

Consultation for a restrictions procedure should have clearly identified objectives and be time-bound. The depth of consultation should also be proportional to the severity and complexity of the situation. The approach for and means to carry out any informal consultation depends on the case, e.g. which types and how wide groups of actors may be affected by the considered restriction. The consultation can take any form from addressing selected actors with targeted questions to an open call for contribution via internet. The documentation of stakeholder consultation is discussed in chapter 5.7.

Appendix III ppendix III illustrates types of information that may be sought from different types of consultees for different parts of an Annex XV restrictions report. The table is not exhaustive and both the types of information and the types of consultees will vary on a case - by- case basis.

The Agency and the Commission services are not included in the table. The Agency Committees will be in charge of assessing the restrictions dossier once it has been submitted, and the Commission will be in charge of making the decision. However, the Authority may contact them with technical queries or to request advice (for example, in the interpretation of Community legislation).

Authorities should critically assess data from consultation, taking into consideration who is providing information, what vested interest each party has in the introduction (or not) of any restriction and the quality of the submitted information.

4.2.3 Grouping

Grouping of substances may be relevant for the restriction procedure in two different ways.

Firstly, registrants may have grouped substances for the purpose of preparing a chemical safety assessment (Annex I of the REACH Regulation, Section 0.4). This 'CSA grouping' will affect the information basis available for the restriction procedure.

It may concern grouping of substances for which the physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as described in Section 1.5 of Annex XI of the REACH Regulation. This will mean that for those properties that lack data, information can be used or interpolated from substances within the group. Another type of the 'CSA grouping' is when the registrant concludes that the CSA carried out for a substance is sufficient to assess and document that the risks of another substance are adequately controlled even if this other substance has no similar intrinsic. If a registrant uses either of these ways of grouping, he needs to provide in his CSA a justification for this. When preparing a restriction proposal the Authority needs to consider on a case-by-case basis for which substances in the group a restriction is justified.

Secondly, the Authority preparing a restriction proposal may wish to cover a number of related substances by the same Annex XV dossier. This could be the case when the key property in combination with the exposure that causes the risk leading to the proposal of a restriction is shared by several related substances. Examples of such a case from the current restrictions of marketing and use under Directive 76/769/EEC are nonylphenol and nonylphenol ethoxylates, and short-chain chlorinated paraffins. The Annex XV dossier has to provide sufficient information to support the restriction of all substances covered by the proposal.

4.2.4 Transparency

It is important that the process of developing a restrictions dossier is transparent. Transparency means that available information has been taken into account and is reported in an unbiased manner, and all assumptions and methodologies used are clearly explained. In this context, the analysis needs to be:

- *based on sound information*: the reliability of information sources and the subsequent assumptions need to be evaluated and documented in the report;
- *open to review*: assumptions, conclusions and decisions should be open to review so that new or improved information may be taken into account as the development of the restrictions dossier progresses; and
- *reflective of the uncertainties*: areas of uncertainty including how these have been identified, how they impede the assessment and what has been done (or would need to be done) to reduce the uncertainty, should be described in the restrictions dossier.

Uncertainties may influence the preparation of a restrictions dossier. These largely arise because of a lack of information or a lack of knowledge about the consequences of a given action, and may include:

- knowledge uncertainty (for example, uncertainty on the nature of risks from alternative substances or techniques);

- real-world uncertainty (for example, uncertainty on whether all sites involved in risk management will comply with a certain legal requirement or what the socio-economic implications of RMOs might be); and
- scientific or data uncertainty (for example, uncertainty on the quality and/or quantity of toxicity data for the substance of concern).

Uncertainties need to be addressed in the Annex XV restrictions report by:

- defining and documenting uncertainty and its boundaries (i.e. show where uncertainty exists, how it affects the analysis and justification for the proposed restriction);
- describing assumptions clearly; and
- explaining the actions taken to reduce uncertainty.

Guidance on dealing with uncertainty through a range of different analytical methods is provided in the SEA guidance (XXX). Also, the CSA guidance (XXX) provides guidance on dealing with uncertainty in the field of risk assessment.

5 PREPARATION OF AN ANNEX XV RESTRICTIONS DOSSIER

5.1 Overview

5.1.1 What is an Annex XV dossier?

The Annex XV dossier consists of two parts, in parallel to the registration dossiers for substances manufactured or imported in quantities of ten tonnes or more per year per manufacturer/importer which consist of a technical dossier and a Chemical Safety Report (CSR). The two parts of the Annex XV dossier are:

1 The Annex XV report. For consistency between all the documentation prepared under REACH, the format of the parts of the Annex XV report relating to the hazard and risk assessment of the substance follows closely that for (evaluation and of) the CSR. The basic format has been adapted to the specific requirements of the individual Annex XV dossiers in some cases. The formats for Annex XV report are included as Appendices to the guidance. The report will be produced and attached to the technical dossier in IUCLID.

1. A technical dossier supporting the Annex XV report and stored in IUCLID. This can include robust study summaries imported from registration dossiers available in IUCLID. These reference study records may be annotated by the Authority. Robust study summaries or study summaries can also be created by the Authority in the case of additional data being available (see appropriate guidance from the Guidance on registration).

The term Annex XV dossier is used to refer to the package of the Annex XV report and the technical dossier. The guidance on reporting given in Appendix IIrelates to the preparation of the Annex XV report.

5.1.2 Workflow

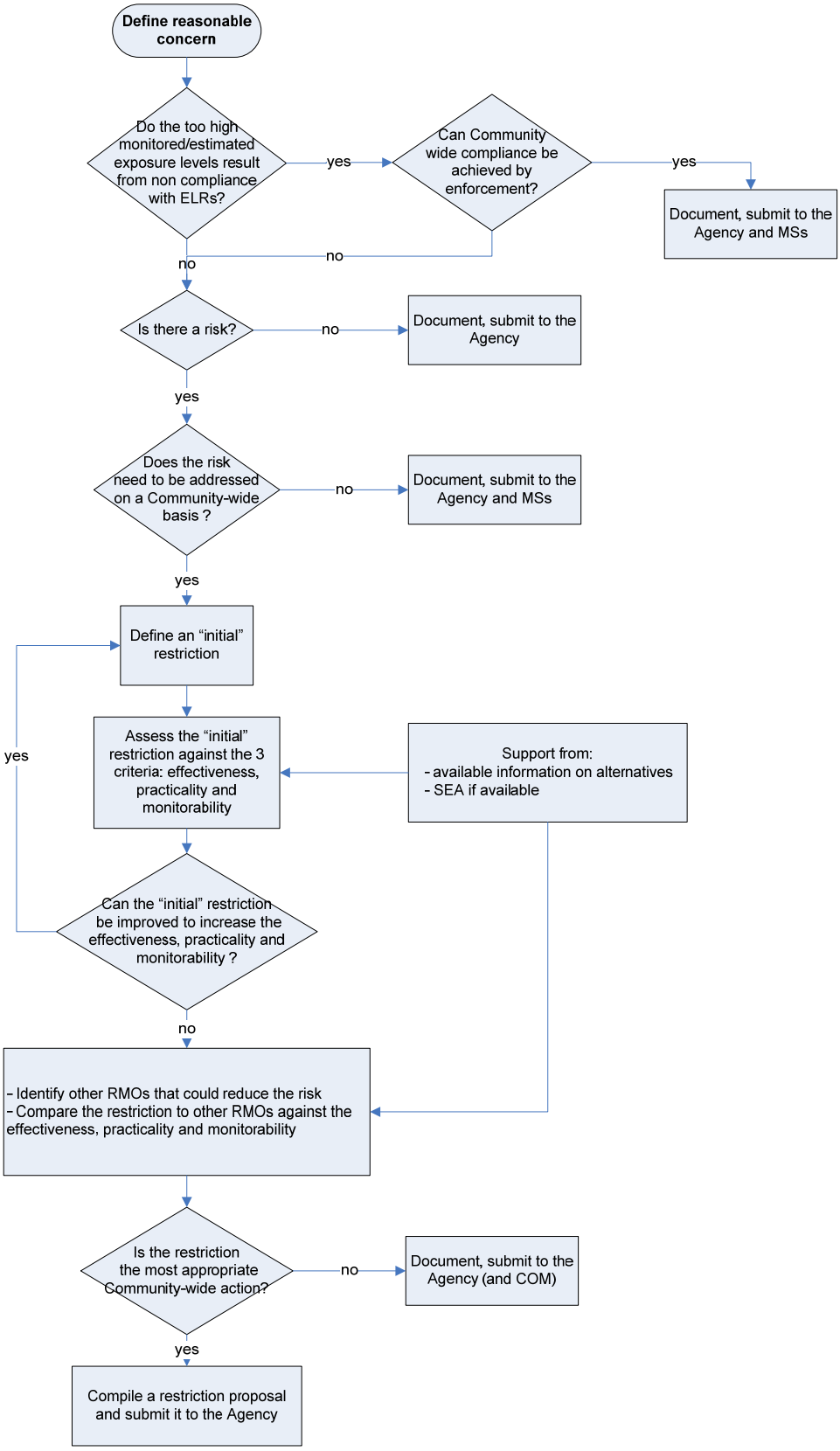
A proposal for a restriction has to:

- show that a substance on its own or in a preparation or article poses a risk that needs to be addressed (chapter 5.2)
- provide justification for restriction at Community level that
  - action is required on Community-wide basis (chapter 5.3)
  - a restriction under REACH is the most appropriate Community wide measure (chapter 5.4)
- include available information on alternative(s) (chapter 5.5)
- describe how stakeholders have been consulted during the preparation of the proposal (chapter 5.7)

In addition a restriction proposal may include a socio-economic assessment (chapter 5.6).

The final proposal for a restriction together with justification and supporting information will be documented in an Annex XV report.

Figure 3 Outline of the successive components of the preparation of an Annex XV dossier proposing a restriction.



The workload for completing an Annex XV dossier will vary from case to case. Firstly, the workload will depend on the extent and nature of the case, e.g., number of uses covered and the importance and complexity of substitution. Furthermore, the workload is expected to be proportional to the availability of existing data. If for example a substance is registered and evaluated the hazard, exposure and risk related parts of the Annex XV dossier will be relatively easy to complete and the highest workload will be on preparing justifications on the need for action at Community level and that the suggested restriction is the most appropriate Community wide measure. In a case where a part or most of the information on hazards, exposures and risks required for the development of an Annex XV dossier is lacking then it is expected that this process will be more resource intensive since the relevant information needs to be gathered and the required assessments and justifications will have to be developed. In cases where further information is needed to substantiate the risk, it is recommended to first propose the substance for inclusion in the Community Rolling Action Plan for substance evaluation and then, if there is a concern, proceed with the Annex XV dossier. It is highly recommended to go through such workload considerations prior to notifying the Agency about the intention of completing an Annex XV dossier due to the restricted timeframe within which the Annex XV dossier has to be completed.

Stage in the restrictions procedure	General types of consultees				
	Authorities in other Member States and non-EU countries	**Trade associations and companies (manufacturers, importers and users)**	**Labour organisations**	**Consumer groups**	**Experts in academic and research community**
Information on the effectiveness of implemented RMMs and compliance with ELRs	▪ Scope for improvement of implemented RMMs ▪ Information on past potential of enforcement of implemented RMMs ▪ Scope for introducing national measures	▪ Scope for improvement of implemented RMMs	▪ Scope for improvement of implemented RMMs	▪ Scope for improvement of implemented RMMs	▪ Scope for improvement of implemented RMMs
Identification of RMOs	▪ Advice on past effectiveness of RMOs and implementation tools ▪ Information on current state and structure of the relevant markets in their territory ▪ Information on any previous risk management options considered and difficulties that were encountered during their implementation.	▪ Advice on past effectiveness of RMOs and implementation tools ▪ Information on current state and structure of the relevant markets	▪ Advice on past effectiveness of RMOs and implementation tools	▪ Advice on past effectiveness of RMOs	▪ Advice on past effectiveness of RMOs

Stage in the restrictions procedure	▪ General types of consultees ▪ Authorities in other Member States and non-EU countries	▪ Trade associations and companies (manufacturers, importers and users)	▪ Labour organisations	▪ Consumer groups	▪ Experts in academic and research **community**
Assessment of RMOs against the three key criteria of effectiveness, practicality and monitorability as well as considerations on any derogations that may be required	▪ Information and past experience pertaining to the assessment of RMOs ▪ Views on the practicality of RMOs (including implementation costs such as the costs of loss of uses of the substance/use of alternatives) ▪ Information on the availability of enforcement mechanisms and monitoring networks ▪ Information on criticality of uses ▪ Information on current R&D in the sectors of concern	▪ Information and past experience pertaining to the assessment of RMOs ▪ Views on the practicality of RMOs (including implementation costs such as the costs of loss of uses of the substance/use of alternatives) ▪ Information on the availability of monitoring networks ▪ Information on criticality of uses ▪ Information on current R&D in the sectors of concern	▪ Information and past experience pertaining to the assessment of RMOs ▪ Views on the practicality of RMOs (including implementation costs) ▪ Information on the availability of monitoring networks ▪ Information on criticality of uses	▪ Views on the practicality of RMOs (including implementation costs) ▪ Information on the availability of monitoring networks ▪ Information on criticality of uses	▪ Views practicality and monitoring issues ▪ Information on criticality of uses ▪ Cost of loss of uses of the substance/use of alternatives ▪ Information on current R&D in the sectors of concern

Appendix IV Appendix IV includes examples of different types of cases where a restriction proposal is considered and the anticipated workload for the preparation of an Annex XV report.

5.1.3 Key terms

RMMs and OCs: risk management measures and operational conditions. This term is used for concrete risk management measures and operational conditions taken by Industry to control the exposure to the substance of concern. These include both emission/exposure reduction equipment and how this is operated as well as relevant process parameters that affect the emission/exposure levels. Registrants document, where required, risk management measures and operational conditions in an Exposure Scenario (ES) as a part of their Chemical Safety Report (CSR).

ELRs: existing legal requirements. This term is used for the existing legislative and regulatory requirements for Industry resulting from Community and national legislation other than restrictions under REACH (for example, environmental quality standards, emission limit values or occupational exposure limits). To comply with these requirements, Industry may have put in place RMMs and OCs or take other action. For the purposes of this document ELRs cover also the existing economic instruments and Industry's voluntary commitments.

RMOs: risk management options. This term is used for any possible changes to legislation or other requirements on Industry (e.g. in permits) to control risks accordingly. RMOs may also cover the use of economic instruments and Industry's voluntary commitments.

5.1.4 What to do when an Annex XV dossier is not appropriate

There may be cases where the Authority carries out work towards an Annex XV dossier but concludes at some point that in fact a dossier suggesting a restriction is not appropriate. Figure 4 shows a number of points in the development of the dossier where the Authority may conclude that a restriction under REACH is not needed or justified. In all cases, it is important that the work that has already been undertaken is not lost but is made available for possible future work. This will effectively involve documentation of the findings so far in an Annex XV dossier format even though the Authority has decided not to proceed further. It is up to the Authority to decide how much of the work they have done needs to be documented. The key outcome must be that the work undertaken by one Authority should be known and available to the Agency and other Authorities so that the process works efficiently and without undue duplication of effort.

The information documented should be submitted to the Agency so that the Agency can make the information available on the REACH-IT system where it will be accessible to other Authorities for future work. It is recommended that the Authority also submits the documented information further to the Member State authorities or to the Commission where action by Member State authorities at the national level or by the Commission under other Community legislation is anticipated. Well documented information in Annex XV dossier format will provide a good basis for taking action also under other Community legislation or at national level.

5.2 Information on risk

The risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I of REACH Regulation. Guidance on developing Chemical Safety Report (CSR) will contain detailed guidance for the assessment of hazard and exposure and for risk characterisation. This guidance gives also advice on how to describe uses for the purpose of developing Exposure Scenarios (ES). The development of a

common system for brief descriptions of uses for the purpose of Annex VI, section 3.5 is also underway. More precise references to this guidance will be added, where relevant, when this guidance is available.

Aim: The aim of this task is to identify the risks that the substance on its own, in a preparation or in an article poses to human health or the environment. Furthermore, evidence needs to be provided that implemented risk management measures and operational conditions are not sufficient.

Scope: This stage includes hazard assessment, exposure assessment and risk characterisation. The basic approach applied in these steps is set out in the Guidance on the Chemical Safety Report. The exposure assessment needs to take into account Exposure Scenarios (ES) implemented by the industry and recommended to actors in the supply chain. It is recommended that the Authority also considers the reasons why the risk management measures and operational conditions described in the ES(s) are not sufficient and, especially, consider whether the monitored or estimated exposure levels correspond to the ESs. Furthermore, it should be considered whether the compliance with REACH or other legal requirements would sufficiently reduce exposure and whether Community wide compliance can be achieved.

The work can be targeted to focus on certain risks. This targeting may affect the hazard assessment or the exposure assessment part or both.

Outcome: This assessment will form a justification that the substance poses a risk to human health or the environment that is not adequately controlled. It will give a basis for the development of other parts of a restriction proposal and define the scope and focus of that work by identifying

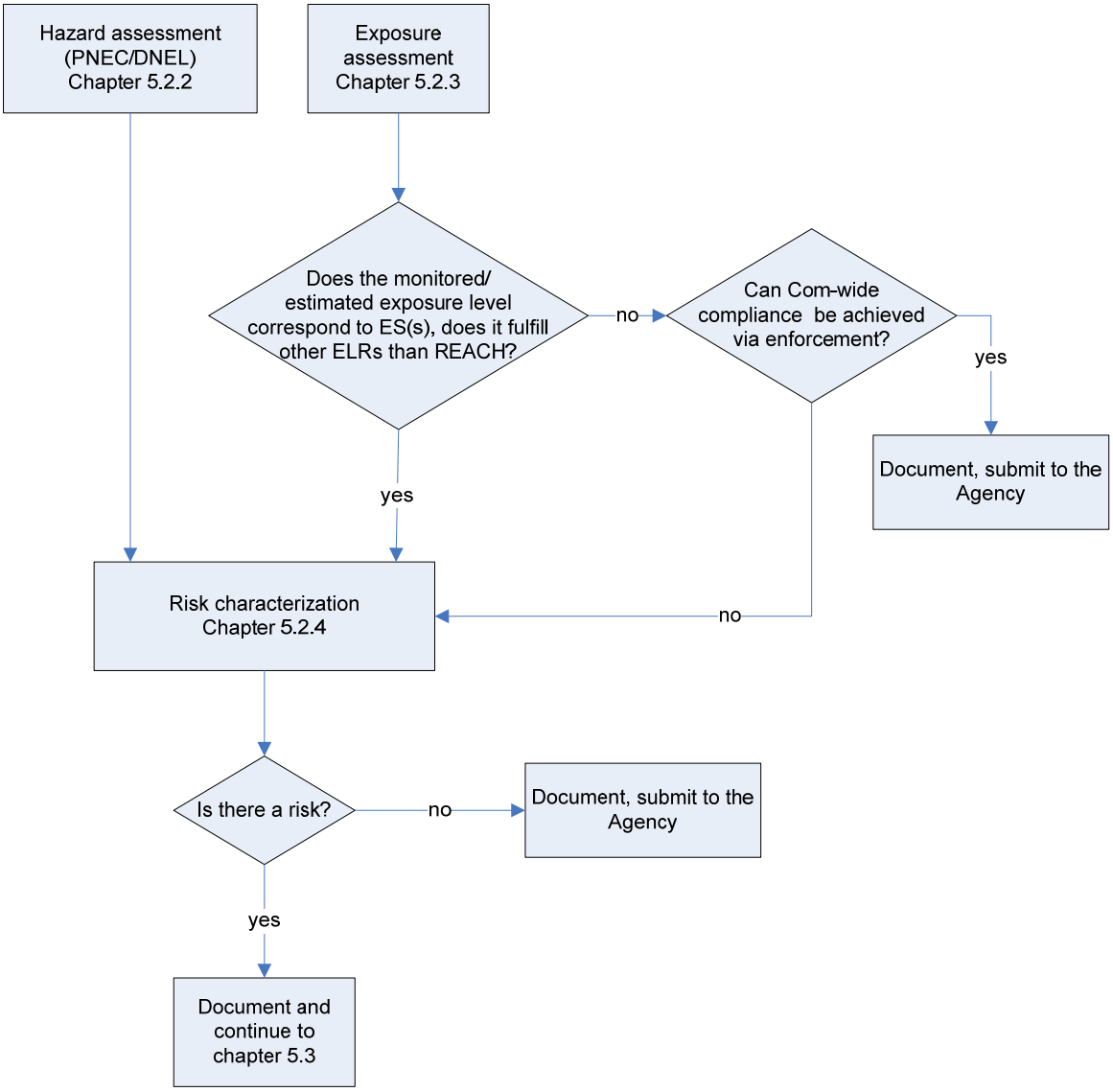
- which manufacture, placing on the market or use(s) cause the risk
- in which life-cycle stage(s) of the substance the exposure causing a risk occurs
- which human populations or environmental compartments are at risk.

The information and assessment will be documented in sections 4 to 9 of the restriction format (APPENDIX I). The results of the assessment will be summarised in the restriction proposal.

Exits from the restriction procedure: If the assessment shows that the substance does not pose a risk, the Authority is requested to document the assessment in the relevant parts of the restriction format and submit this documentation to the Agency with the conclusion that no further action is needed. The Agency will store the assessment in the REACH IT. The purpose of this documentation is to ensure that the work already done is not lost and can be used by other actors dealing with the substance.

