



Draft Stage 1 Alternatives Analysis Guide

DEPARTMENT OF TOXIC SUBSTANCES CONTROL
SAFER PRODUCTS AND WORKPLACES PROGRAM
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Discussion Draft



Important Note

This Guide is not a standard or regulation and it creates no new legal obligation. The Guide is advisory in nature, informational in content, and intended to assist responsible entities who are conducting Alternatives Analysis. This Guide does not alter or determine compliance responsibilities set forth in statutory and regulatory requirements.

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Glossary

Cost Benefit Analysis: Comparison of the net present value by assigning monetary values to benefits and costs. Alternatives with a positive net present value are preferred.

Department: The Department of Toxic Substances Control.

Environmental Releases: An intentional or unintentional emission or discharge of a chemical into the environment.

Exposure Assessment: The process of measuring or estimating the dose or concentration of a substance to which humans and the environment are or may be exposed to, depending on the uses of the substance.

Exposure Factor: Associated with potential relevant factors used to compare a Priority Product with alternatives. May include market presence of the product; the occurrence, or potential occurrence, of exposures to the Candidate Chemical(s) in the product; the household and workplace presence of the product and other products containing the same Candidate Chemical(s) that form the basis for considering the listing of the product-chemical combination as a Priority Product; and potential exposures to the Candidate Chemical(s) in the product during the product's life cycle.

Exposure Pathways: Associated with potential relevant factors to compare the Priority Product with the alternatives. It includes chemical quantity information and the exposure factors.

Functional Unit: Quantified performance of a product system for use as a reference unit for comparison.

Hazard Assessment: Evaluation of a chemical or product based on its hazard traits.

Hazard Traits: Properties of chemicals that fall into the following broad categories of toxicological, environmental, exposure potential, and physical hazard that may contribute to adverse effects in exposed humans, domesticated animals, wildlife, or in ecological communities, populations or ecosystems.

Heat Map Method: Classification system using several scales of colors and signs for the initial screening (i.e., to identify hotspots) of a life cycle assessment.

Life Cycle: The sum of all activities in the course of a consumer product's entire life span, including raw materials extraction, resource inputs and other resource consumption, intermediate material processes, manufacturing, packaging, transportation, distribution, use, operation and maintenance, waste generation and management, reuse and recycling, and end-of-life disposal.

Life Cycle Assessment: Compilation and evaluation of the inputs, outputs and potential environmental impacts of a product system throughout its life cycle.

Life Cycle Cost Accounting (LCCA): Process for evaluating the total cost linked to the purchase, operation, and disposal of a product over its entire life cycle including external costs.

Life Cycle Inventory (LCI): Compiled and quantified inputs and outputs for a product throughout its life cycle.

Life Cycle Segments: Stages or phases of a product's life cycle, including: raw material extraction, resource inputs and other resource consumption, intermediate materials production processes, product manufacture, packaging, transportation, use, operation and maintenance, waste generation and management, reuse and recycling, and end-of-life disposal.

Life Cycle Thinking: A decision-support approach that goes beyond the traditional focus on one life cycle segment towards a more coherent production and consumption strategy that aims at taking into account all of the impacts (environmental, economic and technical) of a product throughout its life cycle.

Monte Carlo Analysis: A technique that allows assessment of the consequences of simultaneous uncertainty about key inputs, taking account of correlations between these inputs.

Multi-Criteria Decision Analysis (MCDA): A technique that involves assigning weights to criteria, and then scoring options in terms of how well they perform against those weighted criteria. Weighted scores are then summed to rank options, and can be used to support decision-making process.

Peer Review: A documented critical review of a scientific or technical work product conducted by scientific experts who are independent of those who performed the work. Peer review can provide an independent evaluation of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to the scientific or technical work product.

Performance: Performance is a measure of how well a product carries out its functions. Manufacturers and users set performance requirements either qualitatively or quantitatively.

Properties: Properties of chemicals that can inform chemical evaluation include but are not limited to: physical state, molecular weight, density, vapor pressure and saturated vapor pressure, melting point, boiling point, water solubility, lipid solubility, octanol-water partition coefficient, octanol-air partition coefficient, organic carbon-partition coefficient, diffusivity in air and water, Henry's Law constant, sorption coefficient for soil and sediment, redox potential, photolysis rates, hydrolysis rates, dissociation constants, or reactivity including electrophilicity.

Product Requirements: The functional, performance, and legal requirements of a product.

(Quantitative) Structure-Activity Relationship Models: Usually referred as (Q)SARs, including both SARs and QSARS, are theoretical models that can be used to predict in a qualitative or quantitative

manner the physicochemical, biological (e.g., toxicological), and environmental fate properties of chemicals from a knowledge of their chemical structure. A SAR is a qualitative relationship that relates a structure to the presence or absence of a property or activity of interest. A QSAR is a mathematical model (often a statistical correlation) relating one or more quantitative parameters derived from chemical structure to a quantitative measure of a property or activity (e.g., a toxicological endpoint). QSARs are quantitative models yielding a continuous or categorical result.

Read-Across: A technique to predict endpoint information (e.g., physicochemical properties, toxicity, environmental fate, and ecotoxicity) for one chemical with data from the same endpoint of another similar chemical (usually on the basis of structural similarity or on the basis of the same mode or mechanisms of action). It may be performed in a qualitative or quantitative manner.

Regrettable Substitutions: Alternatives that have similar or worse adverse public health impacts, adverse environmental impacts, adverse waste or end-of-life effects, or greater materials or resource consumption impacts than the original in the product throughout its life cycle.

Risk Assessment: A procedure to characterize the nature and magnitude of risks to humans (e.g., residents, workers, recreational visitors) and ecological receptors (e.g., birds, fish, wildlife) from chemicals that may be present in the environment. In general terms, the risk depends on the following factors: how much of a chemical is present in an environmental medium; how much exposure a person or ecological receptor has with the contaminated environmental medium; and the inherent toxicity of the chemical.

Scenario Analysis: A “what-if” type of analysis to determine the sensitivity of the outcomes of an analysis to changes in scenarios (i.e., combinations of parameters). Scenario analysis may be thought of as performing multiple sensitivity analyses at the same time.

Sensitivity Analysis: A “what-if” type of analysis to determine the sensitivity of the outcomes of an analysis to changes in parameters. If a small change in a parameter results in relatively large changes in the outcomes, the outcomes are said to be sensitive to that parameter.

Social Costs: Denotes the opportunity cost to society and includes also external costs or externalities.

Social/Socio-economic Life Cycle Assessment (S-LCA): A social impact (and potential impact) assessment technique that aims to assess the social and socio-economic aspects of products and their potential positive and negative impacts along their entire life cycle.

Socio-economic Analysis (SEA): A tool to evaluate what costs and benefits an alternative will create for society by comparing what will happen if this alternative is implemented as compared to the situation where the alternative is not implemented.