If the assessment indicates that the risk would be sufficiently reduced by compliance with already existing legal requirements and that Community wide compliance could be achieved via enforcement, the Authority is requested to document this conclusion in the relevant parts of the restriction format and submit the documentation to the Agency Forum and Member State CAs.

Figure 4 Overview of the identification of risk(s)



5.2.1 Targeting the assessment

The areas (e.g. manufacture/uses, sources of exposure, risks) which the Authority should address in a restriction proposal will be largely determined by the nature of the initial concern leading to the preparation of the dossier. The decision to target the dossier should be considered carefully. Any decision on when and how to target the restriction procedure needs to be taken on a case-by-case basis. It should be recognised that targeting may not be the most effective way to address the overall risks from a substance. Qualitative or quantitative sensitivity analysis may be used to support decisions on targeting. Further guidance on sensitivity analysis is provided in the Guidance on Socio Economic Analysis. The targeting decision, boundaries of the restriction proposal and underlying justification for the targeting need to be documented. Some advantages and drawbacks to targeting are summarised in the box below.

Advantages and drawbacks of targeting

Advantages may include:

- simplifies the process;
- allows resources to be used effectively; and
- the proposal for a restriction can be prepared more quickly.

Drawbacks may include:

- danger of oversimplification. Links between sources of exposure and the actual populations / environmental compartments exposed may not be obvious;
- important sources of exposure may be neglected and so not be considered;.
- the substance may have effects on endpoints other than those considered;
- the substance may have to be reassessed at a later time to address other issues;
- there may be a need to make changes to adopted restrictions later if all areas are not addressed; and
- limited coverage in the dossier may make comparison with alternatives difficult.

Two types of targeting could be considered. The first, the 'rapid restriction' targeting, is where only a limited part of the possible assessment is included. This would relate to cases where a specific concern requiring prompt action is identified, where the effects and the related exposure are clearly defined and can be addressed directly. Only those parts of the dossier relevant to the concern would be completed, taking account of relevant parts of any CSRs submitted under registration.

The second type of targeting, the 'CSR review targeting', focuses the review and assessment work on those areas considered to be of most concern, and refers to CSRs (where available). When undertaking this, the Authority may cover other areas not covered in the CSRs, where considered relevant. This may produce a more complete assessment and will be more useful in comparing the substance with possible alternatives. The assessment will be more robust if the Authority is able to review relevant information in the CSRs. The Authority should make clear in the Annex XV dossier which areas have been reviewed and agreed by the Authority, and which have been taken from the source document without further review.

The following are some examples for further targeting when reviewing information during the preparation of an Annex XV dossier :

- Human health risk versus environmental risk - it may be clear from the registration information or from substance evaluation that there is no concern about health effects, so that the dossier could address only the environmental aspects (or vice versa).
- Identifying key sources of release or exposure - not all sources may be significant:
  - The concern may be for the compartment to which the substance is released, and only certain uses (or manufacture) and related lifecycle steps may have direct releases to this compartment. Attention could be focused on these sources. There may be a need to investigate to some extent that releases from other uses do not transfer significantly to the compartment of concern after release.
  - Targeting may also take place where concerns arise from diffuse emissions and for background concentrations. In such a case, it may be possible to make order of magnitude estimates of emissions from different sources, and to identify those which are not significant contributors. These may then be omitted from further investigation.

- Human exposure is estimated as a combination of workplace, consumer and exposure through the environment. It may be possible to make a quick comparison between these possible contributions and determine that one or more do not lead to significant exposure, in which case they can be neglected. Where exposure through the environment is significant, the comments in the point above will be relevant.

- Targeted compartments - if the substance has properties which indicate that it stays in one compartment, then only the effects data for that compartment will be relevant.

Targeting may also be relevant for alternatives, but Authorities should be aware of the possible drawbacks from targeting which are relevant when considering alternatives. This issue is discussed in chapter 5.5 of this guidance and further comments on the targeting of specific aspects of the risk assessment are included in the following sections.

5.2.2 Hazard assessment

Aim: The objective of the hazard assessment in the context of restrictions proposals is to identify PNEC and DNEL values, or to determine values with other appropriate methodologies in the case of non-threshold effects, for use in the risk characterisation.

Scope: The Guidance on the Chemical Safety Report describes how to prepare health and environmental hazard assessment. The basic steps required for this section are:

- Information collection.
- Information review.
- Dossier sections completion

The amount of work required for these steps will depend to some extent on the degree to which the Authority is producing a targeted assessment, and also on the stage in the REACH process at which the substance is being considered, but the same general principles apply. In principle, any of the endpoints included in the Annex XV restriction report format could be relevant, and so the guidance in this section is of necessity presented in general terms. Hence for the most part no distinction is drawn between health related endpoints and environmental endpoints. There are, however, some instances where more specific comments are made or directions to more specific guidance given.

Outcome The information and assessment will be documented in sections 5 to 7 of the restriction format (APPENDIX I).

Information collection

The information needed is the PNEC and DNEL values related to the endpoints identified by the Authority as being relevant for the production of the dossier, or the study summaries from which the PNEC and DNEL values are to be derived. This may include supporting information on related endpoints or substances, and physico-chemical data needed for the interpretation of the studies.

Information sources under REACH are considered in Section 4.1 of this guidance. The main parts of the CSRs or technical dossiers of relevance are:

Topic	Sections in technical dossiers	Sections in CSR (all in Part B)
Human health hazard assessment	Section 6	Section 5
Environmental Hazard Assessment	Section 5	Section 7

Information review

In most cases the starting point will be a review of the DNEL and PNEC values in the registration dossier(s). Criteria for the validity and relevance of studies are included in the CSA guidance (XXX) and this guidance should be used. In many cases there will be just one data set as submitted by the lead registrant. In cases where the registrants did not share data in compiling their registrations, the reasons provided for this should be examined. There may be a broader data base available when the different submissions are combined, and this could allow the revision of the PNECS and/or DNELs (which should be done in case this reduces or removes the concern which prompted the Authority to consider preparation of the dossier).

Bearing in mind the comments on targeting in chapter 5.2.1, the Authority is encouraged to review as many of the PNEC and DNEL values included in the registration dossiers as possible, recognising the likely limitations on available resources.

There are two possible outcomes from this review.

1. The PNECs and DNEL values are found to be suitable. In this case no further review work is required and the relevant dossier sections can be completed (see below).
2. The Authority does not agree with the derived PNEC and DNEL values. (This could be due to different interpretation of the studies on which the values are based, or to new information not included in the registration dossiers. New information may come from clarification or generation of data through substance evaluation.) In this case the Authority will need to derive new PNEC or DNEL values based on the revised interpretation of studies or on new data, using the methods in the CSA guidance.

In the situation where there are no CSRs available for the substance, the Authority will need to develop their own values from the data collected from other sources. These data should be reviewed using the CSA guidance (XXX), and the same guidance followed in deriving the PNEC and DNEL values.

The above comments are relevant to the consideration of alternative substances as part of preparing the Annex XV restriction dossier (see Section 5.5).

Preparing the report

The relevant sections of the Annex XV restrictions report (APPENDIX I) are *Section 5* on human health hazard assessment and *Section 7* on environmental hazard assessment. The work required to complete the dossier will depend on the outcome from the review of the CSRs or of the available information.

5.2.3 Exposure assessment

Overview of task

Aim: The objective of the exposure assessment is to make a quantitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. The exposure assessment needs to take into account the Exposure Scenarios (operational conditions and risk management measures) recommended to and implemented by actors in the supply chain.

Scope: The process of exposure assessment is described in the Guidance on the Chemical Safety Report, covering health and environmental exposure. The amount of work required will depend to a certain extent on the stage in the REACH process at which the substance is being considered. However, in most cases additional work on the exposure assessment is required for the Annex XV purposes. The exposure needs to be estimated for each exposure scenario, in other words in necessary detail to give clear basis to identify which manufacture or use(s), and which related life-cycle stages may cause the risk. This is necessary to enable proper identification of risks that need to be addressed.

The main parts which need to be considered in an exposure assessment in relation to an Annex XV restriction report are the same as for a CSA: emission estimation, distribution, calculation of predicted exposure concentrations, use of measured levels. However, for the purposes of a restriction proposal exposure assessment may need to take into account other sources of the exposure than those resulting from (a single) registration. The exposure assessment needs to take into account the implemented ESs (OCs and RMMs) and reflect as much as possible real world situation.

The exposure assessment section in this guidance should be considered as a tool to generate exposure levels information. The underlying methods can be used in a variety of situations of which the main ones are:

a. the assessment of exposure under the current situation and conditions in order to demonstrate a current risk;
b. the assessment of exposure remaining after the proposed restrictions are in place, to demonstrate the removal or reduction in risk; and
c. the assessment of exposure for alternative substances.

Point a includes the situation based on implemented RMMs and OCs as described in the ES, or based on a revised interpretation of these measures after review by the Authority according to chapter 5.2.3.1 of this guidance.

Points b and c are considered in the relevant sections below (chapters 5.2.3.2 and 5.5)

General considerations

Two examples of reasons to reassess the exposure assessments submitted by registrants and calculate revised exposure concentrations are provided here. One is that the existing registration dossiers do not address the total exposure. This is likely to arise where there are a number of separate registrations, and may relate to exposure of the environment or to human exposure. There could also be other sources of a substance, such as formation from the breakdown of another substance, or natural sources. The Authority may also wish to consider the potential contributions from manufacturers or importers who have not yet submitted registrations. Consideration of the aggregated emissions to the environment will lead to changes in the regional emissions to the environment and hence to the regional concentrations (and in the local PECs too). For human

exposure, combinations of exposures from different scenarios can be considered, together with revised indirect exposure through the environment. The exposure estimates need to take into account the ES (RMMs and OCs)in place, as reviewed by the Authority according to chapter 5.2.3.1.

A second reason is that the Authority considers that the ES used as basis for exposure estimation in the CSA will not function as described, leading to other exposures or higher levels than documented in the CSR (following review as described in chapter 5.2.3.1). This will lead to changes in emissions, with direct changes to the local concentrations and occupational, consumer or indirect human exposure concentrations as well as an effect on the overall emissions and regional concentrations. Note that the effectiveness of RMMs and OCs may also be assessed by the Agency as part of a compliance check.

Information on the physico-chemical properties of the substance and those which govern its environmental fate and distribution is needed to move from the emission estimates to exposure concentrations. These data are not considered in this guidance, the Authority should use the CSA guidance and dossier evaluation guidance in reviewing the available information and selecting the values to be used in the assessment.

The calculation of exposure concentrations requires the use of suitable models. Models for calculation of predicted concentrations are considered in the CSA guidance in terms of their suitability of the exposure assessment, and these are not discussed further here. It is assumed that in the majority of cases, the Authority will use the same model(s) as used in the CSR. If the Authority considers that a different modelling approach should be used to that used in the CSR, then this will need to be documented and justified.

Some comments on the use of measured levels are included below in this guidance, but more details can be found in the CSA guidance.

It is assumed in this guidance that at least one registration dossier containing an exposure assessment is available for the substance. If no exposure assessment is available, then the Authority would need to develop such an assessment from the beginning. The process is described in the CSA guidance and this should be followed. It is recommended that such a process be carried out in partnership with the manufacturer(s) and/or importer(s) of the substance, if at all possible. This aspect is not considered further in this guidance.

5.2.3.1 Assessment of effectiveness of implemented Exposure Scenarios and checking the compliance with ELRs

Overview of task

Aim: The Authority should assess the effectiveness of the implemented Exposure Scenarios (ES) defining the operational conditions (OCs) and risk management measures (RMMs) as appropriate. The results of this assessment will be used in the development of a well-informed and realistic exposure assessment that takes into account the existing risk management practices along the supply chain.

Furthermore, the Authority should consider as appropriate and as far as reasonable whether the implemented OCs and RMMs fulfil the existing legal requirements (ELR). Furthermore, in cases where they do not seem to fulfil the ELRs, to consider whether the compliance could reasonably be achieved by enforcement. .

Scope: The assessment of the effectiveness of the ES (OCs and RMMs) should cover:

- ESs implemented by Manufacturers/Importers (M/I) and, where available, documented in the relevant CSRs
- ESs recommended, where required, by M/I to downstream users and documented in the relevant CSRs
- ESs implemented by Downstream users (DU) and, where available, documented in the relevant DU CSRs
- ESs implemented by DUs in addition to those recommended in the ES(s) (either due to other existing legal requirements than REACH or due to other reasons (e.g. technology used, product quality reasons etc.))

To be able to consider the compliance with ELRs the Authority needs to identify the relevant existing legal requirements that aim at reducing emissions and exposures or affect them. ELRs cover, as appropriate, both REACH and other legislation. Secondly the Authority needs to compare the ESs provided by actors in the supply chain with the identified ELRs to estimate whether the current requirements are fulfilled. The level of detail of such assessment depends on the case.

Outcome: The assessment of the effect of ESs on exposure is an inseparable part of any exposure assessment. For the purposes of a restriction proposal this aspect of the exposure assessment is highly relevant and needs to be documented transparently as one of the reasons for considering the need for proposing a restriction is that the ESs implemented have shown not to be in practice as effective as foreseen.

The outcome of the assessment of the effectiveness of OCs and RMMs will also be used when considering whether the estimated or modelled exposure level is a result of non-compliance with ELRs.

The overview of the ELRs already regulating the emission(s) / exposure(s) of the substance can also be used in the identification of alternative RMOs (section 5.4.4). Any observation related to the problems in enforcing ELRs should be taking into account in the assessment of enforceability of the proposed restriction

and the alternative RMOs

The information will be documented in section 9.1 of the restriction format (APPENDIX I).

Carrying out the task

The basic steps to carry out this task are

- Identification of the ELRs
- Identification and assessment of the effectiveness of the implemented ESs (OCs and RMMs)
- Comparison of the implemented ESs with ELRs

The information that can be used for identifying ELRs and for performing the assessment of implemented OC and RMMs and the possible information sources are outlined in **Errore. L'origine riferimento non è stata trovata.** 1.

Table 1 Information and requirements for identification of ELRs and for assessing the effectiveness of implemented ESs

Types of relevant information	Possible sources of information
Identification of ELRs relevant for the emissions of / exposure to the substance • Community legislation • National legislation • International initiatives • Voluntary commitments by the industry, economic instruments	• Legislation • Database of notifications under Directive 98/34/EC[2] • MS competent authorities International fora which the EU or individual Member States are parties to. Examples are: o the United Nations Environment Programme (and the United Nations Economic Commission for Europe); o and the International Labour Organisation. o OECD o marine protection organisations, such as OSPAR, HELCOM, BARCOM; o the International Maritime Organisation; • Industry associations
• Identification of the implemented OCs and RMMs :	• Registration dossiers, • CSRs including ESs, • Safety Data Sheets, including ESs • Data communicated in accordance with Article 32; • the relevant Community and national legislation defining (minimum) OCs and RMMs; • consultation with Industry and Member State competent authorities

[2] The 98/34/EC Directive (formerly 83/189/EEC) sets up a procedure which imposes an obligation upon the Member States to notify to the Commission and to each other all the draft technical regulations concerning products and Information Society Services before they are adopted in national law.

• Assessment of the performance of implemented OCs and RMMs: • emission / exposure mitigation rates • monitored emission / exposure levels • evidence of adverse effects on human health and the environment from the substance; and • information on occurrence of RMMs (share of the actors using certain equipment etc) and when they have been / will be taken into use	• RMMs and OC library (Guidance on the Chemical Safety Report); • Information on the use and effectiveness of RMMs from equipment suppliers, industry, IPPC BREF documents, • Information on the use and effects of OCs from industry, IPPC BREF documents, • Emission / exposure monitoring data from authorities, research institutions, industry • Information from enforcement projects and joint inspections and other tasks undertaken my the Agency Forum

Identification of the existing legal requirements (ELRs)

The starting point for the identification of the relevant legal obligations is the requirements under REACH. The identification of other ELRs will focus on Community-wide ELRs and their implementation in the Member States. However, depending on the case it may be useful to review also national ELRs. Differences in ELRs at national level may explain geographical variation in identified risk. The national ELRs may also be used when considering whether the identified risks should be addressed at Community-wide or national level (chapter 5.3). Observations related to non-compliance and its variation between MSs may also be relevant where available e.g. from the Forum.

International conventions, agreements and other initiatives require or encourage contracting parties (Member States, EU or both) to take action. These actions may involve new legislation or changes in existing legal requirements. These initiatives do not directly oblige industry to take action. However, a description of the international initiatives relevant for the substance under scrutiny is useful on the one hand to get a more holistic picture of the status of the substance and on the other hand the proposed restriction may contribute to fulfilling the agreed obligations under the international fora.

Questions that may be considered when identifying and describing ELRs[3] include

- Scope of the requirement: Which industry sectors or uses are covered? Which emission(s) /exposure(s) are covered? Is the substance in question directly mentioned, does the implementation require identification of the substances or is it question of a generic obligation? For national ELRs: which MSs have same or similar requirements?
- Timetable for the implementation
- What measures have been taken by the industry to fulfil the ELR?
- Information on enforcement: how is the enforcement arranged in different MSs? Are there enforcement reports available?

[3] ELRs cover also industry's voluntary commitments and any existing economic instruments

Appendix V provides a non-exhaustive list of other Community legislation under which substance-specific conditions are set.

Identification and assessment of the effectiveness of the implemented Exposure Scenarios (ESs)

Industry needs to comply with both REACH and other existing legal requirements (ELRs). Registrants need to document ESs (OCs and RMMs) they have implemented for the manufacture and own uses in their CSR. For downstream uses the M/I needs to recommend OCs and RMMs that adequately control the risks related to the substance in question. However, other legal obligation may require that DUs implement further measures that affect the emission(s) of / exposure(s) to the substance. These measures need be taken into account when assessing the exposure even though they are not included / required by the relevant ESs. The same basic principle applies to industry's voluntary commitments.

The assessment of the effectiveness should aim at establishing the actual reduction in emissions/exposure that results from the implementation of OCs and RMMs. Questions that may be considered include

- Are there differences in exposure scenarios (ESs) included in different CSRs?
- Effectiveness of the measure or combination of measures in reducing emission(s) / exposure(s), including variation in the effectiveness and reasons for that? Are there differences between the effectiveness of the ESs assumed in the CSA and the observed effectiveness?
- application of the different measures: What is the proportion of relevant actors that are applying each measure
- timeline of the implementation: for how long has the measure been used, are there still actors implementing the measure? What is the timetable for implementing ELRs?

Comparison of the implemented OCs and RMMs with ELRs

The aim is to consider whether the estimated / observed exposure levels are a result of non-compliance with REACH requirements or requirements set under other legislation. How to best carry out this comparison and the scope and level of detail of that comparison depend on, e.g., the content of the requirement and how crucial it is to the exposure levels in question. Observations related to non-compliance and its possible variation between MSs may also be of relevance for the justification of the need for action at Community level.

Furthermore, if the conclusion is that legal requirements exist but are not properly complied with, the Authority should consider whether Community wide compliance can be achieved via enforcement. Enforcement may have proven to be impossible in practice, e.g. due to increase in the number of actors or because the enforceability was not rightly assessed when designing the requirement. Such conclusions and reasons should be documented and taken into account when assessing the enforceability of the proposed restriction (see chapter 5.4.5). It is further recommended that these conclusions and underlying reasons are communicated to the Agency Forum and relevant MS enforcement authorities as well as to the authorities responsible for the legislation in question.

If the conclusion is that the risk is due to non-compliance with ELRs and there are no solid reasons why enforcement would be impossible, it is recommended that the Authority documents this conclusion and submits the documentation to the Agency Forum and MS CAs. If practicable (e.g. it

is a question of limited number of well defined actors) it is also advisable to inform the actors that are in non-compliance.

Example 2 illustrates a case where the DUs did not in practice apply RMMs and OCs defined in an ES and better enforcement was not considered to be sufficient. Furthermore, in this illustration the ESs were proven not to be as effective as assumed in the CSR and they did not always ensure adequate control even when properly applied.

5.2.3.2 Environmental exposure

The CSA guidance (XXX) includes information on this aspect (Section 8). The extent to which this will be needed will depend on the number of registration dossiers available and the complexity of the use pattern of the substance. For simple use patterns it should be possible to use the information in the registration dossiers almost directly. Where there are several registrations, it may be more convenient for the Authority to combine the information under the general life cycle steps, and deal with broader areas as covered by these life cycle steps than with each ES separately. This can also help when considering options for risk management which will apply across the life cycle step. In simple cases there could be a direct correspondence between the ES and the life cycle step.

As indicated in chapter 5.2.3, the main aspects to be considered are aggregated emissions and revised RMMs as a result of the Authority review. Any revision of emission estimates as a result of revised RMMs should be carried out before calculating aggregated emissions in cases where both aspects are relevant, hence the first section here is related to RMMs.

RMM related issues

Section 5.2.3.1 provides guidance on assessing the effectiveness of implemented RMMs. The result of this assessment may be a change in the abatement factor(s) applied in calculating emissions (see the Guidance on the Chemical Safety Report for more on abatement factors). This section describes some possible situations and the calculations which could be performed in these cases to provide input to the demonstration of risks (and in some cases to the consideration of RMOs).

A situation may arise where there are several registration dossiers for the same substance from different manufacturers and importers, which indicate different risk management measures for the same use. In this case, the amounts to which each measure relates should be known. The regional and continental emission estimates in the registration dossiers can be added together in the same way as for the simple combined exposure case (see chapter 5.2.3). However, it may be necessary to look in more detail at the different measures identified and examine why they are different. Depending on the outcome, it may be decided to apply one of the measures to the whole tonnage used in this area. This will result in a revised emission estimate for this area, and hence a different overall exposure. This may help in identifying possible RMOs.

Similarly where different assumptions have been made in developing the exposure assessment between registration dossiers, perhaps in terms of the emission and abatement factors used or the amounts assumed to be used at a single location, then these should be reviewed together. It may be useful to examine the effect of applying the assumptions from one registration dossier to another to see whether large differences result. If so, the further investigation of the assumptions would be advisable. More data for the evaluation of exposure can be obtained through substance evaluation.

A more difficult situation may apply if more than one risk management measure is included in the same ES. This might be for example where either waste water treatment on site or collection and disposal as hazardous waste were identified as suitable risk management measures. If there is

information on the proportion of users likely to use each method then this could be taken into account. In the absence of such information, an approach would be to calculate the emissions assuming that all of the users apply one of the measures, and then re-calculate assuming that they all use the second measure. However, there may not always be an obvious realistic worst case option if the measures lead to releases to different parts of the environment, so it may be necessary to carry both options through to the overall emissions. In the example mentioned above, the option to collect wastes and spills and treat these as hazardous waste would be expected to lead to low emissions if operated correctly, and so the other option could be taken as a realistic worst case.

The Authority can consider the likely effectiveness of the proposed risk management measures in the ES. Where there are concerns about whether these measures would be implemented by all users then the emission estimates could be adapted to take into account other assumptions about their effectiveness. For example, an implementation of 50% could be assumed if this was considered more realistic; then 50% of the use could be assumed to have the indicated emission and a (presumably) higher emission rate (from a lower abatement factor) used for the other 50%. This would be used for the overall emissions; for individual sites the measure would be assumed to be present or absent. Such calculations will be useful in considering whether enforcement of measures can provide the required level of risk management.

Aggregated or total exposures

A common reason for preparing an Annex XV restriction dossier is likely to be that there are a number of registration dossiers for a substance and the Authority has concerns that the overall exposure is not addressed in the individual registrations. In such cases an estimate of total exposure is required, using estimates of total emissions. In order to calculate overall background (regional) concentrations it is necessary to compile estimates of emissions from the whole life cycle of the substance. Estimates are needed for emissions to air, waste water, surface water, industrial soil and agricultural soil (not all of these may be relevant for all substances). The result will be revised regional concentrations for each compartment, which can be used in their own right in the risk characterisation, but will also modify the PEC or indirect human exposure values for local situations from the registration dossier ES.

The basic principles of calculating total emissions are described in the CSA guidance. The following notes relate to situations which may arise when considering restrictions (some will also be relevant to substance evaluation).

<u>Simple cases</u>

In this simple case there are a number of registration dossiers available.

- Each of the registration dossiers covers the full life cycle of the substance produced or imported by the registrant, and each has calculated the regional and continental emissions over the whole life cycle.
- The life cycles covered by the individual registration dossiers relate to different use patterns and do not overlap.
- There are no other sources of the substance.
- The Authority has reviewed the risk management measures included in the registration dossiers and concluded that they are appropriate.
- The physico-chemical properties and the environmental fate data used in the individual registration dossiers are the same.

- The exposure concentrations in the registration dossiers have been calculated using the appropriate software tool, incorporating the risk management measures in place.

In this case the regional and continental emissions from each registration dossier can be added together directly, and used to calculate the overall regional concentrations using the same model. In fact the regional PEC values from each of the registration dossiers can be added together for each compartment to give the overall regional values in this case.

In the case above the individual registration dossiers cover different use patterns and so it is realistic to assume that the region would receive the estimated regional inputs from each of these (this might not be correct for production if the production sites are widely dispersed, but for the purpose of the example this is assumed to be a minor contributor to the total emission). In other cases it is possible that the individual registration dossiers will contain emission estimates relating to the same uses (these are assumed here to be based on the same ES). Here it may not be appropriate to add these contributions directly. Instead, the total amount used for the common use across the registration dossiers should be determined, and a realistic estimate of the amount used in the region made. The emissions related to this regional amount can then be estimated as a proportion of the total emissions from this use (the sum of the emissions in the individual registration dossiers).

Other potential situations

Combining the various estimates of emissions from the individual registration dossiers will give overall emissions to the environment. Assuming these have been calculated on an EU-wide basis, an estimate of the proportion relevant for the regional emissions is needed. Information on the distribution of user industries should be considered. This may come from the registration dossier. Other sources of such information include emission scenario documents, possibly published risk assessment reports, and discussions with the submitter of the registration dossier or downstream users. In the absence of such information the assumption would be that all of the releases occurred in the region unless dealing with household use by consumers, in which case 10% use in a region would be assumed.

Some registration dossiers may address environmental emission estimation in a simplified way through the use of worst case defaults when risks to the environment are not expected, for example, where the substance is not self-classified as dangerous for the environment (but is classified for health and so a risk assessment has been conducted for the CSR). The level of detail in such a registration dossier may be relatively low in this area, as the assessment may be handled at a generic or screening level. It is perhaps unlikely that such a substance would be considered for an Annex XV restrictions dossier in relation to the environment, but there may be considerations relating to, for example, human exposure through the environment. In such cases, care will be needed in interpreting the ES and emission estimates in the registration dossier. It should be noted that even in such cases the registration dossier should demonstrate the absence of risk, so such concerns may only arise following a re-evaluation of the hazard assessment, during a substance evaluation for example. There will clearly be scope to refine the ES in such cases, and this will need to be taken into account in considering the possible measures to address the identified risk. It may be that some measures are in fact already in place but not included in the ES; discussion with the manufacturer or importer during the substance evaluation process may resolve this.

A more complex situation would be where there are several registrations which include the same use, and the ES for this use have different levels of detail. Calculations based on aggregated emissions (taking the emissions directly from the CSRs) indicate a risk. In such a case the Authority should look carefully at the contribution each of the ES makes to the total emissions. It would be expected that the more detailed scenarios would lead to lower emissions (on a kg/tonne used basis, the overall emission from the scenario also depends on the quantity of substance used). The

Authority can calculate the emissions assuming that the more detailed scenario is applied to all of this use (this situation is like that considered in chapter 5.2.3 where different measures are in place). Where this reduces or removes the risk, this indicates a possible RMO, but as discussed above there may be scope to revise the less detailed ES and provide a better description of the real situation.

Calculated concentrations

Once the regional emissions from all sources have been established, the regional concentrations can then be calculated using the total emissions and the appropriate models. The total emissions should include any other sources, as considered in chapter 5.2.3. The calculations methods for regional and local concentrations are described in the Guidance on the Chemical Safety Report.

As a first approximation, where the local emissions have not been changed, then local PEC values from the registration dossiers can be modified using the new regional PECs to replace the regional values in the CSR assessments. This revision of the local PECs may be needed, because the effect of considering total emissions may not be a risk at regional level but increased PEC local values which are now above the PNEC as a result of higher regional levels. This approach works best for the PEC values for surface water, soil and air. The situation for PEC values for sediments, fish and earthworms for secondary poisoning, and the food chain for human exposure is more complex and more detailed calculations (using the methods in the CSA guidance) will need to be performed to get precise values for these. However it is recommended that as a first approach, the correction outlined above is firstly applied to see if further calculation is warranted.

Other sources

There may be sources, relevant for estimating environmental as well as human exposure,. of release which are not considered in the registration dossiers, or that have not been fully quantified. These should be investigated by the Authority in order to determine if these are significant. This may involve identifying the quantities involved and the resulting emissions from the source. Depending on the nature of the sources, it may be necessary to estimate local emissions and hence local concentrations. However, if the sources are diffuse ones, then it is likely that only the overall emission estimates will be needed. A source of emission may be included in some registration dossiers but not in others, in which case the coverage should be extended to cover all relevant tonnages. In such cases it is suggested that initially at least the same approach is used as in the registration dossier which does include the source.

These other sources are considered in the environment section, because they are most likely to affect the environmental concentrations. They will of course have an effect on the indirect exposure of humans through the environment.

One example of a possible additional source is where the substance of interest can be formed through the breakdown of other substance(s) in the environment. This situation is perhaps most likely to come to light through studies published in the literature, or possibly through a substance evaluation process of the other substance(s). Two examples of this type of situation are included in **Example 1**. To address this type of situation, the Authority will need to estimate the potential for release from this source in relation to other sources. This involves estimating the release of the other substance(s) to the environment, the fate and degradation of the substance(s) in the environment and where possible an estimate of the amount of the substance of interest produced. These issues may be addressed in the registration dossiers for the other substance(s). It may be possible to perform rough calculations based on the amounts of the substance(s) released and a worst case estimate of the amount of the substance of interest formed. These can be compared to the releases from other sources, and if they are a minor contribution then this source can be neglected. If the source appears to be significant based on this initial approach, then more detailed estimates of the production of the

substance of interest could be made. It is likely that in most cases there will be a high degree of uncertainty in such cases. It should be noted that if such a source is found to make a significant contribution to the risks, then the risk management options may need to consider restrictions on the other substances as well as on the substance of interest.

There are other sources which can not be related to specific other substances. Combustion processes are one example where a substance can be produced as a result of the reaction taking place during the burning of materials. Emissions from such sources are generally estimated using information on the extent of the activity (for example, how much wood is burned as fuel) and emission factors for the substance from the process. Both the extent of the activity and the factors can be applicable at a generic level, so covering a range of processes. They can also be applied at a greater level of detail. The Authority should adopt a step-wise approach to such sources. A broad generic calculation of possible emissions will show if the source is significant. If so, a more detailed investigation should be carried out to refine the estimates. As this source does not relate to the use of the substance, it is unlikely that producers/importers or users will have specific information relevant to help in refining the assessment.

Some substances produced and used, and so subject to REACH, also occur naturally in the environment. This aspect may be included in the exposure assessment in the CSR, and the Guidance on the Chemical Safety Report includes a section on the assessment of metals which has relevant material in relation to background concentrations of natural substances. The natural occurrence of a substance is clearly not related to any particular producer or importer, or to the amounts produced or imported, and so any treatment of this aspect in a CSR will probably address the natural sources as a whole. Therefore there should not be any issues of aggregation of emissions from such sources across a number of CSRs. Where there are a number of CSRs for a naturally occurring substance, the Authority should check the approaches used to address this in the CSRs. The Authority can review the approaches and select the one they think is most appropriate for the substance, and then apply this in their assessment of exposure. Emissions from the usual life cycle stages can be handled in the same way as for other substances.

5.2.3.3 Human exposure

The considerations for the exposure of humans are the same two basic aspects as those for the environment. One is to make sure that the combined exposure from different sources is taken into account. The second is to consider the effectiveness of the proposed RMM. As for the environmental emissions, any changes required as a result of considering the effectiveness of the RMMs should be made before estimating combined exposures.

RMM related issues

The examination of different registration dossiers may show different approaches to the estimation of exposures for the same (or very similar) routes. Where such differences are found, the ES in the different registration dossiers should be examined closely to identify the reasons for the differences. This may show that different RMMs are recommended, and the Authority should review these (see Section 5.2.3.1) and decide on which is the most appropriate or most likely to be used.

The Authority may also have information which shows that the proposed RMMs will not have the effect indicated, for example specific information on the efficiency of an air filter. In such cases new calculations of exposure can be made using the Authority interpretation of how the RMM will work. The same models as indicated in the exposure assessment should be used unless there are

good reasons for considering this not to be suitable for this purpose. Guidance on the use of models and calculation methods for assessing human exposure are included in the CSA guidance [XXX].

Note that exposure via the environment may be significant in some cases and so consideration of RMMs related to environmental emissions may be important.

Combinations of exposure

The Authority should examine the exposure assessments included in the registration dossiers and look for exposures which are considered in some and not in others. This may be because they are not relevant for the life cycle of the substance in all registration dossiers.

For example, one registration dossier addresses only worker exposure as this is the only relevant step, and a second addresses both worker and consumer exposure. The combination of the consumer exposure with the first worker exposure is not covered in either registration. Estimating the combined exposure in this case is a relatively simple matter. The CSA guidance includes sections on combined exposures of this type.

Exposure of humans via the environment also needs to be taken into account. Indications that this may be significant would be where the exposure through the environment makes a significant contribution to the daily intake of humans according to the calculations in the registration dossier and the total exposure is close to the DNEL.

When combining human exposures, the Authority needs to make sure that the combinations are realistic. So the combination of two different working day exposure from two scenarios would not be appropriate. Where the same exposure route is included in several registrations, this does not necessarily lead to higher exposure of individuals.

For example, two registrations assess the exposure of consumers to a dye from cloth. Adding the exposures would not be appropriate as consumers do not wear an increased number of clothes – what this means is that more people are probably exposed to the dye.

However, the presence of the substance in a range of consumer products may well lead to a higher total exposure, and these may not all be addressed in each registration dossier. Where there are parallel assessments of exposure through the same route, then the higher (highest) value would be the most appropriate to use.

The Authority may also wish to consider whether combined exposure via the environment to a number of local sources is possible. This may occur where there are a large number of users in different use areas, and it is likely that there will be examples of each in a locality. If these are assessed in different CSRs then the possible combined exposure will not have been assessed. Direct combination or weighting in relation to numbers of sites may be possible.

5.2.3.4 Measured concentrations

It is possible that regional PECs may be based on measured concentrations, which by definition would represent the overall exposures from all relevant sources. These could in principle apply to all registration dossiers, so if they are considered valid then they could be used to replace any

calculated values. The Authority may consider that information on measured levels indicates that emissions reported in the registration dossiers are being under-estimated. The Authority should review the measured data carefully. If it is possible to derive representative values for regional concentrations, then these should be used as regional PEC values in the Annex XV dossier, and used in the calculation of new local PEC values.

There may also be measured levels data relevant to local situations. The Authority will need to consider carefully the degree to which these data can be considered to be representative of a particular use across the EU. If such representativeness cannot be demonstrated clearly, then the data should be considered not suitable for a community-wide risk assessment.

Where suitable monitoring data for human exposure are available they can be used directly in place of calculated concentrations.

The Authority should consider any information on measured concentrations included in the CSRs.

Guidance on the review of monitoring data is included in the CSA guidance.

5.2.4 Risk characterisation

Overview of the task

Aim: The Authority needs to identify the risks which are not sufficiently managed.

Scope: The basic approach to risk characterisation is set out in the guidance for production of the CSA. In simple terms it involves the comparison of the estimated or measured exposure levels with the appropriate DNEL or PNEC values.

There are potentially a large number of possible risk characterization endpoints which could be included. Where the assessment has been targeted then this can be reduced to a smaller number. It is important to make clear in this section of the report exactly what parts of the possible assessment have been considered. It is useful to restate what areas have been reviewed or assessed for this dossier and what (if any) risk characterization results have been taken directly from the available registration dossiers.

When the main focus of the Annex XV restriction report is on aggregated exposures for the environment, it may be sufficient to include only the risk characterisation for this combination, where this shows a risk which is not managed. However, a more likely situation would be that the combined emissions lead to a revised regional PEC, which when combined with the local emissions leads to risks on a local scale. These would then need to be included in the risk characterisation.

Where the revision of the PECs is due to a reinterpretation of the RMMs, then only the results related to the specific Exposure Scenario may be needed. However, the Authority should make sure that all endpoints which might be affected by the change in assumptions are considered in the risk characterization. As an example, a higher exposure to workers through air may be assumed to be more realistic, but this could also lead to greater emissions to the environment via the air. This could also apply to the consideration of proposed measures to address an identified risk. In the same situation as above, extra air extraction could be used to reduce worker exposure, but could lead to an increase in air emissions.

It may help the case being made to consider the uncertainty in the risk characterisation, on both the exposure and effects side. The Guidance on the Chemical Safety Report has a section on this.

Producing the report

This is *Section 10* of the *Justification* part of the Annex XV restriction report (APPENDIX I). In terms of what to include in the report, the Authority will need to present the risk characterisation results which demonstrate that there is a risk. Where other parts of the risk characterisation are calculated which do not show a risk, they should be included for completeness as far as possible.

5.3 Justification for the need for action on a Community-wide basis

Overview of task

Aim:	A restriction proposal needs to provide justification why the identified risk needs to be addressed at the Community level.
Scope and Outcome	Such justification needs to show that action on a Community-wide basis is the most appropriate option for reducing the identified risk. This part of the justification will be documented in section 14 of the restriction format (appendix I)
Exit from the restriction procedure	If the analysis proves that action at the Community level is not needed but the identified risk should rather be addressed at national level the Authority is requested to document the identified risk and this conclusion in the relevant parts of the restriction format and submit this documentation to the Agency and Member State CAs.

The justification for the need for the risk management action to be taken on a Community-wide basis needs to be based on risk-related considerations and needs to take into account market-related considerations. The aspects considered under these two basic elements and their relative importance will vary case by case.

<u>The risk related considerations may cover</u>

- the severity of the risk:
  - the nature and reversibility of the adverse effect
  - uncertainty in the risk assessment and the severity of consequences of wrong conclusions from the assessment
- the extent of the risk:
  - the population affected (e.g. consumers), including any vulnerable sub-groups,
  - the number of people affected
  - the area of the environment that is affected, and the geographical distribution within the EU
  - the use of substance in industry, its distribution via the supply chain including service-life of articles and waste stage

In general terms the higher the hazard and the extent of the risk the more important it is to take measures to ensure the protection of human health and the environment throughout the Community.

<u>The market related consideration</u> cover the effects of the risk management measures on the internal market

The key question that an Authority needs to answer is, *"If no Community-wide action is taken but risks are addressed at the national level, will there be a distortion of the internal market?"*. This will effectively involve the consideration of the likely effects of any possible national-level RMOs to the functioning of the internal market and evaluation of likely imbalances and inequalities that could arise. If national-level measures are taken, the burden on the enterprises subject to any new national-level regulations may result in them becoming less competitive in the internal market. This may occur if they are not allowed to manufacture a certain chemical substance or use it in specific processes, possibly resulting in an increase in their prices, a decrease in their portfolio and a loss in their share of the market. More generally, the introduction of national-level measures as opposed to a Community-wide restriction could impact upon the flexibility of those enterprises subject to the measures and their ability to respond to the changing demands of the market.

Carrying out the task

The development of the justification for the proposed restriction may involve the steps listed below. It should be noted that the order in which the issues are considered depend on the case.

- Based on the risk assessment conducted, identification of the key characteristics of risks which warrant action on a Community-wide basis.
- Identification of key monitoring data, estimates and projections (also presented in the *Information on risk*) that support the argument for action on a Community-wide basis. This could include, for example, monitored pollution levels being significantly elevated across the Community or statistics from authorities in several Member States showing an increased number of cases of workers/consumers suffering adverse health effects from exposure to the substance of concern.
- Identification and description of the possible national risk management options. Procedures described in section 5.4.4 of this guidance (identification of other Community-wide risk management options) can be used when developing this section.
- Identification and analysis of data on the distribution of the substance in the markets across the Community. This could include an analysis of how widespread and how controlled the manufacture, marketing and use of the substance are across different Member States.
- Assessment of any possible national-level RMOs against the key criteria of effectiveness (including proportionality), practicality and monitorability (see Section 5.4.5 of this guidance for more detail on these criteria); information on the distribution of the chemical (manufacture and use) in markets across the Community as well as the findings of an available SEA may be of significance.
- Assessment of the effects of possible national RMOs on internal market.

On the basis of the information gathered and analysed, the Authority has to draw a conclusion whether national-level RMOs could deliver the required reduction in the identified risk while not disrupting the internal market. There may be cases where a measure taken at the national level may be capable of sufficiently reducing the risk. Such examples would be when managing:

- risks that affect limited and defined geographic locations in the Community due to specific environmental conditions;
- risks associated with specific processes which take place only in specific Member States;
- risks associated with market imbalances in specific Member States; or

- risks that require urgent action in specific Member States and the action may be taken at the national level more quickly in comparison to action at the Community level.

Note that the geographical scope of the risks is not the sole defining factor: even if the identified risk is relevant to only a part of the Community, action on a Community-wide basis may be needed because the markets may develop throughout the Community in the future and the scope of the risk may cross the national boundaries. In all cases, for a national-level RMO to be suitable, it should be able to effectively reduce the risk while ensuring the balanced and fair functioning of the internal market across the Community.

Producing the report

Refer to Appendix IIfor more information on how to fill in the relevant section of the Restriction report.

Example 2 An example where action on a Community-wide basis is needed

Substance E is a liquid/gas which is produced in the European Union in a volume of ~100,000 tonnes. Substance E is already regulated in the working environment with occupational exposure limits already in force in x Member States. During the preparation of a restriction proposal, in the absence of more detailed information, reasonable worst-case scenarios have been used in the assessment of risk. The reasonable worst-case exposures leading to concern (i.e. the critical exposures) are 105 mg/m^3 and 97 mg/m^3 for repeated dose toxicity and acute toxicity respectively. The Time-Weighted Average (TWA) limits in Member States range from 90 to 475 mg/m^3 while the current Community TWA stands at 210 mg/m^3. Only one Member State has a TWA below the worst-case exposure of 105 mg/m^3 for repeated dose toxicity. On the other hand, only five Member States have an occupational exposure limit for short-term exposure; these limits range from 450 to 850 mg/m^3, considerably higher than the established worst-case exposure level of 97 mg/m^3 for acute toxicity.