Total Cost Assessment (TCA) Methodology: The consideration of all the environmental and health (E&H) costs associated with a decision, including direct costs, Indirect costs, future and contingent liability cost, intangible internal costs, and external costs.

Transparency: Open, comprehensive and understandable presentation of information.

Uncertainty Analysis: A systematic procedure to evaluate the uncertainty introduced due to the AA process due to a broad range of factors including a lack of information, scientific knowledge, imprecision of model, etc. Uncertainty is a characteristic of all predictive analysis. Uncertainty can have a significant effect on type and amount of information that are collected to support decision and should be taken into account in communicating the outcome.

Discussion Draft

Introduction

California's Safer Consumer Products (SCP) program challenges product designers and manufacturers to reduce or eliminate toxic chemicals in the products consumers buy and use. The SCP regulations establish innovative approaches both for the Department of Toxic Substances Control (Department) to identify Priority Products containing chemicals of concern, and for responsible entities to identify, evaluate, and adopt better alternatives. The SCP approach requires an alternatives analysis that considers important impacts throughout the product's life cycle and follows up with specific actions to make the product safer. The Department prepared this guidance document to help responsible entities to conduct the alternatives analysis and meet the regulatory requirements.

Background

When toxic chemicals contained in products present potential harm to consumers or the environment, manufacturers or regulatory agencies typically address them on an individual, case-by-case basis, often providing different formulations, and occasionally banning the use of a particular chemical in certain types of products. But the result of a quick replacement approach may not be preventative or protective. A hastily substituted alternative is not always completely evaluated and can cause regrettable substitutions. A comprehensive alternatives analysis with a broad scope will consider a wide variety of effects and avoid shifting the problem from one phase of the life-cycle to another, from one region to another, or from one environmental impact to another.

The Department's 2008 California Green Chemistry Initiative outlined policy goals that expand the focus of impact evaluation to include additional stages like product design, product manufacturing, and the product's

Regrettable Substitution – In 2006 the California legislature enacted a law to limit the concentration of lead in children's jewelry, due to its neurotoxic effect on children. When manufacturers substituted cadmium, a known carcinogen, to provide density in jewelry, the legislature enacted changes to limit cadmium, effective January 1, 2012.

end-of-life management. By considering effects from a life cycle perspective, manufacturers can create products that are benign by design and that avoid unintended consequences from the outset.

The Department affirmed this shift in focus when it adopted SCP regulations that require manufacturers to evaluate product ingredients systematically and to answer two fundamental questions:

- Is this ingredient necessary?
- Is there a safer alternative?

To address the second question, the regulations present a framework and steps for the alternatives analysis¹ (AA) process to evaluate potential alternatives.

Application of the Guide

The purpose of this guidance document (Guide) is to provide useful approaches, methods, resources, tools, and examples to help responsible entities fulfill the regulatory requirements for the AA. The regulations provide the process for conducting the AA and are enforceable; the Guide helps people to understand the process by describing the steps of the AA process and describing how they fit together to achieve the regulatory goals. The Guide also relates the steps in the AA process to other types of alternatives assessments, describing both common and dissimilar elements when applicable.

Because the SCP program emphasizes life cycle thinking, it expands the categories of factors that manufacturers should consider when developing, making, and evaluating products. These expanded factors include moving beyond traditional product performance and price considerations toward a more comprehensive cost and effectiveness evaluation that includes health, safety, and environmental considerations throughout a product's life cycle. Applying life cycle thinking can help identify opportunities and lead to innovative solutions that help improve environmental performance, societal image, and economic benefits.

The Guide provides a variety of resources, descriptions of the framework in the regulations, and examples of approaches a responsible entity could use to evaluate the effects associated with a Priority Product or an alternative. In particular, the Guide provides information about:

- The two stages of the AA process.
- Approaches for conducting AA steps.
- Tools and methods that may be useful for specific steps in the analysis.
- Approaches for identifying and collecting needed data.
- Examples to illustrate steps in the analysis.
- Administrative requirements, including reporting requirements.

Information in the Guide describes the general process for conducting an AA and applies to a wide range of conditions, products, alternatives, and impacts. The Department designed the Guide to meet the needs of a wide range of responsible entities and to apply to a diverse set of product types. It is a resource not only for AA analysts, preparers, practitioners, and responsible entities, but also for the Department when it evaluates submitted AA Reports and supporting documentation. As information about products, chemicals, alternatives, and available data expands over time, future updates of the Guide are likely to highlight more specific details.

¹ In the Safer Consumer Product regulations, the term “alternatives analysis” intentionally differentiates this effort from the practice of “alternatives assessment” which may only entail a chemical hazard evaluation and comparison or may include a breadth of considerations but not be as comprehensive as the analysis required by the regulations.

The Guide IS:	The Guide IS NOT:	Comment:
Guidance	Regulations	This guidance is an advisory resource. It is not a regulatory document or legal standard, either for conducting an AA or for reporting AA results. The regulations provide a comprehensive description of the requirements and the Guide provides a detailed discussion of individual steps. The appendices provide lists of tools, methods, approaches, and a variety of useful resources.
Dynamic	Static	The Department will periodically update the Guide to address tools, methods, resources, and approaches regarding AA. The Department will also continue working on AA through projects and in a collaborative manner with those conducting AA's.
Multi-purpose for multiple audiences	Meant to be used solely as a step-by-step guide	This guidance is a comprehensive, multi-purpose resource and it is intended to be useful for many audiences. It includes details on a variety of subjects related to the AA process described in the regulations. Chapters are organized topically and roughly follow the steps outlined in the regulations.
A menu of options	A checklist	Since this document is intended for broad use, it is not specific to a particular geographic location, company size, or product type. Therefore, not all of the content may be applicable to all users. Readers should view the guide as a menu of options to use only if relevant, rather than a checklist of required actions.

Before conducting an AA, practitioners should review the applicable laws and understand the requirements of the SCP regulations. This Guide does not explicitly state how to meet the requirements, nor does it provide a single, specific approach for conducting an AA or its steps. The responsible entity will decide which approaches, assumptions, tools, methodologies, data, and decision frameworks will best suit its particular situation. A credible third party may help responsible entities perform or review all or part of the analysis.

When performing an AA, a responsible entity must ensure that the elements of the analysis are consistent with the regulatory requirements, scientifically robust, and complete. An AA must be technically sound and include reliable data sources, appropriate assumptions, and well-documented decision-making methods. To demonstrate the scientific validity of the AA, the responsible entity must document data quality, assumptions,

and decision methods in their AA Reports. To produce consistent, robust, and reproducible AA studies, analysts should adhere to the following overarching tenets while conducting an AA:

Completeness – Read, understand, and comply with all regulatory requirements of the AA process.

Applicability – All methods used and data collected for the AA should be appropriate and sufficient for the product, chemicals, and processes involved. The responsible entity should disclose all relevant information used for its evaluations and decision-making, and the information needed for the Department and stakeholders to assess the robustness and reliability of the analysis and conclusions.