With regard to the irritating properties of the substance, the CSRs show that the use of personal protective equipment eliminates the risk to occupational health. However, the Authority has reasons to question this both due to evidence that PPE is not in practise used (in other words the ES is not applied correctly by DUs) and due to lower efficiency of PPE than assumed in the CSRs.: Health risks from the use of solutions of Substance E for building surface cleaning cannot be minimised by a normal workplace protection procedures (including personal protection equipment) due to the very high irritancy of the substance, and the current practices in the Industry, especially the presence of mobile workplaces within many small-sized enterprises. Moreover, statistical data from authorities in Member States suggest that a considerable number of people employed in the cleaning industry are admitted to hospital with respiratory problems each year and these problems appear to be associated with the use of solutions of Substance E. A

survey among workers in the cleaning sector of seven large Member States suggests that only half of the workers have access to appropriate personal protection equipment on a daily basis. For around 30% of workers, the availability of such equipment will depend on the location of work and on the equipment made available from the employees. With regard to incidence of respiratory problems, those not using personal protective equipment are five times more likely to suffer acute adverse effects and three times more likely to develop a longer-term respiratory disease. The use of personal protective equipment, however, does not guarantee complete protection: almost 10% of those regularly using personal protective equipment have suffered from respiratory diseases in the last 18 months as a result of using preparations of Substance E.

Overall, the existing measures and controls on exposure to Substance E in the workplace appear to be insufficient; moreover, the risks are applicable to the whole of the Community. Even in the small number of Member States where the existing risk management measures are sufficient stringent, exposure to unacceptable levels of Substance E is not adequately prevented. This in combination with existing data from the health services of several Member States on the prevalence of respiratory problems associated with the Substance support the case for action on a Community-wide basis.

Example 3 An example where Community-wide action is needed to prevent market distortions

Substance F is produced in the EU at a volume of around 10,000 tonnes per year and finds several uses one of which is as a dye carrier in the textiles industry. An estimated 500 textile finishing workshops in the EU use this substance. Of them, more than half are believed to be small enterprises. The use of the substance has traditionally been confined predominantly to seven neighbouring Member States (hereafter referred to as Region X).

The available CSRs and Safety Data Sheets indicate that precautions need to be taken to prevent accidental releases of the substance to the aquatic environment. However, the Agency has been notified that an undisclosed number of textile finishers use the substance outside the conditions described in the Exposure Scenarios developed by the manufacturers. This process is used for achieving specific finishing effects and downstream users have generally kept its details confidential.

A recent case of acute pollution of a lake in a Member State in Region X as a result of releases of Substance F from a textile finishing installation in 2004 highlighted the potential risk from this confidential process: the relevant competent authority investigated the incident and concluded that the confidential finishing process is based on aged technology and gives rise to significant amounts of wastewater and spent solutions that contain Substance F. Notably the relevant trade associations (both those of EU remit and national ones) have been involved in information campaigns to persuade their members across the Community to generally switch to alternative, more modern processes in the finishing of textiles. The information available to the trade associations, prior to the aforementioned accident, suggested that the confidential process had been obsolete for the last 5-10 years throughout the Community.

Following the lake pollution incident, it has been established that between 10-20% of the total of 500 textile finishing workshops may be involved in this finishing process Of them, less than 40% (i.e. 4-8% of all 500 workshops or 20-40 installations) in the Member States in Region X appear to be able to control emissions of Substance F by using modern equipment that recycles wastewater, while most of the rest dispose of their wastewater through licensed contractors. Workshops in Region X which confirmed their use of Substance F in the confidential process submitted information which suggests that the finishing process in question is still in use not

only in non-EU countries but also in EU countries outside Region X which until previously were believed by authorities to have abandoned this process altogether.

In the process of developing a restriction dossier, the Authority in charge has considered the option of introducing limits on releases of Substance F or even a restriction on its use. For the Authority, issues of concern were:

1. There have been calls for any restriction to be imposed only to enterprises and Member States that have been confirmed as being linked to the identified risk since releases result in risks at the local level rather than the regional or continental. EU textile finishers based outside Region X have also supported the introduction of a restriction (or other RMOs) at the national level only in Member States associated with the risk.

2. On the other hand, workshops in Region X which are confirmed users of the process in question have provided some confidential market research information suggesting the competitors from the other EU regions may account for at least 20% of the total EU market turnover in that particular use. They have also argued that the installation of advanced technology would result in significant downtime and expense and they expect that prices of their products would increase with consequent, loss of their market share and possible loss of employment. At the same time, enterprises outside Region X would be allowed to use this process and that would help them improve their position in the internal and global markets. Moreover, enterprises elsewhere in the EU would be allowed to use this process which would give them a competitive advantage in the internal and global markets.

3. A limit on releases of Substance F that could sufficiently reduce risks would be lower than limits currently in place in Member States outside Region X; hence there would be an unequal burden of meeting legislative obligations across the Community. Moreover, different Member States regulate these installations under different legislative frameworks.

The Authority considered the above and concluded that a Community-wide restriction (as opposed to a national measure or an emission limit) may be justified as the most appropriate RMO which will provide adequate protection of the environment and at the same time will ensure equal access and opportunity for all players in the internal market particularly given the current uncertainties on the location of users of the process of concern. The proposed restriction was that Substance F may not be used in textile finishing in the particular finishing process associated with the risks.

5.4 Refinement and assessment of the proposed restriction

5.4.1 Overview of the task

Aim: The aim of this task is to

- define the scope and conditions of the proposed restriction
- provide justification that the proposed restriction is the most appropriate Community wide measure assessed against the three criteria: effectiveness, practicality and monitorability

Scope: The task includes

- defining initially the restriction,
- assessment of initial restriction against effectiveness, practicality and monitorability and, where necessary, improvement of the initial restriction on the basis of the results of this assessment,
- identification of possible other risk management options (RMOs), and
- comparison of the restriction to the other RMOs

Defining the final proposal for a restriction can be an iterative process, where the scope of the restriction and any conditions are refined based on the findings when assessing the effectiveness, practicality and monitorability of the initial proposal. The scope of a restriction defines which uses or actions are covered by the restriction. Conditions of the restriction may include for instance timeline(s) from which the restriction applies, concentration limit(s) above which the restriction applies or conditions under which the restriction does not apply (derogation from the restriction). Information on alternatives and socio-economic analysis, where available, provide input for defining the restriction and for assessing it against the three criteria.

The possible other RMOs are identified to have a reference point against which the proposed restriction is compared to find out whether the proposed restriction is the most appropriate measure. How widely the Authority should identify other RMOs and to what level of detail it should assess them depends on the case. Information on alternatives and socio-economic analysis, where available, provide input also for this comparision.

Outcome:

The outcome of this task will be a proposal for a restriction. This proposal needs to define which manufacturing, placing on the market and uses are to be restricted and any conditions related to those restrictions. This part of the justification will be documented in the “Proposal for Restrictions” section of the restriction format.

This task will provide also a justification for that the proposed restriction as defined is the most appropriate Community wide measure. The justification will be documented in section 15 of the restriction format (Appendix I)

Exit from the restriction procedure:

If the comparison of the proposed restriction against other possible Community level RMOs shows that a measure under another legislation is more appropriate way of addressing the risk than a restriction under REACH the Authority is requested to document the assessment and this conclusion in the relevant parts of the restriction format and submit this documentation to the Agency.

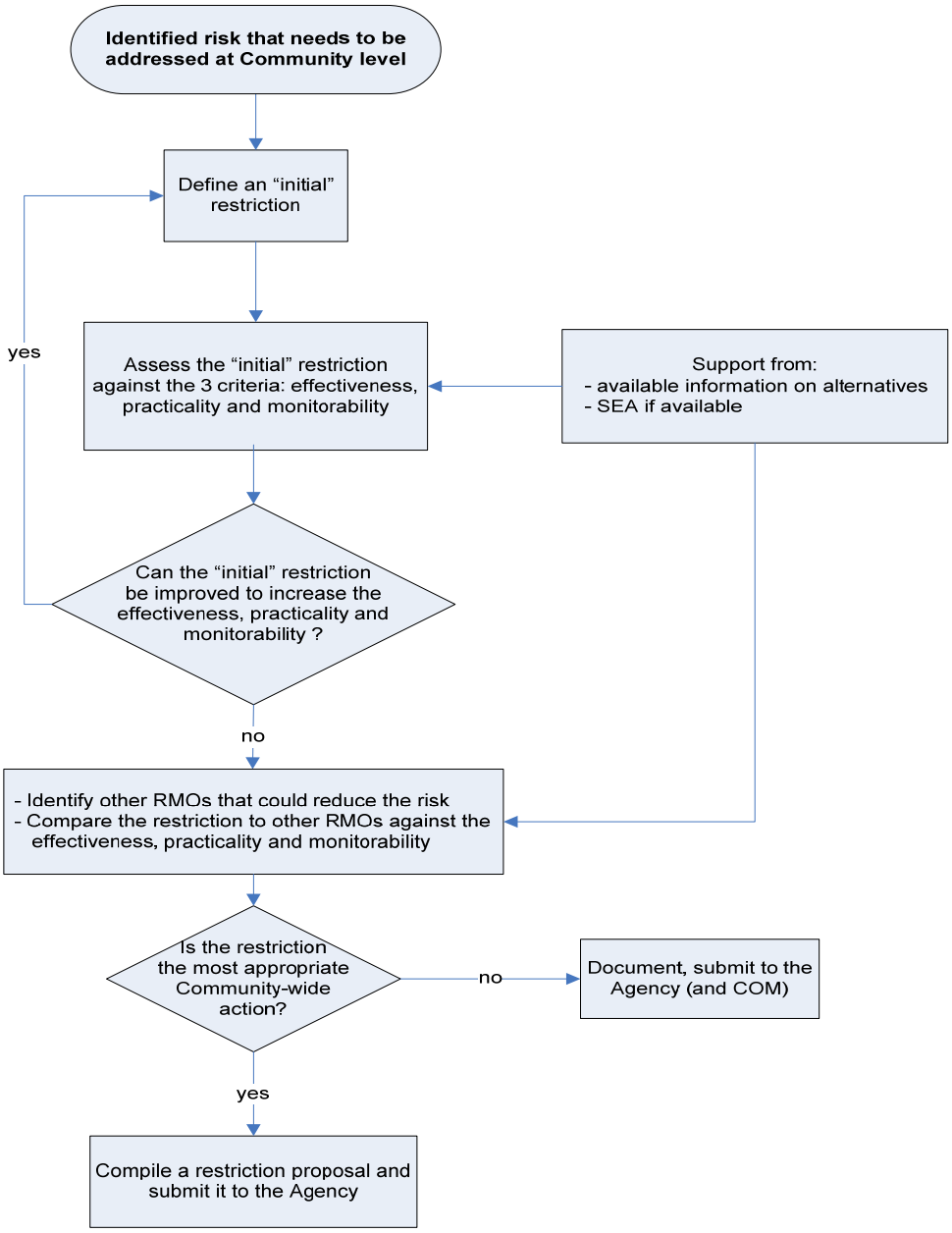
Figure 6 gives an overview of the refinement and assessment of the restriction proposal. The identified risk gives the basis for the drafting the restriction. In addition to defining which uses

cause the risk and describing the characteristics of the risk, the analysis of the effectiveness of implemented OCs and RMMs and of the compliance with ELRs provide background for developing the restriction proposal.

Availability and characteristics of alternatives (chapter 5.5) is crucial for the effectiveness and practicality of the proposed restriction and considered other RMOs. Therefore the available information on alternatives provides an important input from the drafting of the initial restriction to final justification.

Socio-economic analysis (chapter 5.6) assists in understanding the implications of the proposed restriction and other RMOs. The drafting of initial restriction and its assessment against the three criteria may give a reason for the Authority to conduct an SEA to analyse the overall impacts on the society. Information from the SEA, where conducted, will give input for the final justification that the restriction in the form defined by the proposal is the most appropriate measure.

Figure 5 Overview of the refinement and assessment of the proposed restriction



5.4.2 Risk to be addressed

The information on hazard and exposure and the results of risk characterisation conducted provide a starting point for drafting an initial restriction. Information on the risk include:

- which use(s) / manufacture/other handling cause the risk
- in which life-cycle stage(s) the exposure resulting in risk occurs
- which human populations face the risk (workers, consumers or specific groups of them) and the main exposure route
- which environmental compartments are at risk

This information is used to define the scope of a restriction and to identify whether other RMOs can address the risk related to the relevant exposures.

5.4.3 Drafting an initial restriction

The drafting of the initial restriction should take into account the three basic criteria as defined in Annex XV:

> (i) effectiveness: the restriction must be targeted at the effects or exposures that cause the identified risks, capable of reducing these risks to an acceptable level within a reasonable period of time, and proportional to the risk
>
> (ii) practicality: the restriction must be implementable, enforceable and manageable
>
> (iii) monitorability: it must be possible to monitor the implementation of the proposed restriction.

A restriction under REACH is defined as any condition for or prohibition of the manufacture, use or placing on the market. The basic structure of restrictions may vary a lot, including e.g.

- Total prohibition of manufacture, marketing and use
- Restrictions on certain uses / uses in certain processes
- Restriction on marketing a substance on its own, in preparation or in articles for consumers

A restriction will normally include conditions defining to which situation the restriction applies and how it should be implemented. Unconditional or conditional derogation for certain uses are one example of this (see below). The Authority may include conditions in the initial restriction or the assessment against the three criteria may call for adding conditions to get the restriction more effective, proportionate and practical and more monitorable. Other factors to be taken into account when drafting a restriction include equal treatment of EU manufacturers and importers and interfaces with other Community legislation. For enforcement purposes the restriction has to contain a concentration limit. The default limit is 0.1 %. However, lower values can be used, where needed, case by case if an internationally recognised test method exists.

Drafting of an initial restriction will be based on the identified risk (chapters 5.2 and 5.4.2). Information on currently existing legal requirements and compliance with them from chapter 5.2.3.1 may give background for the drafting of an initial restriction. Information from the analysis of alternatives (chapter 5.5) and socio-economic assessment (chapter 5.6) can be used to define the form of restriction and the conditions.

Derogations

Derogation excludes certain uses from the restriction either totally or under prescribed conditions. A well-developed derogation can increase the effectiveness and proportionality of a proposal for a restriction by:

- targeting the proposed restriction to the risks;
- accounting for the availability and suitability of alternative substances and techniques;
- defining where exactly the proposed restriction applies and how and when its implementation should take place; and
- ensuring the functioning of the internal market .

The Authority may include a derogation in the initial restriction or the assessment of the effectiveness, practicality and monitorability of the initial restriction may highlight a need for a derogation. The impact of a derogation on these three criteria need to be taken into account in the final assessment of the proposed restriction.

The Authority needs first to identify the uses, and where relevant manufacture and marketing, of the substance for which derogations may be needed based on the information on risk (chapters 5.2 and 5.4.2) and on the available information on the availability, technical suitability and risks of alternatives (chapter 5.5). Consultation with stakeholders may also provide relevant information and arguments on the need for derogations (see box below). An SEA, where available, may contribute to the identification and justification of the uses for which a derogation is needed (chapter 5.6). Generally, the main reasons for including derogations into a restriction proposal are related to:

- technical considerations (when it is not possible to produce the end-product or achieve the same functionality by using an alternative);
- human health and/or environmental considerations (when the alternatives pose a greater risk(s) than the substance of concern);
- economic considerations (the use of an alternative would result in significant economic impacts or distortion to the internal market); or
- regulatory and contractual considerations (for example, the use of products that contain the substance requires prior approval and without a derogation there would be insufficient time available to gain approval for alternative products).

Possible role of a voluntary stakeholder consultation in identifying the need for derogations

Depending on the case, the need for derogation may arise from:

- an Industry argumentation (for example, where Industry wants to protect a particular critical application of the substance of concern);
- an argumentation by another Member State (when, for example, a derogation would be needed in the context of some of the policies of that Member State);
- the analysis of collected information and from general consultation with interested parties, other Member States and the Agency (for example, the analysis of information on the availability, technical suitability and risks of alternatives); and
- the information and analysis presented in any SEA developed by the Authority.

A derogation included in a restriction for a certain use of substance can be with or without conditions. Under an **unconditional derogation** the use of the substance is allowed to continue in the future without any conditions attached to that use. This type of derogation may result from a combination of high criticality and importance of the application of concern, a recognised lack of suitable and safer alternatives and high associated costs of the proposed restriction.

Alternatively derogation may include conditions, for instance

- **process-limited derogations**, use is allowed within a certain process, or by utilising a specific technique, when there is evidence that a process which utilises/involves the substance is not associated with unacceptable risk (as opposed to other processes)
- in **time-limited derogations**, use is allowed only for a certain period of time, within which Industry will have to introduce changes or develop alternatives. Consultation of stakeholders, literature and the information on alternatives may provide evidence that a period of time is required before changes in processes or alternatives are introduced.
- A time-limited derogation may be **progress-limited** when use of the substance is allowed with Industry's commitment to work towards the development of alternatives. The derogation is contingent upon Industry showing that progress in the research on and development of alternatives is actually being made. Such a derogation could require Industry to set up monitoring schemes, establish reporting requirements and schedules.

Derogation is justified if the benefits outweigh the drawbacks. The box below gives examples of issues to be considered when assessing the potential advantages and drawbacks of including a derogation in a restriction.

Examples of potential advantages and drawbacks of including a derogation in a restriction

The potential advantages of a derogation may include:

- the protection of uses of the substance which are critical to society as a whole;
- benefits to human health and the environment from avoiding the use of less safe alternatives. Quantification of benefits can be useful (the SEA guidance (XXX) can be consulted);
- the limitation of potentially disproportionate costs to certain Industry sectors;
- the protection of the functioning of the internal market and of the competitiveness in the global market of EU enterprises which might otherwise be impacted upon by the proposed restriction

Possible drawbacks of a derogation may include:

- any residual risk to human health and the environment from the derogated uses;
- the potential for those granted a derogation to obtain a competitive advantage over EU competitors not covered by the derogation.

Example 4 Examples of derogations protecting the functioning of the internal market

Well-developed and targeted derogations could make a restriction more balanced and support its justification. This could be the case in the following examples:

- a number of SMEs is involved in the activity targeted by the proposed restriction. The proposed restriction is expected to result in enterprises investing in new technology; however, many SMEs are unable to make such an investment in the short term due to its disproportionate cost. Hence, a time-related derogation would protect the role of these SMEs in the internal market; and
- a number of enterprises are using very different technologies which are highly integrated within the supply chain, and the end-users vitally rely on the performance of the end-product (for instance, users of silicon wafer chips). The substance of concern may be one of the few qualified chemical substances that can ensure that the end-product meets the requirements of specified performance tests. If the chemical is banned or its use is seriously restricted, the quality and performance of the end-product will change and may not meet the requirements of the end-users. Therefore, a restriction on the use of the substance of concern could distort the market by making the enterprises using the substance uncompetitive, as they would not be able to meet the requirements of the end-users of their products. Hence, a derogation could be considered as a step towards the protection of a potentially very critical application.

Example 5 Examples of conditional derogations

Application for which a process and progress-limited derogation is proposed

Unacceptable risks to the environment from the use of hydraulic fluids based on Substance N have been identified. The Authority considers that a restriction is the most appropriate option for Community-wide action, especially given the international nature of the aviation industry.

The information collected during the preparation of the restriction dossier suggests that there are no current alternatives for hydraulic fluids for aircraft systems and there is no known alternative chemistry which will provide adequate protection to the relevant aircraft systems.

Changing formulations in aviation hydraulic fluids requires extensive review, testing, and approval by all airframe manufacturers prior to use of the new formulation in commercial aircraft. Historically, this process has taken at least 10 years from identification of the need for changes to actual commercial manufacture.

In recognition of the long timeframes involved in cdeveloping a replacement and getting this approved, this application could be derogated. The Authority might consider the inclusion of a derogation in the restriction proposal according to which Substance N may be used in aviation fluids. Conditions for the derogation might include:

- the derogation would be subject to on-going review to evaluate progress in developing alternative hydraulic fluids, albeit with no set deadlines for phase-out, as there are no candidate replacements at this time;
- the aviation industry would need to report to the Commission on a 2-year basis on progress made in the development of substitute chemicals and/or hydraulic fluids.

  The aviation industry would be expected to present evidence of research progress on substitutes (chemicals and technologies); and
- the derogation would be re-assessed (and extended, withdrawn or modified) after 10 years from entering into force.

Application for which a time-limited derogation is proposed

Substance N is no longer used in the manufacture of fire fighting foams, there being suitable alternatives. Current (and future) risks are associated with the use of remaining Substance N-based fire fighting foam stocks (which may have up to 12 years' shelf life remaining).

Analysis during the restriction procedure suggests that a restriction should be introduced on the marketing and use of the substance for its use in fire fighting foams. However, the use of the available alternatives is accompanied by uncertainties as regards the possible overall reduction in environmental risk; as a result, measures requiring the immediate destruction and replacement of Substance N-based foams could result in unknown risks to environment.

A derogation might be considered to be appropriate; this could be a conditional five-year delay in destruction of the remaining foams. The five-year delay in destruction of these foams would allow to reduce the environmetal impact from the destruction, provide for the users for a smoother transition to alternative formulations and would reduce the costs associated with an immediate replacement of Substance N foams. This five-year delay, however, could be conditional on a number of actions by the holders of foams:

- the removal of stocks from active service;
- at the end of the five years period all remaining foams containing Substance N would be destroyed in accordance with waste legislation;
- in the event that Substance N-based foams are required within the five year period, contained fire waters would not be permitted to be released to wastewater without the notification and agreement of the relevant national authorities and the application of emissions controls based on existing legislative requirements and guidance

5.4.4 Identification of possible other RMOs

The identification of possible RMOs will concentrate on the identification of appropriate Community legislation other than REACH that could be used to address the identified risk(s).

Appendix Vpresents a non-exhaustive list of EU legislation that the Authority may consider. In addition there may be sector or use specific legislation that can be used (e.g. directive on fuel quality where the risk arises from the use of a substance as additive in petrol). The aim of the identification of other RMOs is to find those that have potential to reduce the identified risk, i.e. their scope cover the use(s) in question and requirements under them can address the relevant exposure. Issues to be considered when identifying the potential RMOs include in addition to information on risk as described above

- Information on currently existing legal requirements and compliance with them from chapter 5.2.3.1. The past performance of RMOs when applied for other substances / uses / manufacturing (so that those RMOs that have proved insufficient in the past in cases of similar risks or for similar substances may not be considered further).
- Current (and foreseeable) practices and capabilities of the Industry sectors of concern that may render an RMO feasible or unfeasible (for instance, if a limit value on emissions would need to be set so low that the available technology does not allow for such a limit to be met under normal operational conditions, such measure cannot be implementable)
- Available information on alternatives (from chapter 5.5). Other RMOs than a restriction may be more suitable for controlling the identified risk from uses for which no alternatives exist and efforts of finding other RMOs can be focused to those uses.

Examples of identification of possible RMOs

- if an unacceptable risk to the aquatic environment has been identified, the Water Framework Directive could be a possible legislative framework for addressing the risk;
- if the risks are associated with the emissions of the substance from Industry sectors within Annex I of the Integrated Pollution Prevention and Control Directive, this could provide a possible legislative framework; and
- if the substance is a volatile organic compound, then the Volatile Organic Compounds Directive could be considered.

It should be noted that the identified risks may be best addressed by a combination of RMOs. Such a combination may also include a restriction under REACH for certain uses. In that case, the Authority should submit to the Agency an Annex XV dossier proposing a restriction for these uses and document the need for other Community wide measures for the rest of the uses.

Voluntary actions by industry may also be considered as an alternative for a restriction under REACH, however, voluntary actions have a relatively limited scope in this process. The ES(s) should include OCs and RMMs implemented or recommended by industry, including those based on existing voluntary commitments (if any). The effect of such voluntary actions is, therefore, already taken into account in assessment of 'remaining' risks.

Emissions due to aggregated tonnages may cause risks even if each M/I has implemented or recommended OCs and RMMs that adequately control the risks caused by his volume. This is an example of a case where a voluntary action by industry could still provide an option to reduce the risks sufficiently. Industry would in this case include the necessary RMMs and OCs in revised ES(s), document them in CSR(s) and communicate them to downstream users via SDS(s). However, this procedure would be a result of communication with relevant industry during the preparation of an Annex XV dossier and, in case the voluntary action by industry reduces the risks to an acceptable level, the MS would not anymore need to submit an Annex XV dossier to the Agency. If the consultation with industry or other information would show that a voluntary action is not feasible, effective, practical or monitorable, the MS can document these considerations in the Annex XV dossier justifying why a restriction under REACH is the most appropriate measure.

Documentation

The identified RMOs need to be shortly described for further comparison with the proposed restriction. It is also useful to give an overview on how the possible RMOs would address the identified risks. Table 3 gives an example of possible way to present the RMOs.

Table 2 Generic example of presentation of the applicability of the initial restriction and other considered RMOs to the identified risks

Use of the substance	Compartment/population at risk	Applicability of identified RMOs				
		Initial restriction	RMO 1	RMO 2	RMO 3	RMO4
Use 1	Endpoint 1 (e.g. aquatic environment)	✓	✓	✓		
	Endpoint 2 (e.g. occupational exposure)	✓		✓	✓	
Use 2	Endpoint 1 (e.g. aquatic environment)	✓	✓	✓		
	Endpoint 2 (e.g. terrestrial environment)	✓		✓		✓
	Endpoint 3 (e.g. STP micro-organisms)	✓		✓		✓
Use 3	Endpoint 1 (e.g. aquatic environment)	✓	✓	✓		

5.4.5 Assessment of the proposed restriction

Annex XV gives three main criteria that are relevant for a restriction: effectiveness, practicality and monitorability. These three criteria are used for

- developing the restriction proposal: The three criteria guide how to define the scope and conditions of the initial restriction. Assessment of the initial restriction against the three criteria is used to reveal needs to and ways how to improve the initial restriction.
- the criteria guide the identification of possible other RMOs
- the final justification need to show that the proposed restriction is the most appropriate Community wide measure assessed against these criteria.

The other RMOs considered are used as a reference point for assessing whether the proposed restriction is the most appropriate Community-wide measure. In cases where the development of the restriction proposal and identification of other RMOs show that one or a combination of these other RMOs would be more appropriate than restriction under REACH, the Authority may wish to assess this/these other RMOs more closely to provide the relevant Commission service better basis for taking appropriate action.

The following chapters list factors that can be taken into account in the assessment. The level of detail and depth of the assessment as well as the weight the different factors deserve depend on the case. The Authority should include in the assessment a description and analysis of uncertainties related to the assessment.

The following chapters refer to the assessment of the initial restriction but the same considerations will also be relevant for the assessment of the proposed restriction and the considered other RMOs.

5.4.5.1 Assessment of the effectiveness

Effectiveness criteria are further described in Annex XV: ‘the restriction must be targeted at the effects or exposures that cause the identified risks, capable of reducing these risks to an acceptable level within a reasonable period of time, and proportional to the risk’;

The assessment of the effectiveness needs to combine the two different aspects of the effectiveness: risk reduction capacity and proportionality of the initial restriction.

Risk reduction capacity:

- Does the initial restriction reduce the exposure to a level allowing adequate control of the identified risk?
- The assessment of the effect of the initial restriction on the exposure level related to the identified risk may vary from a statement based on a rough estimation to a calculation of the 'new' exposure situation according to guidance in chapter 5.2. For example, if the initial restriction prohibits a certain use but not all uses there may be a need to check that the regional concentration is reduced low enough.
- Do the alternatives required due to the initial restriction cause other risks to the human health or the environment?
- Based on the available information on alternatives (chapter 5.5) estimation of foreseeable risks to the human health and the environment.
- How long will it take before the initial restriction has reduced the exposure level to an acceptable level?
- What can be regarded as a reasonable period of time for reducing the exposure depends on the scale and severity of the risk.

Proportionality:

- Is the initial restriction targeted to the identified risk and does it not inadvertently affect uses or actors in the supply chain which are not associated with the identified risk?
- Do the efforts needed from the actors to implement and from the authorities to enforce the initial restriction correspond in amount or degree to the adverse effects that are being avoided;
- Does the initial restriction ensure a good balance between costs and benefits and is it cost-effective
- What is the length of time allowed for the actors to comply with the restriction?
- Depending on the availability of alternatives and actions needed to change to using them the time allowed for the actors to comply with the restriction may have a major effect on the costs of the restriction.
- Is the initial restriction consistent with legal requirements already in place;

In cases where the assessment of the risk reduction capacity concludes that the initial restriction does not ensure reduction of the exposure to a level that allows adequate control of identified risk in reasonable timeframe or that the initial restriction is not targeted to the identified risk, the Authority need to either change the scope or conditions of the restriction or check if other possible RMOs can address the risk. Also a combination of a restriction on certain uses and other RMOs addressing the remaining application may be a possibility. The Authority needs also to check that the measures taken by the industry to comply with the restriction will not cause equivalent or higher level of other risks.

In the same way, the assessment of proportionality may require refining the initial restriction or closer consideration of other RMOs.

Bringing these two aspects of the effectiveness of the initial restriction together may show that refining of and decision making on the restriction proposal would benefit from the SEA. Where the Authority finds that the uncertainties related to the assessment may have a major effect on the conclusions, the Authority may decide to generate more information or conduct an SEA to reduce uncertainties.

5.4.5.2 Practicality

Annex XV defines that the practicality of the proposed restriction and of the other RMOs involves three aspects: implementability, enforceability and manageability

Implementability: the actors involved have to be capable in practise to comply with the initial restriction. To achieve this, the necessary technology, techniques and alternatives should be available and economically feasible within the timeframe set in the restriction

Enforceability: The authorities responsible for enforcement need to be able to check the compliance of relevant actors with the proposed restriction or other considered RMOs. The restriction should be drafted in a way that allows the enforcement authorities to set up an efficient supervision mechanism(s). The resources needed for enforcement have to be proportional to the avoided risk.

Manageability: the proposed restriction or other considered RMOs should be manageable (taking into account the characteristics of the sectors concerned, for instance, the number of SMEs) and understandable to affected parties; the means of its implementation should be clear to the actors involved and the enforcement authorities and access to the relevant information should be easy. Furthermore, the level of administrative burden for the actors concerned and for the authorities should be proportional to the risk avoided.

5.4.5.3 Monitorability

According to Annex XV it must be possible to monitor the results of the implementation of the proposed restriction. Monitoring is here understood widely and may cover any means to follow up the effect of the proposed restriction in reducing the exposure. The most appropriate means of monitoring depend on the type of restriction and the related conditions. Such monitoring may include for example

- follow up of the amounts of substance manufactured and imported
- follow up of the amounts of substance used for different uses
- measuring of the concentration of the substance in preparations or articles
- measuring of the relevant emission and/or exposure levels
- follow up of the measures taken to reduce the exposure levels in accordance with conditions set in the restriction

To assess the monitorability of the initial and final proposed restriction and of the other RMOs considered the Authority should outline a monitoring proposal. Such a proposal should include the indicators that need to be monitored, the stakeholders to be involved in the monitoring activities, the scope and location of monitoring and the frequency of monitoring.

Factors to be considered when assessing the monitorability of the initial restriction include:

- Availability of indicators: are there indicators to monitor the results of the restriction that are feasible and allow sufficiently accurate monitoring of the results (for instance, is it possible to practically monitor the concentration of the substance in articles imported into the Community or the implementation of a restriction in an Industry sector with a large number of SMEs? Or, are the available (preferably standardised) scientific methods suitable for reliably measuring the concentration and fate of the substance in the environment?);
- Ease of monitoring: the cost and the proportionality of the distribution of the administrative burden for those responsible for the monitoring activities; the monitoring of the proposed

restriction or other considered RMOs should be easy to set up and administer and its cost and administrative burden should be proportional to the risk avoided

- Availability of monitoring mechanisms: consistency with the existing monitoring responsibilities of the authorities and actors involved; are the current monitoring mechanisms suitable for the monitoring or can they easily be adapted to cover the proposed restriction or other considered RMOs?

The overall assessment of the monitorability should answer the question of whether the outlined monitoring system allows to observe if the risk reduction targets have been achieved with proportionate resources?

5.4.5.4 Overall assessment of the proposed restriction and comparison to other RMOs

The Assessment of the initial restriction against the three criteria is used to refine the restriction and find out if there is a need to consider other RMOs more closely. When the assessment concludes that the initial restriction can not anymore be refined the Authority needs to combine the separate assessments against the three criteria to an overall assessment of the proposed restriction.

This overall assessment need to take into account the uncertainties related to the assessment against the individual criteria and related to combining them. This overall assessment and the related uncertainties may reveal that conducting an SEA would be useful for further refinement of the restriction proposal or for the decision making purposes.

The overall assessment of the proposed restriction needs to be compared to the considered other RMOs. This comparison will provide a justification that the proposed restriction is the most appropriate Community wide measure. The presentation of the results of the overall assessments and the comparison is important especially when several options have been identified as potentially suitable for the management of the identified risk. The presentation should aim to provide a clear illustration of the strong and weak points of each option and to rank the options against the key criteria. Such a table may be included in *Section 15* of the *Justification for proposed restrictions*.

Table 4 presents an example of how the comparison of the proposed restriction and considered other RMOs can be summarised. The Authority may choose how to score the identified options against the criteria; this could be by using ‘pluses’ and ‘minuses’ or terms such as ‘low-medium-high’ or any other qualitative or semi-quantitative indicators.

Table 3 Example o**f an assessment matrix of the proposed restriction and considered other RMOs against the three key criteria**

Criterion	Parameter	Proposed restriction	RMO 1	RMO 2	RMO 3
Effectiveness	Risk reduction capacity				
	Proportionality				
	Overall				
Practicality	Implementability				
	Enforceability				
	Manageability				
	Overall				
Monitorability	Availability of indicators				
	Ease of monitoring				
	Availability of monitoring mechanisms				
	Overall				

If the comparison of the proposed restriction against other possible Community level RMOs shows that a measure under another legislation is more appropriate way of addressing the risk than a restriction under REACH the Authority is requested to document the assessment and this conclusion in the relevant parts of the restriction format and submit this documentation to the Agency. It should be noted that this conclusion can be achieved already earlier in the process, for instance, when assessing the sources of emissions and exposure as in example 6

Example 6 Example of the referral of a substance to another legislative framework

Due to the high volume of Substance I used in the EU and monitoring data indicating a risk, the Agency on request by the Commission started developing an Annex XV dossier. During the development of a restriction dossier, it was concluded that the only significant release of Substance I is due to the breakdown of one of its precursors, Substance J. In fact, an environmental risk arises from several precursors to Substance I but the production of these precursors has decreased significantly and the main risk remaining is caused by the use of Substance J as a herbicide.

Substance J is being dealt through other legislative measures i.e. the Biocidal Products Directive and the Plant Protection Products directive. As a result, no restriction dossier is to be developed for this particular risk from Substance I and the documentation of risk should be referred to the Commission services responsible for the implementation of the two aforementioned Directives.

5.4.6 Documenting the proposed restriction and the justification

The proposed restriction is documented in the *Proposal* part of the Annex XV restriction report. The proposal for a restriction needs to specify the scope of the restriction: what are the uses covered by the proposed restriction and any general or use specific conditions. Conditions may include for instance concentration limits, conditional or unconditional derogations, timeframes for the implementation or other aspects defining the exact boundaries and ways of implementing the restriction.

The justification that the proposed restriction is the most appropriate Community wide measure will be included in *section 15 of the justification* part of the restriction report (APPENDIX I).

5.5 Information on alternatives

5.5.1 Overview of the task

Aim: Annex XV requires the Authority to document the available information on alternative substances and techniques in the restriction proposal.

The aim is to provide information for the analysis of whether the equivalent function provided by the substance can be obtained by other substances or techniques and for assessing the net impact of the proposed restriction to the human health and the environment. This will facilitate in defining a proportionate restriction that is targeted to the identified risk.

Scope: The term 'alternative' is used in this guidance to mean alternative chemical substances or alternative techniques (processes and technologies) or combinations thereof that can be used to replace (partially or totally) the substance of concern in a given use or a number of uses by providing the equivalent function that the substance delivers in those uses or by making the function redundant.

Available information on alternatives may cover any information relevant for developing the restriction proposal, for its later assessment by the Agency and for the decision making by the Commission, including

- information on the risks to human health and the environment related to the manufacture or use of the alternatives; and
- technical and economical feasibility, availability, including the time scale.

The depth of the analysis of alternatives beyond documenting what is readily available will rely on the decision of the Authority. The Authority should take a flexible approach so that the time and effort allocated to the assessment of alternatives is proportional to the needs of each case.

Outcome: Information on alternatives is used when refining the restriction proposal. It is used in developing the justification that the proposed restriction is the most appropriate Community wide measure especially when assessing the effectiveness and practicality of the proposed restriction (ref Chapter 5.4.5). Furthermore, the information can be used if the Authority decides to develop a socio-economic analysis or interested parties submit input to one.

In addition, the available information on alternatives needs to be documented in the restriction report sections 11 to 13.

5.5.2 Information sources

The information sources on the risks for human health and the environment related to alternative substances are the same as described in chapter 4. Consultation with stakeholders (see Chapter 4.2.2), literature, statistics and experience from the implementation of other legislation are the main information sources for other aspects on alternatives: availability, technical and economical feasibility of alternatives and risks to human health and environment related to alternative techniques.

Consultation with Industry stakeholders and other experts could be particularly relevant in the assessment of the availability and technical and economical feasibility of alternative substances and techniques. Downstream users (associations or individual companies), in particular, who know the technical requirements of their process and products and have a vested interest in using the best raw materials and techniques, may provide useful information. Other possible consultees include manufacturers and importers (associations or individual companies) of alternative substances and techniques, MS authorities having experience on using alternatives e.g., from the implementation of other legislation and research organisations.

The Authority should scrutinise any information made available from consultees taking into consideration the consultees' vested interests, the business relationships between organisations holding similar or opposite views on restrictions and alternatives, and the scientific robustness of the submitted information. The Authority should present in the *Information on stakeholder consultation* part of the restriction report what information was supplied by whom and how this has been used to ensure the transparency of the analysis. Any uncertainties on or assessment of the quality or completeness of the information submitted by stakeholder may also be discussed therein.

5.5.3 Issues to be considered

The guidance on developing an socio-economic analysis (SEA) and the guidance on preparing an authorisation application will also contain guidance relevant for identification and analysis of alternatives. The references will be added, where necessary, when these other parts of the guidance package are available.

Description of the use and function of the substance

Information on and assessment of risk(s) (chapter 5.2) provides a list of uses that cause a risk to human health or the environment. For the purpose of collecting available information on alternatives a description of uses should be completed by a description of the technical or other functions provided by the substance in these uses. Furthermore, an explanation why these functions are needed may be useful. This is essential to ensure that the identification of alternatives is based on a sound understanding of the role played by the substance in the production process and final products. The function that a substance serves may be due to its mechanical, physical or chemical properties, and the substance may act as an input to production, i.e. a raw material, or as a processing aid. In some cases, a substance may be used for environmental or health and safety reasons. The different functions provided by a substance should be described in terms of their:

- technical and processing related role – what are the specific technical performance requirements for the function;
- quality, durability or end product performance related role; and
- economic importance in terms of reduced costs.

For different functions, data on the associated quantity of the substance used and on trends in use would be useful for assessment of future availability of alternatives. If possible to obtain information on the number of companies using the substance, on their size (turnover and number of employees) and on their locations would further complete the picture.

5.5.3.1 Identification of alternatives fulfilling the function(s)

Once the functions provided by a substance have been described, alternative substances and techniques that meet the equivalent function or make the original function redundant, i.e. **alternatives that are technically feasible**, can be more easily identified.

Substitute substances or processes that are already being used by some companies are usually selected for further assessment because they provide an obvious starting point against which the risk, performance and cost of other alternatives can be compared. However, more innovative alternatives can also be considered. For example, one may wish to consider other alternatives such as new technologies involving product re-design (e.g. provision of a powder in a solid or liquid form) and/or changes in processes (e.g. adoption of metal working techniques that require no lubricants).

Questions to be considered when collecting information include

- For which of the uses of concern the alternative is technically feasible? What are the uncertainties related to the technical feasibility (e.g., only laboratory / pilot plant scale evidence of the functioning, used in other process but under different conditions (pH, temperature…) etc)
- Whether or not adoption of the alternative substance would require changes in any of the processing systems associated with the chemical of concern? Is research and development necessary in order to move to the alternative? Would training of users be required?
- Would the use of alternative technique result in complete or partial replacement of the substance in the uses of concern? What research and development is necessary in order to apply the alternative technique? Would training of users be required?

5.5.3.2 Assessment of availability of alternatives

An important issue in identifying the availability of alternatives is timing: alternative substances may not be available immediately or they may not be available in the required tonnages but could become available at some point in the future. To assess this, knowledge of the relevant markets and the current trends and research within them would be useful. It would also be useful to consider any experience with the use of alternatives within or outside the Community. On alternative techniques the same basic consideration applies: is the necessary equipment already available in market in sufficient quantities.

The time needed to invest, install and take into operation alternative techniques should be considered. This applies also to alternative substances that need changes in processes or equipment.

There is a reciprocal relationship between a proposed restriction and the availability of alternative substances and processes: limited availability of alternatives may limit the choices for restrictions but, at the same time, a restriction may affect the (future) availability of alternatives. The Authority may use the available information to make assumptions on the time that may be required for the alternatives to become available and, based on these assumptions, to consider the need and conditions of a time-limited derogation for one or more uses

Questions to be considered when collecting information include

- What tonnages of alternative substance would be required?
- At what tonnage are they currently used in the EU / worldwide, what are the trends in manufacture and uses?
- What is needed to change to the alternative techniques? Is there knowledge on the suitability and availability of e.g. equipment or raw materials required to transfer to the alternatives?
- Is there need for further research and development?
- What is the timeframe for investing to, installing and taking to operation the necessary equipment?

Experience suggests that even with the alternative substances and/or technologies already known, it may take up considerable time to carry out the quality and performance tests. Examples in the box below illustrate this:

- Sometimes years of continuous development are needed to bring alternatives with an equal and comparable performance to existing formulations on the market (e.g. surfactant formulations).
- for certain uses some alternatives exist but that a significant period of time for research would be needed for alternatives to be made available at the industrial scale (e.g. additives in the rubber industry).
- Similarly, no alternatives for certain substances in aviation hydraulic fluids are available at present. According to industry sources, there have been many attempts to find alternatives for certain substances.
- Even with the alternative substances and/or technologies already known, it may easily take up more than 3 years for users to carry out the quality and performance tests. In other cases the alternatives might be already available but the approval procedure required by other specific pieces of legislation for the alternative, introduces a further delay into the process.

Example 7 Variable availability of alternatives when more than one uses require risk management action

Substance K is used in a variety of uses. Those of interest include: (a) mist suppressant in the metal finishing sector; (b) component in surfactant formulations; (c) chemical agent in several uses in the rubber industry; (d) chemical agent in the semiconductors industry; and (e) chemical component of aviation hydraulic fluids.