Consistency – Observe strict conformity within all steps of the AA to support internal consistency and comparability with similar analyses.

Accuracy – Use an iterative approach to reduce uncertainties in all calculations, data management, and models used in the AA and in reporting of results. Revisit assumptions.

In addition to these tenets for conducting SCP AAs, other practitioners have developed more general guiding principles for alternatives assessment. For example, in October 2012 a group of 26 environmental health scientists, advocates, funders, and policy makers met to discuss building a chemical commons approach to collaborate and share information about the practice of alternatives assessment. This group developed a definition and set of principles for chemicals alternatives assessment. These [Commons Principles for Alternatives Assessment](#), depicted below, are designed to guide a process for well informed decision making that supports the successful phase-out of hazardous products, phase-in of safer substitutions, and elimination of hazardous chemicals where possible. Because the commons principles complement our tenets and are consistent with the goals for the AAs in the SCP regulations, responsible entities may find these guiding principles helpful as they conduct an AA.

The Commons Principles for Alternatives Assessment:

REDUCE HAZARD Reduce hazard by replacing a chemical of concern with a less hazardous alternative.

This approach provides an effective means to reduce risk associated with a product or process if the potential for exposure remains the same or lower. Consider reformulation to avoid use of the chemical of concern altogether.

MINIMIZE EXPOSURE Assess use patterns and exposure pathways to limit exposure to alternatives that may also present risks.

USE BEST AVAILABLE INFORMATION Obtain access to and use information that assists in distinguishing between possible choices. Before selecting preferred options, characterize the product and process sufficiently to avoid choosing alternatives that may result in unintended adverse consequences.

REQUIRE DISCLOSURE AND TRANSPARENCY Require disclosure across the supply chain regarding key chemical and technical information. Engage stakeholders throughout the assessment process to promote transparency in regard to alternatives assessment methodologies employed, data used to characterize alternatives, assumptions made and decision making rules applied.

RESOLVE TRADE-OFFS Use information about the product's life cycle to better understand potential benefits, impacts, and mitigation options associated with different alternatives. When substitution options do not provide a clearly preferable solution, consider organizational goals and values to determine appropriate weighting of decision criteria and identify acceptable trade-offs.

TAKE ACTION Take action to eliminate or substitute potentially hazardous chemicals. Choose safer alternatives that are commercially available, technically and economically feasible, and satisfy the performance requirements of the process/product. Collaborate with supply chain partners to drive innovation in the development and adoption of safer substitutes. Review new information to ensure that the option selected remains a safer choice.

Guide Chapter Summary

The Guide begins with descriptions of the AA framework that highlight administrative requirements and specific steps in the approach that frame and scope the work of the analysis. The following chapters address particular technical aspects of the analysis. In addition, the guide includes appendices detailing specific

methods, tools, and resources cited and described in the chapters. The following list includes a brief summary of each of the Guide chapters.

- Chapter 1 AA Framework.** This chapter focuses on the AA framework and steps presented in the SCP regulations. It emphasizes the two-stage AA approach and describes the iterative nature of the analysis.
- Chapter 2 Product Requirements and Alternatives.** This chapter discusses methods for determining the functional, performance, and legal requirements of the product when identifying potential alternatives.
- Chapter 3 Relevant Factors.** This chapter explains the concept of relevant factors and describes how to identify and use the relevant factors in the analysis.
- Chapter 4 Impact Assessment.** This chapter describes methods and approaches for collecting information about the health, safety, and environmental impacts for the analysis.
- Chapter 5 Screening Alternatives.** This chapter presents approaches a responsible entity may use to narrow the list of alternatives that will be thoroughly evaluated in the second phase of the AA.
- Chapter 6 Exposure Assessment.** This chapter describes methods and approaches for collecting information about exposure estimates, exposure-related data sources, and models.
- Chapter 7 Life Cycle Impact Assessment.** This chapter describes methods and approaches for collecting information about life cycle impacts, including description of certain life cycle impacts databases and tools.
- Chapter 8 Economic Analysis.** This chapter describes the economic analysis needed for the second phase of the AA and methods for collecting and evaluating the needed economic information.
- Chapter 9 Information Needs and Transparency.** This chapter presents a structured way to collect data and address data gaps. It also describes quality aspects of the information and the importance of transparency in the AA Reports.
- Chapter 10 Alternatives Comparison.** This chapter describes ways to present the findings of the analysis and approaches for evaluating and comparing the product and its alternatives to make a final selection decision.
- Chapter 11 Review and Evaluation of AA Reports.** This chapter presents a selection of indicators the responsible entity may use to assess the merit of the information and findings in the AA. It also presents a general evaluation approach the responsible entity, and the Department, may use to check compliance with the substantive and administrative requirements for the AA.

Chapter 1 – AA Framework

This chapter presents the AA framework outlined in Article 5 of the SCP regulations.² It describes the steps in the AA process and some of the compliance options available to the responsible entity, both when conducting an AA, and when preparing the corresponding AA Reports. Figure 1-1 illustrates the regulatory AA process. Activities in blue are the responsibility of the Department, and responsible entities perform the activities depicted in orange.

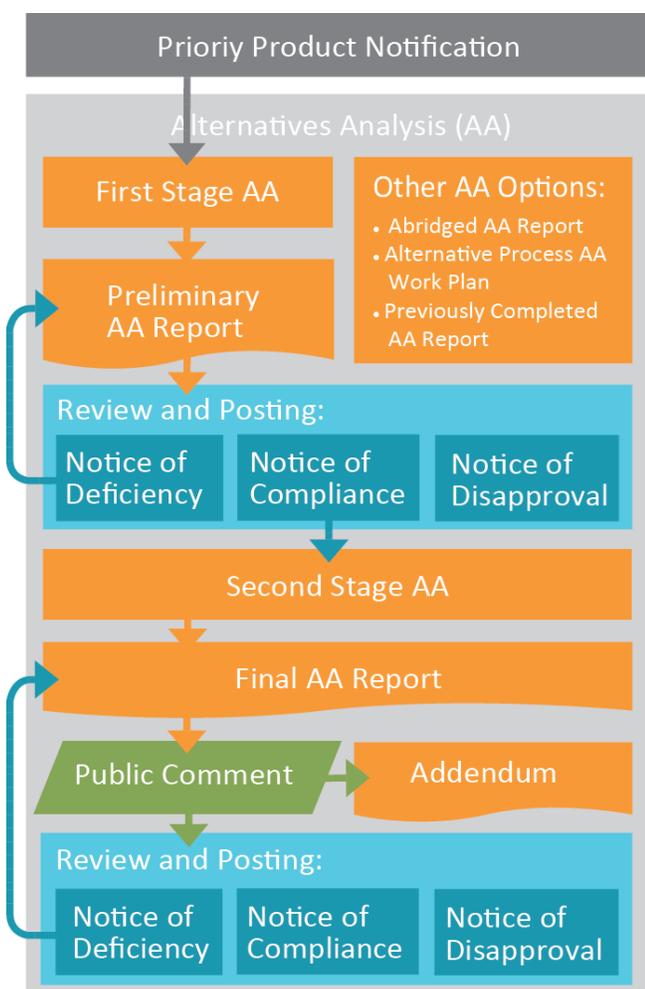


Figure 1-1: AA Process in SCP Regulations

A responsible entity is any business that manufactures, imports, distributes, sells, or assembles consumer products listed as Priority Products that are placed into the stream of commerce in California. (CCR section 69501.1(a)(60))