Information received through consultation suggests that there are currently no known alternative chemical mist suppressants to Substance K for the metal finishing sector; previous generations of chemical mist suppressants having failed due to excessive pitting of coatings and rapid breakdown during electrolysis. However, this does not necessarily mean that Substance K cannot be replaced. Consultation and literature review has suggested that its use may not be necessary if the chemical that produces the mist which poses occupational health risks is replaced. Substitution of the mist-prone chemicals would result not only in the reduction of the likely health risks but may result also in significant cost savings. However, it appears that suitable alternatives for the chemical that tends to create hazardous mists may not be available for all metal finishing processes.

With regard to surfactant formulations, as a result of many years of continuous development, alternatives to Substance K have been indicated as providing an equal and comparable performance to formulations based on Substance K.

For the rubber industry, alternatives to Substance K on an Industry-wide basis (or even an enterprise-wide basis at the research scale) are not currently available, although efforts are reportedly being made. Consultation has suggested that replacement efforts have resulted in an 83% decrease in the total amount of Substance K used in synthetic rubber products since 2000.

For the semiconductors industry, suitable alternatives are not currently available; for certain uses, some alternatives do exist but work on these is still ongoing. Industry sources have suggested that at least five years of research would be necessary for alternatives to be made available at the industrial scale.

Similarly, no alternatives for aviation hydraulic fluids are available at present. According to industry sources, there have been attempts over the last 30 years to find acceptable alternatives to Substance K. There are currently no promising leads for a substitute for Substance K now in use, and there are no assurances that an acceptable alternative will be identified in the short or longer term.

From the above, it can be concluded that the approach to different uses of the substance cannot be uniform. The Authority should consider whether derogations should be introduced for certain metal finishing applications and for the use of Substance K in the rubber, semiconductor and aviation industries. Time-limited derogations could be a suitable option, especially in the rubber and semiconductor industries where the availability of alternatives may change in the bear future.

Assessment of human health and environmental risks related to the alternatives

This assessment of risks related to the alternatives has a comparative nature. It should document whether the transfer to alternative substance or technique would result in reduced overall risks to human health and the environment. It is therefore important not only to consider the risks that are considered unacceptable and resulted in developing the restriction proposal, but alsopossible other risks resulting from the alternative. The aim is to assess the effects of the adoption of alternatives in

- reducing the identified risk (it does not contribute to the identified risk at the same or higher level)
- causing other risks that can not be adequately controlled

For example, in relation to alternative substances, the work involved may include:

- collecting data on the properties of alternative substances from manufacturers and importers or other sources (e.g. registration dossiers on alternatives when these have been registered, or from other sources when registration has not yet taken place);
- examining the hazard profiles of the alternatives to determine whether they would result in a lower level of risk;
- examining information on environmental concentrations of the substitutes and data on current levels of exposure from publicly available sources or impacts associated with alternative options; and
- if appropriate, quantifying and valuing the change in risk following the approach set out above for the substance of concern.

It would obviously not be appropriate to require that the risks associated with alternative substances or techniques are assessed in the same detail as the risks associated with the substance of concern. The level of effort that is to be put into this aspect above the documentation of available information will be a matter of judgment and up to the Authority. For example, the simple comparison of hazard profiles may indicate that alternative chemicals present a clearly lower level of risk. In these cases, no additional assessment may be necessary. When a comparison of hazard profiles or a lack of data raises concern, then there may be a need for more detailed assessment of any changes in risk following the appropriate parts of chapter 5.2 of this guidance and the guidance on preparing chemical safety assessment. Appendix VIincludes considerations on the assessment of alternative substance and illustrates a tiered approach for an assessment.

Assessment of economical feasibility of alternatives

The authority is requested to document the available information on the economical feasibility of the alternatives. That could include for the main alternatives, if data are available:

1. Describe the net compliance and other costs (taking into account both increases and decreases in costs) faced by actors in each link of the supply chain;
2. Assess financial viability and the ability of the different actors to pass costs down the supply chain; and
3. Where impacts on competitiveness are likely to be significant at the sectoral level, consider trade and wider economic and employment effects.

5.5.4 Reporting the information on alternatives

The available information on alternatives needs to be documented in the sections 11 to 13 of the restriction report. It would be useful to summarise the available information on alternatives as an overall assessment. This should give for alternatives that are technically feasible and which deliver the same functionality as the substance of concern an overview of the knowledge on the risks to human health and the environment and on the economic feasibility.

The Authority may consider summarising the available information in tables such as Table 5.

Table 4 Example of a table for the evaluation of potential alternative substances [*substance name*] in [*use*]

Parameter		Questions to be answered	Alt 1	Alt 2	Alt 3
Technical feasibility		Can it perform the same functions as the substance in question?			
		Will it require changes (in processes, equipment, storage facilities, training, etc.)?			
Availability	Current and future availability	Is it available in the required tonnage / amount in the EU / worldwide?			
	Timeframe	How fast could enterprises make the switch? What would be the downtime, if any?			
Risk assessment	Human health	Information on the hazards: properties causing the concern for the substance to be restricted / other properties			
		Information on risks related to properties causing the concern for the substance to be restricted / other properties. Information on other risks related to the alternatives.			
	Risk to the environment	Information on the hazards: properties causing the concern for the substance to be restricted / other properties			
		Information on risks related to properties causing the concern for the substance to be restricted / other properties. Information on other risks related to the alternatives.			
	Assessment of net risk	Would the alternative result in a sufficient reduction in the net risk? Are there new risks associated with the alternative?			
Economic feasibility	Net costs	Net compliance and other costs (taking into account both increases and decreases in costs) faced by actors in each link of the supply chain			
		Financial viability of the alternatives			
		Ability of the different actors to pass costs down the supply chain			
		Trade and wider economic and employment effects			
Uncertainties. What is the level of uncertainty in the assessment of the feasibility, risks and economic viability of alternatives?					

Note: The analysis presented in the *Information on alternatives* could be summarised in this table with the use of crosses and minuses or 'low-medium-high' or, in the case of costs and benefits, by providing the estimated monetary costs and benefits for each alternative, if this information is available. For the assessment of the overall uncertainty, 'low-medium-high' indications may be provided for each alternative; a detailed discussion on uncertainty in the main text should also be provided.

5.6 Socio-economic assessment

Aim:

Annex XV invites the Authority preparing a restriction proposal to analyse the socio-economic impacts of the proposed restriction.

The aim of an SEA is to facilitate the Authority in preparing a proportional and well informed restriction proposal. Furthermore, an SEA included in Annex XV dossier is valuable for the SEA Committee when it gives its opinion on the proposal and for the Commission taking the decision.

Scope:

An SEA aims at assessing the proposed restriction in terms of

- the net benefits to human health and the environment and
- the net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole.

'Net benefits' above should take into account reduced risk due to restriction and possible risks caused by the transfer to alternatives. Similarly, 'net costs' should take into account both costs to actors due to restriction and possible cost savings caused by the transfer to alternatives.

It would be useful if an SEA prepared covered all relevant aspects effecting the benefits gained by introducing the proposed restriction and costs caused by it. However, as there is no legal requirement to produce an SEA the Authorities are encouraged to include in the restriction proposal any relevant parts of SEA or inputs to one in absence of full SEA. In any case it is crucial to document clearly which aspects have been covered.

The methods to be used when developing SEAs for restriction proposals are described in the Guidance on Socio Economic Analysis.

Outcome:

SEA is used when refining the restriction proposal. It is used in developing the justification that the proposed restriction is the most appropriate Community wide measure especially when assessing the effectiveness and practicality of the proposed restriction (ref chapter 5.4).

Furthermore, an SEA or inputs to one will be documented in 'socio-economic analysis' section of the restriction report.

5.6.1 The importance of socio-economic analyses in the preparation of restriction dossiers

Although an SEA is not a mandatory part of a restriction proposal, Authorities may wish to prepare one as an SEA:

- helps in ensuring that the restriction proposal is proportional and well-informed
- facilitates the assessment of the effectiveness and practicality of the proposed restriction

- provides a good basis for the SEA Committee to prepare its opinion on the proposal and for the Commission to take the decision; and
- provides a valuable mechanism for involving stakeholders in the decision-making process and developing a shared understanding of the implications of imposing a restriction (or other legal requirements or of taking no action).

Interested parties are able to comment the Annex XV dossier and the proposed restriction, as well as submit full SEAs, or inputs to one, to the SEA Committee. It will be up to the SEA Committee to balance in its opinion the inputs received from such parties with the information provided by the Authority. Thus, preparation of an SEA by the Authority during the restriction procedure can help ensure that the Authority's arguments on the justification for the proposed restriction are given due weight in the overall decision-making process.

5.6.2 Incorporation of the findings of an SEA into the Annex XV restriction report

The process of preparing an SEA will bring together information from several of the other components of the restriction procedure and, in turn, will provide inputs to an Annex XV restriction report. This is illustrated in Figure 6.

Information that may feed from the development of other parts of the Annex XV restriction report into the SEA process includes:

- description of the type and magnitude of risk
- information on the Industry sectors and uses associated with unacceptable risks (from the risk assessment and risk characterisation);
- information on existing legal requirements (ELRs) and on the effectiveness of implemented exposure scenarios (OCs and RMMs);
- description of the proposed restriction and information on possible other risk management options (RMOs) and appropriate legislative frameworks for their implementation;
- description of the remaining (and possible new) risks when the proposed restriction or the possible other RMOs are in place
- information on the availability, risks and feasibility of alternative substances and techniques.

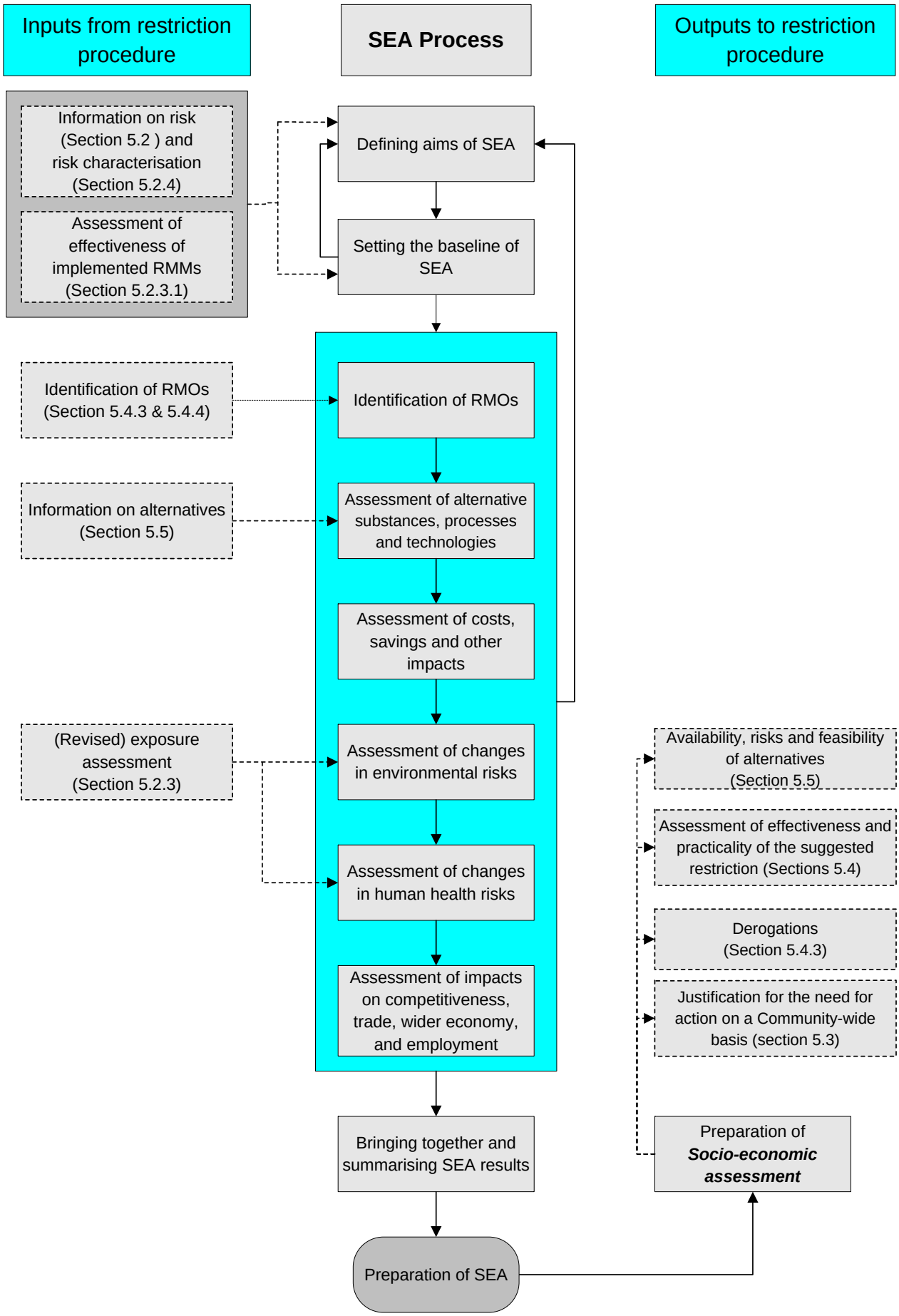
The SEA process should build on such data but may also involve the collection of additional data from manufacturers, importers and downstream users submitting information through consultation (for instance, information on current markets for the substance and its products, expected trends in usage, innovations or technical developments within the sectors of concern, etc.). The analysis of this information will result in the development of the SEA document the results of which will be summarised in the *Socio-economic assessment* part of the Annex XV report. However, the SEA findings should not be used in isolation to the remainder of the restrictions report but rather feed into several other parts of the report under preparation, such as:

- the identification of RMOs, which may benefit from any additional information to be made available to the Authority through consultation for the SEA;
- the assessment of alternatives, which may benefit from any additional information on the availability of alternatives as well as the assessment of their economic feasibility;
- the assessment of the effectiveness and practicality of the proposed restriction and their comparison to other RMOs, which may benefit from any additional information alternatives and from the assessment of costs, savings and other impacts under different RMOs;

- the refinement of an initial restriction proposal by identification which uses / manufacturing / marketing should be restricted and under which conditions to ensure a proportional restriction that is targeted to the identified risks, which may benefit from the analysis of alternatives and the assessment of costs, savings and other impacts for different RMO within the SEA; and
- the overall assessment of advantages and drawbacks and the market-related considerations for the proposed restriction, which may benefit from the general analysis and conclusions of the SEA and, particularly, the analysis of potential market harmonisation issues.

The Guidance on Socio Economic Analysis provides more detail on the incorporation of the findings of an SEA into an Annex XV restriction report.

Figure 6 Links between SEA and the preparation of an Annex XV restriction report



5.6.3 Socio-economic considerations in the absence of an SEA

Since an SEA is not a compulsory component of the restriction procedure, it is possible that it may not be undertaken during the preparation of an Annex XV restriction report. In the absence of a full SEA, the Authority may wish to consider some of the key elements of an SEA to support its arguments in the Annex XV restriction report. Such elements could be:

- the prevailing trends in the manufacture, marketing and use of the substance in the EU;
- the costs of alternatives, the benefits and risks arising from their use and any impacts from their use on product quality or availability; and
- a discussion on the importance of the substance to enterprises and Industry sectors of concern

These key elements may be further supported by additional analysis on more complex issues such as:

- a discussion on how innovation and technological development may affect future use of the substance;
- a discussion of the comparison of the costs of the restriction to the benefits; and
- a discussion on uncertainty in cost estimates.

The need for and the level of detail of the discussion on the above issues will be influenced by the characteristics of risk, the range of available RMOs and any constraints on time and resources.

5.7 Information on stakeholder consultation

Annex XV requires the Authority to document any consultation of stakeholders and how their views have been taken into account. The Annex XV report should describe:

- who has been consulted
- what information has been asked for, how the consultation was carried out and when in the process of preparing an Annex XV report
- how the information has been taken into account in preparing the Annex XV dossier
- if the information was not taken into account, the main reasons for that

The information obtained from the stakeholder consultation should be reported in a transparent way. The report should include an overview of the evaluation of the uncertainties related to the information and the subsequent assumptions made. These assumptions, conclusions and all decisions should be open to review.

6 REFERENCES

Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Official Journal, P196, 16.8.1967, p 0001-0098.

Council of the European Union (2006). Common position adopted by the Council with a view to the adoption of a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC of the European Parliament and of the Council and repealing Council Regualtion (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2001/21/EC. Council of the European Union, 12 June 2006, Brussels.

OECD (2005). Manual for Investigation of HPV Chemicals. Chapter 3.2. Guidance on the Development and Use of Chemical Categories in the HPV Chemicals Programme. Organisation for Economic Co-Operation and Development (available from: http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html).

UNECE (2005). Globally Harmonized System of Classification and Labelling of Chemicals (GHS). First Revised Edition. United Nations Economic Commission for Europe (available from http://www.unece.org/trans/danger/publi/ghs/ghs_rev01/01files_e.html).

7 GLOSSARY AND ABBREVIATIONS

Annex XV dossier	A dossier produced in compliance with Annex XV. This consists of two parts, a technical dossier and the Annex XV report.
Annex XV report	A report produced as part of the Annex XV dossier according to the guidance and format outlined in this document.
BCF	Bioconcentration factor.
CAS number	Chemical Abstracts Service registry number
CMR	Carcinogenic, mutagenic and toxic to reproduction.
CSA	Chemical safety assessment.
CSR	Chemical safety report.
DMEL	Derived minimum effect level
DNEL	Derived no effect level
Downstream user	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. Art 3(13) of REACH Regulaion
ELR	Existing Legal Requirement (see Section 5.1.3)
Exposure scenario	The set of conditions, including opearional conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposure of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate. Art 3(37) of the REACH Regulation
Full study report	A complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed. Art 3(27) of REACH Regulation
IARC	International Agency for Research on Cancer
Intermediate	A substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance. *(continues)* Art 3(15) of REACH Regulation
IPCS	International Programme on Chemical Safety
IUCLID	The database underlying the REACH-IT system.

Log Kow	The $\log_{10}$ value of the octanol-water partition coefficient. Also often referred to as log P.
Manufacturer	Any natural or legal person established within the Community who manufactures a substance within the Community. Art 3(9) of REACH Regulation
NOEC	No observed effect concentration.
OECD	Organisation for Economic Co-operation and Development
PBT	A persistent, bioaccumulative and toxic as defined in Annex XIII.
PNEC	Predicted no effect concentration.
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
POP	Persistent organic pollutant.
REACH-IT	The information technology (IT) system for creating and administering documentation under REACH.
Restriction	Any condition for or prohibition of the manufacture, use or placing on the market. Art 3(31) of REACH Regulation
RMM(s)	Risk management measure(s) (see Chapter 5.1.3).
RMO(s)	Risk management option(s) (see Chapter 5.1.3).
Robust study summary	A detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Art 3(28) of REACH Regulation
Study summary	A summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study. Art 3(29) of REACH Regulation
Substance	A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. Art 3(1) of REACH Regulation
vPvB	Very persistent and very bioaccumulative as defined in Annex XIII.

APPENDIX I FORMAT FOR RESTRICTION REPORT

Annex XV dossier

RESTRICTION PROPOSAL

Substance Name:

EC Number:

CAS Number:

Submitted by:

Version

RESTRICTION PROPOSAL

Substance Name:

EC Number:

CAS number:

Restriction proposal:

INFORMATION ON HAZARD AND RISKS

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifier of the substance

Chemical Name:
EC Number:
CAS Number:
IUPAC Name:

1.2 Composition of the substance

For each constituent/ impurity/ additive, fill in the following table (which should be repeated in case of more than one constituent). The information is particularly important for the main constituent(s) and for the constituents (or impurity) which influence the outcome of the dossier.

Chemical Name:
EC Number:
CAS Number:
IUPAC Name:
Molecular Formula:
Structural Formula:
Molecular Weight:
Typical proportion %

Real proportion (range) in %

1.3 Physico-Chemical properties

Table 1 Summary of physico-chemical properties

REACH ref Annex, §	Property	IUCLID section	Value	[enter comment/reference or delete column]
VII, 7.1	Physical state at 20°C and 101.3 KPa	3.1		
VII, 7.2	Melting/freezing point	3.2		
VII, 7.3	Boiling point	3.3		
VII, 7.4	Relative density	3.4 density		
VII, 7.5	Vapour pressure	3.6		
VII, 7.6	Surface tension	3.10		
VII, 7.7	Water solubility	3.8		
VII, 7.8	Partition coefficient n-octanol/water (log value)	3.7 partition coefficient		
VII, 7.9	Flash point	3.11		
VII, 7.10	Flammability	3.13		
VII, 7.11	Explosive properties	3.14		
VII, 7.12	Self-ignition temperature			
VII, 7.13	Oxidising properties	3.15		
VII, 7.14	Granulometry	3.5		
XI, 7.15	Stability in organic solvents and identity of relevant degradation products	3.17		
XI, 7.16	Dissociation constant	3.21		
XI, 7.17,	Viscosity	3.22		
	Auto flammability	3.12		
	Reactivity towards container material	3.18		
	Thermal stability	3.19		
	[enter other property or delete row]			

2 MANUFACTURE AND USES

2.1 Manufacture

2.2 Identified uses

3.3 Uses advised against

3 CLASSIFICATION AND LABELLING

3.1 Classification in Annex I of Directive 67/548/EEC

3.2 Classification according to GHS

3.3 Self classification(s)

This should include the classification, the labelling and the specific concentrations limits. The reason and justification for no classification should be reported here.