AA Planning

Before undertaking an AA, the responsible entity should undertake an initial planning step to identify and coordinate the resources and expertise needed, and obtain management support. AA involves many facets of facility operations including process engineering, environmental management, financial analysis, and research and development. The responsible entity may already employ individuals with the needed skills, experience, and knowledge to conduct the AA, such as employees able to provide and evaluate process data, toxicological studies, engineering and design, project management, technical feasibility, and economic analyses. A responsible entity may also decide to hire technical

² Article 5 of Chapter 55 of the California Code of Regulations (CCR), beginning with section 69505.

consultants to supplement in-house expertise.³

AA Framework

Although the AA framework specifies the particular elements that the responsible entity must include in the analysis and reports, the methods, approaches, and actions for completing those elements remain flexible. In addition, while the AA provisions do not limit, restrict, or require the responsible entity to undertake the AA steps in the sequence presented in the regulations, the AA Reports must include all of the specified, required elements.

To help responsible entities develop an appropriate scope for the analysis, the regulations break the analysis down into a two-stage process. The first stage of the AA establishes the boundaries of the analysis; the second stage completes the analysis.

During the first stage the responsible entity identifies the goal, scope, legal, functional, and performance requirements of the Priority Product and the Chemical of Concern, and uses this information to identify an array of alternatives to consider. The responsible entity also gathers information about relevant factors to compare the alternatives to the Priority Product, and may eliminate, or screen out, those alternatives that have greater adverse impacts or do not meet the legal, functional, or performance requirements of the Priority Product. When the first stage is completed, the responsible entity documents the analysis findings in a Preliminary AA Report and submits that report to the Department. The report also includes a work plan and proposed implementation schedule for completing the second stage of the AA and the Final AA Report. The following table outlines the steps in the first stage AA.

When establishing an AA team, consider the following skills and fields of expertise:

- chemistry
- toxicology
- environmental fate & transport
- environmental and occupational health & safety
- process engineering
- life cycle thinking
- project life cycle management
- environmental economics
- financial analysis
- public health
- green chemistry
- marketing

Relevant factors are factors that materially contribute to the adverse impacts associated with the Priority Product, and for which there is a material difference between the Priority Product and one or more alternatives (Section 69501.1(a)(60)). Chapter 3 of this Guide presents an extensive discussion of relevant factors.

³ The Massachusetts Toxic Use Reduction Program's certification course discusses the importance of pre-planning and provides descriptions of team members and their roles. Toxic Use Reduction Planning and Certification Course. Curriculum and Resource Guide. Toxic Use Reduction Institute. Fall 2011.

First Stage AA	Considerations
Step 1: Identify Product Requirements & Function of Chemicals of Concern	<ul style="list-style-type: none"> • Identify functional, performance, and legal requirements • Identify the role of the Chemical of Concern • Determine the necessity of the Chemical of Concern • Evaluate removing the Chemical of Concern
Step 2: Identify Alternatives	<ul style="list-style-type: none"> • Identify and consider alternatives • Research and evaluate information that identifies possibly viable alternatives
Step 3: Identify Factors Relevant for Comparing Alternatives	<ul style="list-style-type: none"> • Identify material contribution to one or more adverse impacts and a material difference in contribution to such impacts between the Priority Product and alternatives
Step 4: Initial Evaluation and Screening of Alternative Replacement Chemicals	<ul style="list-style-type: none"> • Compare Priority Product and alternatives by considering relevant factors • Identify viable alternatives • May eliminate alternatives posing greater adverse impacts than Chemical of Concern
Step 5: Consider Additional Information	<ul style="list-style-type: none"> • May consider other factors such as economic impacts, performance
Step 6: Preliminary AA Report	<ul style="list-style-type: none"> • Include AA Work Plan for second stage • See Appendix 1

During the second stage AA, the responsible entity follows the approved work plan to compare the Priority Product with the alternatives still under consideration using all available information for the relevant factors. The second AA stage contains an in-depth analysis that refines the relevant factors and product function descriptions of the first stage and expands the analysis to consider additional impacts, including life cycle and economic effects. The evaluation and comparison steps as described are iterative so the responsible entity may incorporate new and more detailed information throughout the analysis. The following table shows the steps in the second stage AA.

Second Stage AA	Considerations
Step 1: Identify Factors Relevant for Comparing Alternatives	<ul style="list-style-type: none"> • Re-evaluate relevant factors identified in first stage • Consider required relevant factors: <ul style="list-style-type: none"> • Product function and performance; useful life • Economic Impacts: <ul style="list-style-type: none"> ○ Public health and environmental cost ○ Cost to government agencies and non-profit organizations ○ Internal cost
Step 2: Compare the Priority Product & Alternatives	<ul style="list-style-type: none"> • Compare Priority Product with alternatives with respect to relevant factors and associated exposure pathways, and life cycle segments • Reiterate analysis as needed
Step 3: Consider Additional Information	<ul style="list-style-type: none"> • May consider other pertinent information
Step 4: Alternative Selection Decision	<ul style="list-style-type: none"> • Select alternative • Support with comparative analysis
Step 5: Final AA Report	<ul style="list-style-type: none"> • See Appendix 1

The information and conclusions generated through these steps establish the basis for the alternative selection and lay the foundation for determining the appropriate regulatory response. The responsible entity must document its decision in the Final AA Report and include a schedule for implementing an alternative, if selected. The Final AA Report must also include any recommended regulatory responses. After the responsible entity submits the Final AA Report, the Department will make it available for public review and collect public comment before making a determination about any applicable regulatory responses. Appendix 1 contains descriptions of the required contents of AA Reports.

Figure 1-2 below shows the steps in the two stages of the AA framework and indicates the chapters in this Guide that support each step. This figure depicts the iterative nature of the analysis, showing how some chapter topics address several steps in the analysis and may apply to both the first and second stages of the AA. For example, it is clear that identifying the relevant factors (Chapter 3) will be key to the assessment and analysis steps in both stages of the AA, and information needs and transparency (Chapter 9) apply throughout the AA.

Figure 1-2. Steps in the AA Process with Corresponding Guide Chapters

		CHAPTERS	
FIRST STAGE	Identify product function, performance, legal requirements		
	Identify role of COC	2	
	Identify alternatives		
	Data collection/research: ■ available information ■ available tools to determine potential impacts	4	Identify relevant factors: 3
	Impact Assessment		
	Initial evaluation and chemical screening	5	
	Preliminary AA Report preparation	1	Information Needs and Transparency: 9
SECOND STAGE	Stage 2 evaluation of function, performance	2	
	Exposure assessment	6	Identify relevant factors: 3
	Life Cycle impact assessment	7	
	Economic analysis	8	
	Comparison and selection	10	
	Final AA Report preparation	1	

Other Compliance Options

In some instances the responsible entity may have already completed an AA, a similar comparative analysis, or prefer to use a different AA approach. The regulations provide options for three approaches that differ from the standard two-stage process:

- Abridged AA
- Alternate Process AA
- Previously completed AA

The responsible entity must demonstrate that the information and analysis for a different approach are adequate for evaluating the Priority Product and the alternatives. If the information or analysis is not sufficiently equivalent to the AA process described in the regulations, the responsible entity will demonstrate how it will augment the approach. A responsible entity may commence work under one AA option and later reconsider and elect to continue under a separate option.

ABRIDGED AA:

An abridged report may apply if the responsible entity cannot identify an available, functionally acceptable, and technically feasible alternative during the first stage AA. The Abridged AA Report contains the analysis findings for the first stage and portions of the second stage of the AA process. This report also identifies milestones and dates for implementing proposed regulatory responses to limit or reduce potential adverse impacts associated with the Priority Product until the responsible entity researches and develops a safer alternative. The following table shows the steps in the Abridged AA and shows how the first four steps for the Abridged AA (first stage AA) are the same as for a typical AA.

Abridged AA	Considerations
Step 1: Identify Product Requirements and Function of Chemicals of Concern	<ul style="list-style-type: none"> • Identify functional, performance and legal requirements • Identify the role of the Chemical of Concern • Determine the necessity of the Chemical of Concern • Evaluate removing the Chemical of Concern
Step 2: Identify Alternatives	<ul style="list-style-type: none"> • Identify and consider alternatives • Research and evaluate information that identified possibly viable alternatives
Step 3: Identify Factors Relevant for Comparing Alternatives	<ul style="list-style-type: none"> • Identify material contribution to one or more adverse impacts and a material difference in contribution to such impacts between the Priority Product and alternatives
Step 4: Initial Evaluation and Screening of Alternative Replacement Chemicals	<ul style="list-style-type: none"> • Compare Priority Product and alternatives by considering relevant factors • Identify viable alternatives • May eliminate alternatives posing greater adverse impacts than Chemical of Concern
Step 5: Consider Additional Information	<ul style="list-style-type: none"> • May consider economic impacts • May consider other relevant information
Step 6: Abridged AA Report Preparation	<ul style="list-style-type: none"> • Must have the required elements of an AA Report

After reviewing an Abridged AA Report and associated public comments, the Department will issue a regulatory response determination notice for the Priority Product, which at a minimum will require the responsible entity to:

- Provide product information for consumers.
- Conduct a research and development project or fund a challenge grant to seek and make available a safer product to replace the Priority Product.

ALTERNATE PROCESS AA

A responsible entity may use an analytical process different from the two-stage AA process if the Alternate Process contains all of the substantive requirements specified in the regulations. When using an Alternate Process AA, a responsible entity must submit an Alternate Process AA Work Plan to the Department for review

and approval along with the Priority Product Notification (within 60 days after the product is listed). The work plan must demonstrate that the responsible entity will meet all the requirements specified within the two-stage AA process, and include detailed information about the approach, steps, methods, procedures, and tools that the responsible entity will use. The work plan must also include the schedule for completing and submitting the Final AA Report.

If the Department does not approve the Alternate Process AA Work Plan, the responsible entity must submit a Preliminary AA Report to DTSC.

PREVIOUSLY COMPLETED AA

Instead of performing a new AA and submitting Preliminary and Final AA Reports, a responsible entity may submit a report for a previously completed AA regarding the Priority Product. The Previously Completed AA may be an AA conducted in-house by the responsible entity, an AA collaboratively prepared by consortia, or a publicly available AA.

If the Previously Completed AA Report does not adequately fulfill the Final AA Report requirements, the responsible entity must supplement the AA Report so that it contains all information specified in the two-stage AA process.

Regulatory Responses

When the responsible entity completes the AA process and submits all of its required reports, the Department will make the Final AA Report available for public comment. After reviewing the report and public comments, the Department will determine if a regulatory response is needed. When selecting and requiring regulatory responses, the Department will give preference to the following selection criteria:

- Alternatives of least concern when they are functionally acceptable, technically feasible, and economically feasible.
- Regulatory responses that provide inherent protection through redesign rather than administrative controls to limit exposure.
- The degree to which the regulatory responses address the adverse impacts, the cost of the regulatory response relative to other possible responses, and government interest in efficiency and cost containment.

The type of regulatory response for a given situation will depend on the specific circumstances of the analysis. For example, if a responsible entity does not select an alternative because information about the alternative is not available, the appropriate regulatory response may be to conduct research to develop additional information. The following table lists the regulatory responses included in Article 6 of the SCP regulations with summaries of the applicable situations.⁴ The SCP regulations provide a detailed process specifying the

⁴ CCR section 69506 *et seq.*

determinations the Department will make and information the responsible entity must provide including reports and notifications for each of the regulatory responses.

Summary of Regulatory Responses

Regulatory Response	Applicability
Supplemental Information and Regulatory Response Revisions	To provide the Department with additional information, primarily to make a final regulatory response decision or fill information gaps identified in AA Report.
Product Information for Consumers	To make consumers aware of the presence of chemicals in the products, their known hazard traits, and required or recommended handling procedures.
Use Restrictions on Chemicals and Consumer Products	To address a situation when the Department has determined that a use restriction is necessary to reduce the potential for the product to contribute to or cause adverse impacts and/or waste or end-of-life impacts.
Product Sales Prohibition	To address a situation when a known safer, viable alternative exists, but the responsible entity does not select it, or when the benefit of the product does not outweigh the adverse impacts associated with the product.
Engineered Safety Measures or Administrative Controls	To contain, control access to, or limit exposure to the Chemical of Concern or replacement Candidate Chemical to reduce potential adverse impacts.
End-of-Life Management Requirements	To identify end-of-life management elements for a consumer product that must be managed as a hazardous waste at the end of its useful life.
Advancement of Green Chemistry and Green Engineering	To require research and development, or funding of a challenge grant to develop a viable safer alternative for a Priority Product.

Summary

A responsible entity may submit any of the following to comply with the requirements of conducting an AA under Article 5 of the SCP regulations:

- Preliminary & Final AA
- Abridged AA
- Alternative Process AA
- Previously Completed AA

In addition a responsible entity may begin under one of the above options and complete the process under another option. Further, a responsible entity may elect to submit a Removal/Replacement Notification in lieu of conducting an AA if it intends to remove or replace a chemical and/or product.