It should be stated whether the classification is made according to Directive 67/548/EEC criteria or according to GHS criteria

4 ENVIRONMENTAL FATE PROPERTIES

4.1 Degradation

4.1.1 Stability

Corresponds to IUCLID 4.1

4.1.2 Biodegradation

4.1.2.1 Biodegradation estimation

4.1.2.2 Screening tests

4.1.2.3 Simulation tests

4.1.3 Summary and discussion of persistence

4.2 Environmental distribution

4.2.1 Adsorption/desorption

Corresponds to IUCLID 4.4.1

4.2.2 Volatilisation

Corresponds to IUCLID 4.4.2

4.2.3 Distribution modelling

4.3 Bioaccumulation

4.3.1 Aquatic bioaccumulation

4.3.1.1 Bioaccumulation estimation

e.g. use of Kow, predicted BCF

4.3.1.2 Measured bioaccumulation data

4.3.2 Terrestrial bioaccumulation

4.3.3 Summary and discussion of bioaccumulation

4.4 Secondary poisoning

Assessment of the potential for secondary poisoning

5 HUMAN HEALTH HAZARD ASSESSMENT

5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

5.2 Acute toxicity

5.2.1 Acute toxicity: oral

5.2.2 Acute toxicity: inhalation

5.2.3 Acute toxicity: dermal

5.2.4 Acute toxicity: other routes

5.2.5 Summary and discussion of acute toxicity

C&L including weight-of-evidence considerations.

5.3 Irritation

5.3.1 Skin

5.3.2 Eye

5.3.3 Respiratory tract

5.3.4 Summary and discussion of irritation

C&L including weight-of-evidence considerations.

5.4 Corrosivity

5.5 Sensitisation

5.5.1 Skin

5.5.2 Respiratory system

5.5.3 Summary and discussion of sensitisation

C&L including weight-of-evidence considerations.

5.6 Repeated dose toxicity

5.6.1 Repeated dose toxicity: oral

5.6.2 Repeated dose toxicity: inhalation

5.6.3 Repeated dose toxicity: dermal

5.6.4 Other relevant information

5.6.5 Summary and discussion of repeated dose toxicity

Classification &Labelling, dose-response estimation including weight-of-evidence considerations.

5.7 Mutagenicity

5.7.1 *In vitro* data

5.7.2 *In vivo* data

5.7.3 Human data

5.7.4 Other relevant information

5.7.5 Summary and discussion of mutagenicity

Classification &Labelling, dose-response estimation including weight-of-evidence considerations.

5.8 Carcinogenicity

5.8.1 Carcinogenicity: oral

5.8.2 Carcinogenicity: inhalation

5.8.3 Carcinogenicity: dermal

5.8.4 Carcinogenicity: human data

5.8.5 Other relevant information

5.8.6 Summary and discussion of carcinogenicity

Classification & Labelling, dose-response estimation including weight-of-evidence considerations.

5.9 Toxicity for reproduction

5.9.1 Effects on fertility

5.9.2 Developmental toxicity

5.9.3 Human data

5.9.4 Other relevant information

5.9.5 Summary and discussion of reproductive toxicity

Classification & Labelling, dose-response estimation including weight-of-evidence considerations.

5.10 Other effects

5.11 Derivation of DNEL(s) or other quantitative or qualitative measure for dose response

5.11.1 Overview of typical dose descriptors for all endpoints

5.11.2 Correction of dose descriptors if needed (for example route-to-route extrapolation)

5.11.3 Application of assessment factors

5.11.4 Selection / identification of the critical DNEL(s) / the leading health effect

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

6.1 Explosivity

Including C&L

6.2 Flammability

Including C&L

6.3 Oxidising potential

Including C&L

7 ENVIRONMENTAL HAZARD ASSESSMENT

7.1 Aquatic compartment (including sediment)

7.1.1 Toxicity test results

7.1.1.1 Fish

Short-term toxicity to fish

Long-term toxicity to fish

7.1.1.2 Aquatic invertebrates

Short-term toxicity to aquatic invertebrates

Long-term toxicity to aquatic invertebrates

7.1.1.3 Algae and aquatic plants

7.1.1.4 Sediment organisms

7.1.1.5 Other aquatic organisms

7.1.2 Calculation of Predicted No Effect Concentration (PNEC)

7.1.2.1 PNEC water

7.1.2.2 PNEC sediment

7.2 Terrestrial compartment

7.2.1 Toxicity test results

7.2.1.1 Toxicity to soil macroorganisms

7.2.1.2 Toxicity to terrestrial plants

7.2.1.3 Toxicity to soil microorganisms

7.2.1.4 Toxicity to other terrestrial organisms

Toxicity to birds

Toxicity to other above ground organisms

7.2.2 Calculation of Predicted No Effect Concentration (PNEC_soil)

7.3 Atmospheric compartment

7.4 Microbiological activity in sewage treatment systems

7.4.1 Toxicity to aquatic microorganisms

7.4.2 PNEC for sewage treatment plant

7.5 Calculation of Predicted No Effect Concentration for secondary poisoning (PNEC oral)

7.6 Conclusion on the environmental classification and labelling

8 PBT, VPVB AND EQUIVALENT LEVEL OF CONCERN ASSESSMENT

8.1 Comparison with criteria from Annex XIII

8.2 Assessment of substances of an equivalent level of concern

8.3 Emission characterisation

8.4 Conclusion of PBT and vPvB or equivalent level of concern assessment

9 EXPOSURE ASSESSMENT

9.1 General discussion on releases and exposure

9.1.1 Summary of the existing legal requirements

9.1.2 Summary of the effectiveness of the implemented risk management measures

9.2 Manufacturing

9.2.1 Occupational exposure

9.2.2 Environmental release

9.3 "Use 1"

For each use include such a sub-chapter. Subsequently, if there is another "Use 2" this will lead to sub-chapter 9.4 "Use 1" including 9.4.1 Human exposure, 9.4.1.1 Occupational exposure, 7.4.1.2 Consumer exposure and 9.4.2 Environmental release. The other sub-chapters will then be renumbered.

9.3.1 Human exposure

9.3.1.1 Occupational exposure

9.3.1.2 Consumer exposure

9.3.2 Environmental release

9.4 Other sources (for example natural sources)

9.4.1 Human exposure

9.4.1.1 Occupational exposure

9.4.1.2 Consumer exposure

9.4.2 Environmental release

9.5 Environmental exposure assessment

9.5.1 Summary of emissions

9.5.2 Predicted environmental concentrations

9.5.2.1 Regional concentrationsAtmosphere

Aquatic compartment

Sediment

Soil compartment

9.5.2.1 Local concentrations

Atmosphere

Aquatic compartment

Sediment

Soil compartment

9.5.2.3 Exposure concentrations of man via the environment

9.5.3 Measured levels

Atmosphere

Aquatic compartment

Sediment

Soil compartment

Secondary poisoning

9.5.4 Selected environmental concentrations of risk characterisation

Atmosphere

Aquatic compartment

Sediment

Soil compartment

Secondary poisoning

9.6 Combined human exposure assessment

10 RISK CHARACTERISATION

10.1 Human health

10.1.1 Workers

10.1.2 Consumers

10.1.3 Indirect exposure of humans via the environment

10.1.4 Combined exposures

10.2 Environment

10.2.1 Aquatic compartment (including sediment and sewage treatment plant and secondary poisoning)

10.2.2 Terrestrial compartment (including secondary poisoning)

10.2.3 Atmospheric compartment

10.2.4 Microbiological activity in sewage treatment systems

INFORMATION ON ALTERNATIVES

11 INFORMATION ON THE RISKS TO HUMAN HEALTH AND THE ENVIRONMENT RELATED TO THE MANUFACTURE OF USE OF THE ALTERNATIVES

12 AVAILABILITY OF ALTERNATIVE, INCLUDING THE TIME SCALE

13 TECHNICAL AND ECONOMICAL FEASIBILITY

JUSTIFICATION FOR RESTRICTION AT COMMUNITY LEVEL

14 JUSTIFICATION THAT ACTION IS REQUIRED ON THE COMMUNITY-WIDE BASIS

15 JUSTIFICATION FOR THE PROPOSES RESTRICTION

15.1 Effectiveness

15.2 Practicality

15.3 Monitorability

SOCIO ECONOMIC ASSESSMENT

OTHER INFORMATION

(It is suggested to include here information on any consultation which took place during the development of the dossier. This could indicate who was consulted and by what means, what comments (if any) were received and how these were dealt with. The data sources (e.g. Technical Dossiers, CSRs, other published sources) used for the dossier could also be indicated here.)

APPENDIX II INFORMATION ON HOW TO FILL-IN THE ANNEX XV RESTRICTION REPORT

Overview

The Annex XV dossier consists of two parts. This guidance considers the production of the Annex XV report. Production of the technical dossier is not addressed here; the appropriate guidance from RIP 3.2/3.3 [XXX] should be followed along with guidance on IUCLID5. Authorities are encouraged to create a technical dossier for the substance as part of producing the restrictions dossier.

The Annex XV restrictions report consists of six parts; these are:

- *Proposal;*
- *Information on hazard and risk;*
- *Information on alternatives;*
- *Justification for restriction at Community level;*
- *Socio-economic assessment; and*
- *Information on stakeholder consultation.*

Proposal

The first part of the Annex XV restrictions report outlines the proposed Community-wide restriction. This contains details on the identity of the substance (substance name, CAS/EC number(s)), registration number(s) (if available), molecular formula, structural formula, purity and impurities). The summary also states the restriction proposed, the uses it applies to, any proposed conditions, specific concentration limits, and any derogation including their conditions and timeframe for their implementation.

The *Proposal* should be a self-sufficient presentation of the conclusions of the restrictions procedure and should be precise and not open to interpretation.

Information on hazard and risk

The second part of the Annex XV report presents the technical and scientific information which demonstrates the risk(s) which are not adequately managed by the registration procedure. It takes the form of a hazard and risk assessment and uses the same basic format as the chemical safety report. The format has ten sections as described below. Specific comments on the content for some of the sections are included in this guidance. For other sections, reference is made to other guidance for their completion.

Section 1: Identity of the substance and physical and chemical properties. The CSA guidance (XXX) should be used to complete this section. It is expected that most (if not all) of the required information will be taken from the registration dossiers.

Section 2: Manufacture and uses. This section should include the results of the analysis of the production and use information in the various CSRs.

Section 3: Classification and labelling. Inclusion of the classification information may be useful in presenting a complete picture of the substance. Chapter 4.1 of this guidance may be useful, as will the CSA guidance (XXX).

Section 4: Environmental fate properties. For the evaluation of these properties, the CSA guidance (XXX) should be used. This section should be used to present the property values which are used in the calculation of the PEC values. It is expected that these will come mostly from the registration dossiers.

Section 5: Human health hazard assessment. This section presents the DNEL values for the substance, with supporting information as required. Some brief notes on this section are included in Chapter 5.2.2, but for the most part the CSA guidance (XXX) should be used.

Section 6: Human health hazard assessment of physicochemical properties. This is unlikely to be relevant for a restrictions dossier. If needed, the CSA guidance should be used.

Section 7: Environmental hazard assessment. This section presents the PNEC values to be used in the environmental risk assessment, with supporting information as required. Some brief notes on this section are included in Section 5.2.2, the CSA guidance (XXX) should be used for the most part.

Section 8: PBT and vPvB assessment. Inclusion of the conclusions of a PBT assessment may be useful in presenting a complete picture of the substance. It may be useful to read the guidance on preparing an Annex XV dossier for a Substance of Very High Concern, as well as the CSA guidance (XXX).

Section 9: Exposure assessment. This section presents the estimates of emissions to the environment, and the subsequent environmental exposures, and the estimate of exposure to workers, consumers and man via the environment. Guidance on this section is included in Chapter 5.2.3.

Section 10: Risk characterization. This section presents the results of the risk characterization. Guidance on this is included in Chapter 5.2.4.

Information on alternatives

The third part of the Annex XV report will provide an overview of the available information on alternative substances and techniques (as discussed in Chapter 5.5 of this guidance). This section will discuss:

Section 11: the information on the risks to human health and the environment related to the manufacture or use of alternatives;

Section 12: the availability of alternatives, including the time scale;

Section 13: their technical and economical feasibility of the alternatives.

Justification for restrictions at Community level

The fourth part of the Annex XV report contains a justification for community-wide action (which is discussed in Chapters 5.3 to 5.4.6 of this guidance). The format for this part of the report has two sections:

Section 14: Justification that action is required on a community wide basis i.e. the outcome of the analysis of the need for action on a Community-wide basis.

Section 15: Assessment of the proposed restriction against the three key criteria. This section of the report presents the assessment of the proposed restriction against the three key criteria of effectiveness, practicality and monitorability in comparison with the other RMOs that have been given consideration.

Socio-economic analysis

This part may be included in the report if an SEA has been undertaken by the Authority. The content and layout is discussed in more detail in the relevant SEA guidance (XXX).

Information on stakeholder consultation

The final part of the Annex XV report concerns any other information that is considered to be relevant to the dossier. These will include:

- List of stakeholders consulted;
- Overview of consultation (for example, details of any consultation which took place during the development of the dossier, including what methods for consultation were used, what comments (if any) where received and how these were dealt with); and
- Other information.

This section should not contain any new technical information. All technical information should be reported in the *Information on hazard and risk* in the Annex XV restrictions report.

APPENDIX III NON-EXHAUSTIVE LIST OF THE TYPES OF INFORMATION THAT MAY BE INFORMALLY REQUESTED AND COLLECTED FROM DIFFERENT TYPES OF STAKEHOLDERS

Stage in the restrictions procedure	**General types of consultees**				
	Authorities in other Member States and non-EU countries	**Trade associations and companies (manufacturers, importers and users)**	**Labour organisations**	**Consumer groups**	**Experts in academic and research community**
Information on the effectiveness of implemented RMMs and compliance with ELRs	• Scope for improvement of implemented RMMs • Information on past potential of enforcement of implemented RMMs • Scope for introducing national measures	• Scope for improvement of implemented RMMs	• Scope for improvement of implemented RMMs	• Scope for improvement of implemented RMMs	• Scope for improvement of implemented RMMs
Identification of RMOs	• Advice on past effectiveness of RMOs and implementation tools • Information on current state and structure of the relevant markets in their territory • Information on any previous risk management options considered and difficulties that were encountered during their implementation.	• Advice on past effectiveness of RMOs and implementation tools • Information on current state and structure of the relevant markets	• Advice on past effectiveness of RMOs and implementatio n tools	• Advice on past effectiveness of RMOs	• Advice on past effectiveness of RMOs

Stage in the restrictions procedure	General types of consultees				
	Authorities in other Member States and non-EU countries	**Trade associations and companies (manufacturers, importers and users)**	**Labour organisations**	**Consumer groups**	**Experts in academic and research community**
Assessment of RMOs against the three key criteria of effectiveness, practicality and monitorability as well as considerations on any derogations that may be required	• Information and past experience pertaining to the assessment of RMOs • Views on the practicality of RMOs (including implementation costs such as the costs of loss of uses of the substance/use of alternatives) • Information on the availability of enforcement mechanisms and monitoring networks • Information on criticality of uses • Information on current R&D in the sectors of concern	• Information and past experience pertaining to the assessment of RMOs • Views on the practicality of RMOs (including implementation costs such as the costs of loss of uses of the substance/use of alternatives) • Information on the availability of monitoring networks • Information on criticality of uses • Information on current R&D in the sectors of concern	• Information and past experience pertaining to the assessment of RMOs • Views on the practicality of RMOs (including implementation costs) • Information on the availability of monitoring networks • Information on criticality of uses	• Views on the practicality of RMOs (including implementation costs) • Information on the availability of monitoring networks • Information on criticality of uses	• Views practicality and monitoring issues • Information on criticality of uses • Cost of loss of uses of the substance/use of alternatives • Information on current R&D in the sectors of concern

APPENDIX IV EXAMPLES OF WORKFLOW AND ANTICIPATED WORKLOAD IN DIFFERENT CASES

The following paragraphs present examples of different substances and the anticipated workload for the preparation of an Annex XIV restrictions report.

Substance A: CSRs and information from substance evaluation give rise to concern

Substance identification:	Substance A; manufactured by three EU companies and imported by five others; each company manufactures/imports it in volumes over 1,000 t/y. Finds several uses.
REACH status:	Substance has been registered by all eight companies, all registration dossiers include a CSR.
Substance evaluation status:	On the basis of dossier evaluation and on grounds of the aggregated tonnage from the submitted registrations, the Agency placed Substance A on the Community rolling action plan for evaluation. The substance evaluation was subsequently completed by a Member State and the further information received clarified and confirmed concerns with regard to exposure from its use in two specific uses.
Trigger for the restrictions procedure:	The available information, including those resulting from substance evaluation, have highlighted the need for a Community-wide restriction. The identified risks are clearly defined and the assessment of the effectiveness of implemented RMMs show that the risk is currently not adequately managed.
Information on alternatives:	Five alternatives are known and already in use in the two uses of concern, although all five are not available in the required tonnages at present. For three, registration dossiers and CSRs are available and implemented RMMs in the uses of concern are documented.
SEA information:	No information on possible socio-economic implications from a possible restriction is available, however, the Authority considering a restriction believes that an SEA is not necessary.
Work completed before the start of the restrictions procedure	The following elements are thus available to the Authority: (a) trigger for considering a restrictions proposal; (b) definition of concern; (c) risk assessment; (d) assessment of effectiveness of implemented measures; (e) assessment of alternatives; and (f) establishing the need for a further risk management action on a Community-wide basis. The Authority has actually already established that a restriction is needed; SEA is not required.
Remaining work under the restrictions procedure and the envisaged workload	The following elements need to be completed by the Authority: (a) derogation issues; (b) preparation and documentation of the justification for the proposed restriction; and (c) compilation and submission of Annex XV dossier to the Agency. Part of the justification for a proposed restriction (the risk-related justification) is available. In this scenario it is expected that the identification of derogations required and the formulation of the justification for the

proposed restriction will be the most resource intensive processes. The workload will very much depend on the amount of consultation that is needed in order to formulate and justify the derogation/s required and the justification of the restriction.

Suggested timing of notification of restrictions procedure

At the discretion of the Authority. Most of the work for the restrictions proposal has already been undertaken.

Substance B: Further information from substance evaluation confirms concern

Substance identification:	Substance B; manufactured by several EU companies.
REACH status:	Substance has been registered by all manufacturers. All the dossiers include a CSR. Dossier evaluation has been completed, testing proposals have been approved and tests conducted and on the basis of test results CSRs have been updated with new ES and RMMs which allow for adequate control of the risks from the substance.
Trigger for the restrictions procedure:	Scientific research supported by monitoring data suggests that releases of Substance B may have been underestimated and the actual regional levels of the substance in the environment may pose unacceptable risks to the aquatic environment and to human health. The implemented RMMs and ELRs may not be sufficient to manage the risks.
Substance evaluation status:	In the light of the new information, a Member State notified the Agency and the Agency included Substance B on the Community rolling action plan and subsequently the Member State undertook its evaluation. The substance evaluation was completed and the further information received confirmed the concerns with regard to the regional concentrations of the substance.
Information on alternatives:	Information from registration dossiers and CSRs is available for a number of other substances of similar chemical structure. None of them are used in the applications of Substance B, although conditions of safe use and RMMs are observed in their individual uses. Current research suggests that Substance B could possibly be replaced in some of its uses with new technology, although this has not been tested on a large scale.
SEA information:	The relevant trade associations representing the manufacturers and users of Substance B have commissioned a study on the socio-economic impacts of different RMOs. The Authority has not decided on whether an SEA should be undertaken.
Work completed before the start of the restrictions procedure	The following elements are thus available to the Authority: (a) trigger for considering a restrictions proposal; (b) definition of concern; and (c) risk assessment.
Remaining work under the restrictions procedure	The following elements need to be completed by the Authority: (a) information on alternatives; (b) establishing the need for further risk management action on a Community-wide basis; (c) derogation issues; (d) preparation and documentation of justification for a proposed restriction; and (e) compilation and submission of Annex XV dossier to the Agency. Part of the justification for a restriction is available. Possibly an SEA (some material is available to the Authority).
Envisaged workload for each Stage	In this case the hazard assessment will be available before the Authority starts work on the restrictions proposal, and the substance evaluation will have provided sufficient evidence that the implemented

RMMs and ELRs are inadequate; therefore, the exposure assessment will practically be available and only the risk characterisation will need to be finalised in detail. The risk-related justification for risk management action and the justification for it to be addressed on a Community-wide basis will generally have been established in advance, however, for most other elements of the restrictions report, additional work will be required (especially on alternatives, derogations and SEA, if the Authority decides to undertake one).

Suggested timing of notification of restrictions procedure

The timing of notification is unclear and will depend on the progress of preparatory work on revising the exposure assessment and, possibly, assessing the availability and suitability of alternatives. If an SEA is to be undertaken, more time will be required for the preparation of the Annex XV restrictions dossier. It is suggested that the Authority at least establishes the need for a Community-wide restriction before formal notification of the restrictions procedure.