Discussion Draft

Chapter 2 – Product Requirements and Alternatives

This chapter describes the initial steps a responsible entity undertakes as it begins an AA. These critical first steps identify the product's function, its expected performance, and any applicable legal requirements, along with defining the role of the Chemical of Concern in the Priority Product⁵. The responsible entity may use the probing questions in this chapter to help gather this information to both identify a broad range of potential alternatives, and then focus the analysis on the most promising ones.

Product Function and Performance

A product's function is the service or utility the product provides. The responsible entity must clearly describe a product's function and its specific application to evaluate whether potential alternatives achieve the same or similar function.

The function can include product qualities or characteristics. For example, if the purpose of a beverage packaging container is to contain and protect its contents, other characteristics, such as opacity, rigidity, or puncture resistance may or may not also be important. Depending on the function specified by the manufacturer, possible alternatives could include aluminum, glass, or plastic. A manufacturer will evaluate each alternative to determine which best meets the functional requirements and desired attributes it has specified for its product and Chemical of Concern. It is possible that different manufacturers will reach different conclusions about potential alternatives.

The AA must consider the functions of both the product and the Chemical of Concern in the product since both can be important when searching for alternatives. Sometimes these functions are closely related. Surfactants in detergents, for example, lower the surface tension of water, making oil and grease more likely to interact with

Initial Functionality Questions:

- What is the purpose of the product?
- What are the product's main functions?
- Must the product meet any legal requirements or performance standards?
- What is the function of the Chemical of Concern in the Priority Product?
- Is the Chemical of Concern necessary?
- Can the Chemical of Concern be removed without significantly affecting the Priority Product's functional performance?
- Is the Chemical of Concern a contaminant?

⁵ In the SCP regulations a Priority Product is a product-chemical combination identified and listed by the Department under CCR section 69503.5. In this Guide the term "product" with a lower-case "p" may refer to a product in a generic sense, that may or may not be determined to be a Priority Product, or it may refer to an alternative under consideration.

the detergent. A Chemical of Concern that functions as a surfactant directly affects the detergent's ability to achieve its cleaning function.

In some instances, however, the main product function may not be the reason a product contains a Chemical of Concern. For example, consider a foam cushion that contains a flame retardant. The function of the foam is cushioning, whereas the function of the Chemical of Concern in the foam is fire retardancy, a quality that may support flammability standards for the product.

Typically, function and performance act together to achieve a product's intended application or use. When the responsible entity describes the function and performance of a product in the AA, answering questions that ask "what," "how much," "how well," and "for how long," may help to ensure the description is complete. For example, paint performs several functions – it coats and protects surfaces, and it can be decorative. In addition paint users may also consider other features, such as drying time, ease of cleanup, "sprayability," durability, or covering ability, to be important aspects of the product performance.

Performance is one of the measures of how well a product carries out its functions. Performance requirements typically include criteria for the minimum acceptable performance of a product, and specify methods to assess these criteria, either qualitatively or quantitatively. A manufacturer may often establish performance criteria for a product by taking consumer demand and industry standards into account.

A manufacturer may have developed internal criteria, which may or may not be shared publicly, or the manufacturer may use performance measurements and tests that are widely known and publicly-accepted within an industry sector. For example, trade associations, governmental agencies, or other standards organizations sometimes establish performance requirements for certain products. In some instances performance standards may also be legal requirements for certain products such as building materials.

Consumer requirements and market expectations also can dictate or help to identify other important

When defining product function, consider the following:

- The purpose or utility of the product itself or the service provided by the product; the task that the product performs. Be as specific as possible.
- The conditions, such as temperatures or light exposure, under which the task, or function, must be performed. These conditions may restrict the alternatives that perform effectively under the particular conditions.
- The extent or duration of the function or service, expressed in use frequency or time frame, such as service life.

When defining product performance, consider the following:

- The desired result expected from the product. For example, a surface disinfectant must prevent bacteria from growing when left on a surface for the specified time.
- The efficacy of the product. In the disinfectant example, efficacy may refer to preventing test bacteria from growing in 59 out of 60 samples.
- The compatibility of the product with different substrates.

characteristics the manufacturer may consider as performance standards. For example, some products have unique customer specifications or criteria for acceptability that a manufacturer cannot alter because it would compromise the product's performance during use. For example, some consumers will prefer high efficiency detergents if they have high efficiency washing machines. Consumers will require detergents to be low-sudsing and quick-dispersing for optimum performance of their washers. In another example some consumers may require particularly rugged construction of ordinary products, such as computers, to withstand vibration, shock, or other environmental stress where the product is intended to be used. In these instances the consumer may require that the products meet the tests specified by military specifications (MIL-STD 810).

A responsible entity may include any product characteristic, criterion, standard, or performance requirement in the description of its Priority Product, and seek alternatives that will also meet those characteristics, criteria, standards, or performance requirements.

During the AA, when evaluating potential alternatives, a responsible entity may consider if the product would remain marketable if its array of attributes or standards changes. Some responsible entities may elect to educate consumers about the benefits of any changes and as a result, consumers may accept such changes if they are aware of the value of a safer product. Although the Department acknowledges the importance of consumer acceptance, the Department will consider how a responsible entity justifies that a viable alternative was not selected because of consumer resistance by describing how it measured consumer acceptance. For example, the Department will be interested in the relevant questions that responsible entities ask consumers to determine acceptance.

Legal requirements

Legal requirements are the specific requirements, performance standards, or labeling requirements that a chemical, product, or product packaging must meet under federal or California law. Government agencies establish legal requirements to achieve broad societal goals, such as safety standards, performance standards, or environmental impact standards.

Legal requirements often include technical standards specified in laws or regulations. Examples include:

- Flammability requirements that mattress sets must meet before sale or introduction into commerce.
- Rules for architectural coatings that limit a paint's volatile organic chemical content.
- Children's sleepwear flammability standards specified in the Code of Federal Regulations.
- Restrictions on the concentration of lead and cadmium in children's products in California requirements.

Role of the Chemical of Concern

It is important to identify the role that the Chemical of Concern plays in the Priority Product's function, such as a plasticizer in plastic products or surfactants in cleaning products. Any alternative involving chemical substitutes may either replace or compensate for that role.

The responsible entity must determine if the function of the Chemical of Concern is a necessary part of the Priority Product, needed to meet the product's functional, performance, or legal requirements. If the responsible entity determines that a Chemical of Concern is necessary, the rationale for that determination must be documented in the AA Reports. If the responsible entity determines that neither the Chemical of Concern, nor a replacement chemical, is necessary to meet the Priority Product's requirements, the responsible entity may remove the Chemical of Concern, and submit a removal notification. The removal notification will act in lieu of conducting and submitting an AA.⁶

- Why is the Chemical of Concern used in this specific application?
- Is the Chemical of Concern necessary for the Priority Product's function?
- Does the Chemical of Concern contribute specific product characteristics needed to meet performance requirements?
- Will the quality or necessary features of the product be affected if the Chemical of Concern is reduced or eliminated?
- Are there characteristics imparted by the Chemical of Concern to the Priority Product that are required to meet legal requirements?

Contaminant means:

A chemical that is not an intentionally added ingredient in a product *and* the source of the chemical in the product is one or more of the following:

- A naturally occurring contaminant commonly found in raw materials that are frequently used to manufacture the product;
- Air or water frequently used as a processing agent or an ingredient to manufacture the product;
- A contaminant commonly found in recycled materials that are frequently used to manufacture the product; and/or
- A processing agent, reactant, by-product, or intermediate frequently used to promote certain chemical or physical changes during manufacturing, and the incidental retention of a residue is not desired or intended.

(Section 69501.2(a)(26)(A))

⁶ If the responsible entity elects to remove the Chemical of Concern in the product without substituting a replacement chemical, the responsible entity may submit a Chemical Removal Intent and/or Confirmation Notification, pursuant to section 69505.2, in lieu of completing the AA and submitting the required AA Reports (see Notification Factsheet).

Sometimes a Chemical of Concern may appear unintentionally in a product in a small, or trace, amount as a by-product of a manufacturing process, or as a contaminant of another material used in the product. For example, 1,4-Dioxane may be a trace contaminant in cosmetic products, detergents, or shampoos that contain the following ingredients: "PEG," "polyethylene," "polyethylene glycol," "polyoxyethylene," "polyethoxyethylene," or "polyoxynoethylene." In this case, the chemical does not directly contribute to the function or performance of the product; it is only found in the product as a contaminant associated with other chemicals that perform a function in the product. Manufacturers can reduce 1,4-dioxane from these chemicals to low levels before the chemicals are used in products for the home.⁷ A responsible entity with an unintentionally added Chemical of Concern in a product should always search for ways to eliminate or reduce the contaminant chemical, such as seeking different chemical sources or specifying higher purity ingredients.

Identifying Alternatives

The responsible entity must use the information it collects about the product function and performance, product requirements, and the role of the Chemical of Concern in the product to identify potential alternatives. When identifying alternatives, the responsible entity should examine a wide range of possibilities, including chemical substitution, alternatives currently available in the marketplace, and possible product or process redesign. The responsible entity determines if the product can meet market needs if the Chemical of Concern is removed from the product, or if there are chemical replacements or substitutions to the Chemical of Concern that have the same or similar use, but are not listed on the Candidate Chemical list. The responsible entity may also consider material or formulation changes, or explore design alternatives that eliminate the need for either the Chemical of Concern or a replacement chemical. In some instances, the Chemical of Concern may serve multiple functions in the product and may require more than one alternative or replacement chemical.

An alternative may include any of the following:

- Removal of a Chemical of Concern from a Priority Product, with or without the use of one or more replacement chemicals.
- Reformulation or redesign of a Priority Product and/or manufacturing process to eliminate or reduce the concentration of a Chemical of Concern in the Priority Product.
- Redesign of a Priority Product and/or manufacturing process to reduce or restrict potential exposures to a Chemical of Concern in the Priority Product.
- Any other change to a Priority Product or a manufacturing process that reduces the potential adverse impacts or potential exposures associated with the Chemical of Concern in the Priority Product, or the potential adverse waste and end-of-life effects associated with the Priority Product that also meets the Priority Products function.

(Section 69501.1(s)(10))

⁷ Agency for Toxic Substances & Disease Registry. Public Health Statement – 1,4-Dioxane. April 2012

Manufacturers and suppliers of chemical ingredients are typically familiar with the uses, limitations, capabilities, and properties of chemicals, and may be good resources for identifying potential chemical substitutes. Similarly, material suppliers may identify potential alternative materials, and product designers may suggest potential redesign concepts or reformulation options. Other sources of information about alternatives include journals, trade shows, trade associations, and scientific studies. Appendix 2 provides a list of information sources that may be helpful for identifying alternatives.

The Interstate Chemical Clearinghouse (IC2) Alternative Assessment Document⁸ and the European Chemical Agency's Guidance for preparing an application for authorization⁹ also can help a responsible entity to identify alternatives. The following questions inspired by these sources can help identify alternatives:

- Are there similar products offered for sale that use a safer alternative?
- Do other manufacturers advertise their product as free of the Chemical of Concern? What alternative was used?
- Do chemical manufacturer(s) offer alternatives to the Chemical of Concern? Is an alternative listed on a manufacturer's website?
- Are there publications from trade journals or input from trade associations, technical articles, or other sources of information that identify potential alternatives?
- Does the chemical supplier offer an alternative?
- Does the chemical supplier's competition offer an alternative?
- Are there safer alternatives identified in online, internet sources?
- Have other AAs identified possible alternatives associated with similar use functions?
- Have state, local, federal or international organizations identified alternatives?
- Are there technical resources that identify chemicals or materials or design changes with similar or equivalent functionality?
- Can changes potentially be made to the manufacturing process or product design to allow the use of the alternative?

The SCP regulations define alternatives as a broad range of options that the responsible entity may consider to replace the Priority Product. While overlap within the range of alternatives exists, the subsequent paragraphs describe some of the specific distinctions among the alternative types.

Removing a Chemical of Concern

Since a principal goal of the SCP regulations is to remove a Chemical of Concern that is not needed for the product function or performance, any alternative that may accomplish this goal is a viable option. If a manufacturer removes the Chemical of Concern entirely, or substitutes a chemical that is not defined in the

⁸ Interstates Clearinghouse. Alternatives Assessment Guide. Version 1.0. December 2013

⁹ ECHA. Guidance on the preparation of an application for authorization. Version 1. January 2011

SCP regulations as a Candidate Chemical, the manufacturer may be exempt from the AA requirement, or subject only to limited notification requirements.

Reformulating or redesigning a Priority Product to eliminate or reduce the Chemical of Concern

Depending on the product type, a responsible entity may fundamentally redesign or reformulate a Priority Product to eliminate or reduce the concentration of the Chemical of Concern in the product. A redesign or reformulation may include considering alternative materials, or changing the manufacturing process to remove the need for a Chemical of Concern or the occurrence of an unintended byproduct or contaminant.

In addition to considering similar materials as replacements, a responsible entity may also consider dissimilar materials. For example, when looking for a substitute for a plastic container, a manufacturer may evaluate other plastic polymers that do not contain a Chemical of Concern, or it may consider other container materials, such as glass, aluminum, or steel in place of plastic. The extent to which a responsible entity will consider a dissimilar material will likely depend on what aspect of the product it manufactures and the definition of the Priority Product. If the definition of the Priority Product includes the container and the responsible entity primarily manufactures the contents of the container, switching to a different container material may be an alternative it will consider. If, however, the responsible entity primarily manufactures the container portion of the Priority Product, switching to a different container material may not be a feasible alternative to its manufacturing business model.

In addition, the responsible entity may consider materials or formulations currently used by others in the industry or other related industries. For example, Japanese manufacturers eliminated bisphenol A (BPA) in some can liners by replacing the epoxy coating containing BPA with a polyethylene terephthalate lamination, which does not contain BPA. The polyethylene terephthalate lamination performs the same function of providing a barrier between the can and the contents to prevent corrosion and contamination. An alternative that focuses on function to identify safer substitutes is termed a functional substitution.