Substance C: Substance not subject to registration and evaluation

Substance identification:	Substance C; not manufactured or imported in the EU. Substances X, Y and Z are precursors to Substance C which forms a building block for their molecules.
REACH status:	Substance C is not subject to registration; Substances X and Y have been registered by all their manufacturers/importers and all registration dossiers include a CSR. Substance Z is subject to registration but not yet registered due to low volume.
Trigger for the restrictions procedure:	Substances X, Y and Z have been identified as being degraded following release to the environment to give rise to Substance C as a breakdown product. Information generated by reference to structurally related substances suggests that Substance C may be very toxic to the environment and to human health; monitoring results suggest that levels of the substance in the environment may be increasing.
Substance evaluation status:	In the light of the recent research and monitoring data, the two registered precursors were added to the Community rolling action plan and subsequently evaluated; a single Member State undertook both substance evaluations and requested from registrants information on the degradation of the substances under environmental conditions and the nature of the degradation products. The further information resulting from the substance evaluations confirmed the risks from Substance C and concluded that implemented RMMs and ELRs targeting the precursors cannot adequately manage the risks from the substance (although the existing measures can adequately control the risks from the precursors themselves).
Information on alternatives:	No information on alternatives to the precursors is available.
SEA information:	No detailed information is available; however, the uses of the precursors that give rise to Substance C appear to be of critical importance as they relate to the manufacture of special type fire fighting foams used in large-scale industrial fires.
Work completed before the start of the restrictions procedure	The following elements are thus available to the Authority: (a) trigger for considering a restrictions proposal; (b) definition of concern; and (c) an assessment of effectiveness of implemented measures.
Remaining work under the restrictions procedure	The majority of the elements of the restrictions procedure will need to be completed by the Authority, although part of the justification for a proposed restriction (the risk-based justification) is available.

Envisaged workload for each Stage	Substance C is a breakdown product of other substances and therefore no registration dossier for it exists. The preparation of an Annex XV restriction dossier will involve extensive work throughout the restrictions procedure. Information from the registration dossiers of the precursors and their evaluation and (Q)SARs could be used, however, a risk assessment of the substance will be necessary to assess the need for and the details of a restriction.
Suggested timing of notification of restrictions procedure	The timing of notification will depend on the progress of preparatory work. An SEA would appear to be an important tool in developing a justified and proportional restriction and if it is to be undertaken, more time will be required for the preparation of the Annex XV restrictions dossier. It is suggested that the Authority first establishes the need for a Community-wide restriction and then considers starting the assessment of alternatives as well as an SEA of possible RMOs before formal notification of the restrictions procedure.

Substance D: Amendment to an existing Annex XVII restriction

Substance identification:	Substance D; manufactured and imported by several EU companies, and has a range of uses.
REACH status:	Substance D has been registered by all manufacturers. All the dossiers include a CSR Three specific uses are already restricted under REACH; a further use has been granted an unconditional derogation.
Trigger for the restrictions procedure:	Enforcement and monitoring of other legislation has provided evidence that existing controls set at the Community level (emission limit values) cannot adequately manage the risk to the environment. The Authority has contacted Industry to request that exposure scenarios are reviewed and RMMs are updated to ensure adequate protection of the environment. The revised CSRs have been evaluated by the Agency and have been found to be inadequate.
Substance evaluation status:	Substance evaluation was completed before the original restrictions were introduced.
Information on alternatives:	The availability and suitability as well as the risks from alternatives are well known and were documented at the time of the original restrictions. Since then new techniques have been developed both for the restricted uses and those not subject to restrictions.
SEA information:	SEAs had been prepared by both the Authority and interested parties at the time of the original restrictions.
Work completed before the start of the restrictions procedure	The elements of the restrictions procedure were developed when the original restrictions were developed and proposed. Below, it is shown which elements would have to be reviewed in the 'new' restrictions procedure.
Remaining work under the restrictions procedure	Since the issues surrounding the use of Substance D are well known, the 'new' restrictions procedure will focus on specific elements such as: (a) preparation and documentation of justification for the proposed restriction; and (b) compilation and submission of Annex XV dossier to the Agency.
Envisaged workload for each Stage	The previous work on developing the original restrictions will provide a solid basis for the 'new' restrictions proposal. The exposure assessment and risk characterisation as amended by the registrants and evaluated in the compliance check by the Agency are likely to lend themselves to quick revision as will probably be the case with the assessment of the RMOs. SEA, if undertaken, could be the element that would require most work. The hazard assessment, risk-based justification for action on a Community-wide basis and the assessment of alternatives will largely be already available.
Suggested timing of notification of restrictions procedure	The timing of notification is unclear and will depend on the progress of preparatory work on revising the exposure assessment and, possibly, assessing the availability and suitability of alternatives. If an SEA is to be undertaken, more time will be required for the preparation of the Annex XV restrictions dossier. It is suggested that the Authority at

least establishes the need for a Community-wide restriction before formal notification of the restrictions procedure.

APPENDIX V EXAMPLES OF EXISTING COMMUNITY LEGISLATION UNDER WHICH SUBSTANCE-SPECIFIC CONDITIONS ARE SET

Instrument	Coverage	Conditions	Notes
Environment-Water			
Directive 96/61/EC Integrated Pollution Prevention and Control (IPPC) Directive	Industry branches listed in Annex 1, mainly large industry installations, for some branches production threshold	• Community emission limit values (not used so far); and • in plant by plant permits emission limit values or other conditions to control the risk for the environment.	• BREFs can be used to support the work of Member State competent authorities.
Directive 2000/60/EC Water Framework Directive (WFD)	Inland surface water, transitional waters, coastal waters and groundwaters	• Community EQS for substances listed in Annex X; • Community wide emission controls for point and diffuse sources of substances listed in Annex X; and • river basin measures to control point and diffuse source discharges liable to cause pollution. • Note however Article 61 (5) (c) (ii)	• Daughter directives for hazardous substances listed in Annex X and for groundwaters under development; and • Annex X will be reviewed regularly.
Directive 76/464/EEC Dangerous Substances Directive Note that this is repealed and replaced by Directive 2006/11/EC	Lists I & II of substances dangerous to the aquatic environment	• List I discharges must be authorised, such authorisation laying down emission standards for discharges to waters and, where necessary, to sewers. Competent authorities were required to draw up an inventory of the discharges; and • for List II, Member States must establish pollution reduction programmes including water quality objectives.	• To be integrated into WFD by 2013

Instrument	Coverage	Conditions	Notes
Environment-Air			
Directive 96/61/EC IPPC Directive	Industry branches listed in Annex 1, mainly large industry installations, for some branches production threshold	• Community emission limit values (not used so far); and • In plant by plant permits emission limit values or other conditions to control the risk for the environment. • Note however Article 61 (5) (c) (i)	• BREFs can be used to support the work of Member State competent authorities • Emission control principle
Directive 1999/13/EC Volatile Organic Compounds (VOC) Directive	Activities listed in Annex I; and solvent consumption thresholds in Annex IIA.	• Emission limit values (Annex IIA); and • fugitive emission values (% of solvent input) (Annex IIA).	• Emission limit values are for the sum of all VOCs used in the activity not for individual substances
Environment-Other			
Directive 2002/95/EC Restriction of Hazardous Substances (RoHS) Directive	Electrical and electronic equipment falling under categories set in Annex IA to Directive 2002/96/EC (Waste Electrical and Electronic Equipment)	• New equipment may not contain Pb, Hg, Cd, Cr(VI), PBB, PBDE; and • exempted applications listed in an Annex.	• Stakeholder consultation on proposals for additional exemptions ongoing
Directive 91/157/EEC, Directive 98/101/EC Note that with effect of 26/9/2008, this will be repealed and replaced by Directive 2006/66/EC	Batteries and accumulators	• Marketing of batteries and accumulators containing more than 0,00005 % of Hg prohibited (exemption: more than 2 % of Hg in button cells)	• The revision of the directives is under preparation

Instrument	Coverage	Conditions	Notes
Environment-Other			
Directive 86/278/EEC Sewage Sludge Directive	Protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture	• Limit values for concentrations of heavy metals in the soil (Annex IA), in sludge (Annex IB) and for the maximum annual quantities of heavy metals which may be introduced into the soil (Annex IC)	• At present, it applies to metals only.
Regulation 850/2004 Persistent Organic Pollutants	It implements the provisions of the Stockholm Convention.	• Dioxins, furans and PCBs are listed as unintentionally released POPs for which the releases should be continuously and cost-effectively reduced as soon as possible.	
Occupational health			
Dir 98/24/EC Chemical Agents at Work Directive	Hazardous chemical agents present at the workplace	• Community binding OELs (annex I); • binding biological limit values (annex II); and • prohibitions of the production, manufacture or use at work of (currently 4) substances listed in Annex III.	• Some indicative OEL values have been established for 63 substances by Directive 2000/39/EC
Directive 90/394/EEC, Directive 99/38/EC Carcinogens and Mutagens Directive	Exposure of workers to carcinogens and mutagens; and covers also substances unintentionally released by processes listed in Annex I.	• OELs in annex IIIA; and • possibility to set other related provisions in Annex IIIB (not used so far).	• Reduction and replacement of carcinogens and mutagens in so far as technically possible • Prevention and reduction of exposure to carcinogens and mutagens via use in closed systems in so far as technically possible

Instrument	Coverage	Conditions	Notes
Occupational health			
Directive 92/85/EEC Pregnant Workers Directive	Exposure of pregnant workers and workers who have recently given birth or are breastfeeding; and covers carcinogenic substances and mutagenic substances.	• Employer to assess the nature, degree and duration of exposure for Annex I substances; and • exposure to agents listed in Annex II to be prohibited.	
Directive 94/33/EC Protection of Young Workers at the Workplace Directive	Harmful exposure to the physical, biological and chemical agents referred to in point I of the Annex	• Article 7 (2) prohibits the employment of young people for work involving harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health	
Consumers			
Directive 98/83/EC Drinking Water Directive	Water intended for human consumption	• Minimum limit values for substances listed in Annex 1 part B	
Directive 88/378/EEC Toys Directive	Toys as defined in Article 1	• Limit values for bioavailability of metals resulting from the use of toys	• Use of certain substances in toys restricted by Directive 76/769/EEC

Instrument	Coverage	Conditions	Notes
Consumers			
Directive 89/197/EEC Food Additives Directive	Additives to be used in foodstuffs	• Positive list of substances (only these to be used in foodstuffs and only certain conditions specified therein)	
Regulation 726/2004/EC Medicinal Products	Safety, quality and efficacy of medicinal products for humans and domestic animals; and medicinal products listed in Annex and medicinal products fulfilling requirements set in article 3.2 and 3.3 and the applicant requests a marketing authorisation at Community level.	• Marketing authorisation of medicinal products for human and veterinary use in the centralised procedure at Community level; • only authorised medicinal products may be placed on the market (authorisation at Community or national level); • the authorisation may include conditions or restrictions; and • an application has to include evaluation of the potential environmental risk and specific arrangements to limit the risk need to be envisaged.	• Directive 2001/83/EC (as last amended by Directive 2004/27EC) and Directive 2001/82/EC (as last amended by 2004/28/EC) cover marketing authorisations for medicinal products for human and veterinary use outside the Centrally authorisation procedure (Community authorisations)
Regulation 648/2004/EC Regulation on Detergents	Detergents and surfactants to be used in detergents	• Lays down requirements on degradability of surfactants to be used in detergents	
Framework Regulation 1935/2004 and all the legal instruments deriving from this, such as Council Directive 78/142/EC on Vinyl chloride Food contact materials	Sets up general requirements for all food contact materials.	• The different legal instruments that have been produced under this Framework Regulation regulate migration levels and contents of different substances in food contact materials	• Follow this link for further details: • http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm
Directive 2004/42/EC VOC Paints Directive	The use of organic solvents in certain paints and varnishes and vehicle refinishing products	• For the paints, the Directive sets up two sets of limit values for the maximum contents of VOCs in g/litre of the product ready for use. • For vehicle refinishing products there is only one set of limit values for the VOC contents. • It also lays down special labelling provisions.	

APPENDIX VI CONSIDERATIONS ON THE ASSESSMENT OF RISKS FROM ALTERNATIVE SUBSTANCES

Aspects Related to Risk Assessment

In order to be able to compare the risks arising from the alternatives available one needs to take a flexible approach towards the assessment of such alternatives. Ideally the assessment should address all possible risks throughout the entire lifecycle of the alternatives, including all relevant compartments and populations, even those not originally associated with the identified risk. The reason for this is that, while an alternative may reduce the specific identified risks, it may pose other risks at different points in its lifecycle or may shift the risks to other compartments/populations when it replaces the substance of concern. In other cases, the use of alternatives may have secondary adverse effects that may not be immediately recognisable, for example, an increase in the production of hazardous waste at the end of the lifecycle or increased energy consumption.

The assessment of alternatives should be based primarily on risk rather than hazard. However, risk-based replacement of the original substance or process may not always be simple or indeed feasible. The tiered approach explained below, starts from a comparison of the hazardous properties, and ultimately ends into a full assessment of the risk arising from the alternatives, each tier increasing the level of complexity and data required. The complexity of the assessment required is highly dependent on the properties of the alternative substances or techniques, in the sense that if for example a clearly less hazardous substance is available then a comparison of the hazardous properties would be enough, or in the case where an alternative technique results in the elimination of emissions of the substance of concern then a description of the emission characterisation would be suitable, nevertheless care should be taken to assess other possible secondary effects of the alternative, such as a possible increases in the production of hazardous waste or increased energy consumption. It may be the case that the substance of concern would have to be replaced not by a single substance but rather a combination of substances or a complete reformulation of products containing the substance or even by alternative substances used within alternative processes. In such cases, the combined effects of such changes may be difficult to predict and assess; therefore, the analysis may at least include an assessment of the potential effects of each alternative used in isolation and some discussion of the envisaged implications of combined effects may be provided.

The comparison of different hazards and their magnitudes, sometimes will also require value judgments about the acceptability of different risks to different endpoints. Simultaneously ranking health, safety and environmental risk may require the Authority to be involved in trade-offs which are not always straightforward. New risks may be difficult to compare to the original risks because they may be of a radically different nature. For example, a chemical substance of low toxicity could have an adverse effect on the earth's ozone layer. Alternatives may be more benign with regard to such effects but they could be, for instance, flammable, toxic or may pose other hazards to the environment. In this case, the Authority should assess the relative importance, gravity, imminence and implications of the different types of risk and decide whether the risks introduced by the alternatives are acceptable and why.

The time and resources available to the Authority to prepare and submit the restriction dossier is limited and this will have an influence in setting the boundaries of the risk assessment of the alternatives.

The assessment of the hazards and risks of alternatives

The depth of the risk assessment of alternatives should be decided on a case-by-case basis. The process of assessing the hazards and risks will be different when considering alternative processes and alternative techniques.

For alternative substances, a tiered approach may be appropriate. Such an approach may include the following levels of increasing complexity:

- *Tier 1*: **comparison of the hazards of the alternative substance to those of the substance of concern**.

  Part A: Collection of hazard information for the alternatives. Where registration dossiers and other REACH-related information (Articles 31 and 32) are available, these should be reviewed by the Authority. If such sources are not available, other sources should be consulted. Where vital information is missing, consideration may be given to generating this, for example, by use of (Q)SARs. Uncertainty on the validity of such results should be acknowledged and documented in the restriction proposal;

  Part B: Comparison of the hazard information of alternatives to that of the substance of concern. This assessment should be used as a screening process to rank alternatives based on their hazard profile in order to help on whether to consider such alternatives as suitable. This comparison should first look at those hazard properties of highest concern such as PBT/vPvB, and CMR characteristics. If both the substance and the alternative substances have similar properties of concern or when all potential alternatives have PBT/vPvB/CMR properties, the Authority should take into consideration information on the potential exposure and any evidence of possibilities to better control the exposure. The same principles apply when comparing less severe hazard properties. If the alternatives have been registered and have been assessed for risks, PNEC and DNEL values for them will be available and these may be compared to those for the substance of concern. Also, the collection and comparison of [information on?] physico-chemical properties of the alternatives may be pursued if it is of particular relevance to the identified risks or when there is an obvious concern about the alternatives.

- *Tier 2*: Revision of risk assessment for the substance of concern when partly replaced by an alternative substance. The Authority will need to establish how the use and releases of the substance of concern may be affected by the use of an alternative substance before the revision can be undertaken.

- *Tier 3*: This would involve the use of information on the alternative substance (properties and hazards) within the Chemical Safety Assesssment for the substance of concern to perform a quick revised exposure assessment and risk characterisation for the alternative for the applications associated with the identified risk; There may be three possible situations of increasing complexity:
  - If the exposure assessment for the substance of concern shows that the release estimates do not depend on the substance properties, then the existing emission estimates for the original substance may be used.
    - When the alternative has similar physico-chemical and environmental fate properties to the original, it may be sufficient to use the existing PEC values for the comparison of the PNEC or DNEL values of the substance of concern and the alternative; or

        - when the alternative does not have similar physico-chemical and environmental fate properties to the original, the emission estimates may be used in conjunction with environmental fate data on the alternative to calculate its PEC values. These should then be used to revise the risk characterisation.
    - If the emission estimates in the chemical safety assessment depend on the substance properties, it may be possible to estimate whether the alternative would have lower or higher emissions than the original substance by simple consideration of the properties. However, it is possible that emissions to one compartment may increase while those to another decrease, and it will be difficult to make a simple judgement on how this would affect the PECs (for regional concentrations at least). In such cases, it may be necessary to estimate the emissions of the alternative substance and then carry out similar calculations as those for the substance of concern to generate PEC values. It may also be necessary to consider the effect of replacing the substance with the alternative in terms of the tonnage of the alternative that would be required. For example, the registration dossier for the alternative will be based on the current tonnage and uses and is unlikely to consider an increase in use or a new use as a result of replacement.

- *Tier 4*: As in Tier 3, plus assessment of risks from manufacture of the alternative substance. If the alternative substance has been registered and the registration dossiers already include an exposure assessment for its manufacture, this can be used in the preparation of the restriction proposal. If such exposure assessment is not available, then the Authority may consider developing a quick targeted exposure assessment for the manufacture of the alternative.

- *Tier 5*: use of exposure scenarios specific to the alternative substance (rather than those for the substance of concern) to perform an assessment of risks for the alternative for the applications of concern across all compartments/populations at risk. This will effectively be similar to Tier 3 only that the Exposure Scenarios will be specific to the alternative substance for the applications associated with the identified risk. If the alternative substance has been registered and the registration dossiers already include an exposure assessment for the applications of concern, this can be used for the purposes of the restriction proposal. If a new exposure assessment is required, the guidance for the CSA should be followed, with any relevant parts from this guidance document.

- *Tier 6*: as for Tier 5, plus assessment of secondary effects from manufacture and use (for instance, waste generation, energy consumption, etc.). This may be undertaken only when the relevant information is readily available.

Performing tiers 1 to 6 would in most cases entail a significant volume of work and may only be pursued if the necessary information is already available i.e. a full safety assessment of the alternative substance has already been undertaken separately. The Authority should start from Tier 1 and work to a more detailed assessment taking into account any information, time and resource limitations and keeping the level of detail proportional to the characteristics and magnitude of risk.

The ultimate aim of the assessment of alternatives is to indicate that alternative substances or techniques that lead to lower exposures or risks are available for given uses and therefore the information needed to arrive to such a conclusion should be reported in the dossier. This should be carried out by completing *Section 2* of the *Information on alternatives*. As the

amount of information to be included will vary on a case-by-case basis, a detailed format has not been developed for this section. Where the information to be presented is extensive, the Authority may find it useful to present it using the relevant parts of the format for the *Information on hazard and risk* part. This may be particularly useful where exposure and risk calculations have been performed. Depending on the extent of the information, a separate annex may be useful.

Example

Four enterprises within the EU manufacture Substance L with a total of six production installations. Substance L is used in a variety of uses including polycarbonate production, epoxy resin production, phenoplast resins, unsaturated polyester resin production, can coating manufacture, PVC production and processing, thermal paper manufacture and others. The risk assessment has suggested that there is a need for limiting the risk in relation to the aquatic and sediment compartments for phenoplast resin production.

The Authority has consulted widely with the EU paper industry and has undertaken literature searches to identify possible alternative substances and techniques. While no suitable alternative techniques for paper recycling have been identified, a total of five have been suggested as replacements for Substance L. The available information for all five of them, however, was very limited compared to that for Substance L. This was due to the fact that these five substances were not registered yet as they were not manufacture/imported in the same tonnages as Substance L. As a result, a number of working assumptions had to be made for the assessment of risk to the environment. The following approach was adopted:

- A review of the properties of each substitute in order to provide an initial PBT/vPvB assessment and comparison with Substance L was carried out;
- The EUSES model was then used to replicate the revised results of the analysis of Substance L undertaken in the risk assessment;
- This enabled the emissions to the environment at continental, regional and local levels to be ‘back-calculated’;
- The EUSES model was then re-run with the same emission quantities (i.e. kg/year) but replacing the key properties for Substance L with values relevant to each substitute in turn; and
- PNEC values for the alternatives have been derived from effects data collected through consultation and literature review.

The findings of this analysis suggest that not all potential alternatives were suitable for replacing Substance L. Alternative substances 1, 4 and 5 generally appear not to pose unacceptable risk to the environment; however, alternative substances 1 and 4 are possible PBT or vPvB substances. Overall, it can be concluded that suitable alternatives for Substance L exist and this should be reflected in the Annex XV restriction report.

Overview of alternatives for Substance L

Parameter	Sub L	Alt 1	Alt 2	Alt 3	Alt 4	Alt 5
vPvB?	No	Possibly	Unlikely	Possibly	Unlikely	Unlikely
PBT?	No	Possibly	Unlikely	Possibly	Possibly	Unlikely
PNEC (aquatic)	1.6 µg/l	16 µg/l	0.42 µg/l	30 µg/l	30 µg/l	100 µg/l
Assessment factor	1,000	10	1,000	1,000	1,000	1,000
Phenoplast resin production						
RCR - aquatic	>1	0.05	**67**	**1.7**	<0.01	<0.01
RCR - sediment	>1	0.56	**760**	**19**	0.06	0.02
RCR - STP	<1	No data	0.06	0.57	0.35	0.35

Note: RCR stands for Risk Characterisation Ratio (= PEC/PNEC)