Redesigning a Priority Product or manufacturing process to reduce exposure

A responsible entity may consider redesigning the Priority Product to address potential exposures associated with the Chemical of Concern. This type of redesign typically does not replace or remove the Chemical of Concern, instead altering the product to limit chemical exposure. For example, an alternative for a plastic with a Chemical of Concern that results in an exposure may specify using one of the following;

- An additive that remains bound in the plastic matrix, preventing chemical release.
- A multi-layered formulation that prevents chemical release.

Other Priority Product changes to reduce impacts

Other types of product reformulation or redesign consider alternatives that address potential adverse impacts not specifically identified in the other categories. For example, a product redesign may consider the end-of-life management of the product that will maximize recycling or control hazardous materials. Responsible entities may consult a number of guidelines intended to help with designing for disassembly, such as the use of fasteners rather than adhesives, or making joints visible and accessible. Similarly, a responsible entity that ships its product over long distances may consider product or process changes that reduce the weight of the product or its packaging to reduce impacts due to transportation.

Summary

When identifying alternatives to the Priority Product, responsible entities must clearly describe the product requirements (functional, performance, and legal). They must determine if the Chemical of Concern is even necessary to meet those product requirements. Potential alternatives can then be initially identified and evaluated if these alternatives can fulfill the product's functional, performance, and legal requirements.

Chapter 3 – Relevant Factors

The SCP regulations use relevant factors throughout the AA to define and adjust the scope and extent of the analysis. This Chapter describes the specific concept of relevant factors outlined in the SCP regulations. It also provides approaches, examples, and databases that may help responsible entities identify relevant factors.

CHAPTER 3 AT A GLANCE

Purpose: Identifying relevant factors is part of the scoping process during the first and second stages of the AA and is an iterative process. Responsible entities will continually re-evaluate relevant factors throughout the AA.

Determination of relevance: A factor, in conjunction with its associated exposure pathways and life cycle segments, is relevant:

- If the factor makes a material contribution to one or more adverse public health impacts, adverse environmental impacts, adverse waste and end-of-life effects, or materials and resource consumption; and
- There is a material difference in the factor's contribution to impacts between the Priority Product and alternative(s) under consideration.

Inputs: A responsible entity will collect and use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to identify relevant factors.

Output: In the AA Reports a responsible entity will document the outcomes for all relevant factors used in the analysis, including the rationale for determining which factors are relevant and the reasons for determining other factors are not relevant.

What are Relevant Factors?

The responsible entity uses relevant factors throughout the AA primarily to characterize, evaluate, and compare impacts associated with the Priority Product and alternatives.

A potential factor becomes relevant if it fulfills **both** of two requisite criteria:

- The factor makes a **material contribution** to adverse public health impacts, adverse environmental impacts, adverse waste and end-of-life impacts, or materials and resource consumption. This relates to a factor that is both meaningful and consequential to an observed outcome or impact.
- There is a **material difference** in the factor's contribution to the impacts between the Priority Product and one or more of the alternatives under consideration. This relates to a factor's contribution to an observed impact that is both meaningful and consequential to the comparison of alternatives.

Beginning with a large pool of potential factors, the responsible entity systematically narrows the list using regulatory criteria,¹⁰ knowledge of the Priority Product and alternatives, and an iterative approach that continually refines the relevant factors throughout the analysis.

Table 3-1 below summarizes the potential factors listed in the SCP regulations for the two AA stages. These factors are sorted according to the three primary categories of adverse and life cycle impacts, product function and performance, and economic impacts. Appendix 3-1 contains a complete, expanded list of potential factors. A responsible entity may use checklists to demonstrate and document the decision process and logic it uses both to identify the factors considered or included in the analysis and to justify those that are eliminated or set aside. Appendix 3-2 contains some example checklists for this purpose. The factors that cannot be quantified by readily available information should not be overlooked; the regulations also allow the use of qualitative information.

¹⁰ CCR section 69505.5(c)(1)

Table 3-1 A summary of potential factors requiring consideration for a two-stage AA.

FIRST AND SECOND STAGE AA	
Adverse Impacts and Multimedia Life Cycle Impacts	
<ul style="list-style-type: none"> • Adverse environmental impacts • Adverse public health impacts • Adverse waste and end-of-life effects • Environmental fate • Materials and resource consumption impacts 	<ul style="list-style-type: none"> • Physical chemical hazards • Physicochemical properties • Associated exposure pathways and life cycle segments
SECOND STAGE AA	
Product Function and Performance	Economic Impacts
<ul style="list-style-type: none"> • Principal manufacturer-intended uses or applications • Functional and performance attributes, and relative function and performance • Applicable legal requirements • Useful life of the product • Whether an alternative exists that is functionally acceptable, technically feasible, and economically feasible 	<ul style="list-style-type: none"> • Public health and environmental costs • Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife • Internal cost impacts

Iterative process

Identifying relevant factors is an iterative and dynamic process the responsible entity conducts throughout the AA. In the first stage of the AA, the responsible entity begins with the factors that formed the basis for the Priority Product listing. The responsible entity may also undertake a broad search of databases and published literature for all available information about the potentially relevant factors. For example, U.S. EPA has developed the Chemview Database to collect and disseminate available information about chemicals.¹¹ The responsible entity may use available quantitative information and analytical tools, supplemented by available

¹¹ As the practice of alternatives analysis and alternatives assessment become more widespread throughout the U.S. and Europe, public and private organizations are developing and expanding chemical and product information databases, such as U.S. EPA's ChemView (<http://www.epa.gov/chemview/>).

qualitative information to identify relevant factors and compare potential alternatives with the Priority Product in the first stage AA. Appendix 3-3 presents an initial list of information sources that, while not exhaustive, provides a starting point for collecting data.

The responsible entity may subsequently identify new relevant factors or eliminate irrelevant ones as it evaluates expanded aspects of the product's life cycle, or as new information becomes available during multiple iterations. In particular, during the second stage of the AA the responsible entity will look again at relevant factors, with associated exposure pathways and life cycle segments, especially if the responsible entity discovers new or different information at this point. For example, a manufacturer of an alternative may pay a third party to test its alternative product using a series of measures. That study may not be available to the responsible entity in the first stage of the AA, but could be available as the AA process develops. In addition, during the second stage AA, the responsible entity will consider factors related to product function, performance and economic impacts. The responsible entity may also need to reevaluate factors eliminated during the first stage AA, as shown in the Example 3-1.

Example 3-1 Iterative process to identify relevant factors

In the first stage AA, the practitioner does not find an apparent difference in CO₂ emissions associated with production and disposal phases between the hypothetical Priority Product (Product X) and the alternative under consideration (Alternative A), as shown in Figure 3a. In this iteration, the responsible entity may eliminate CO₂ emissions from consideration as a relevant factor.

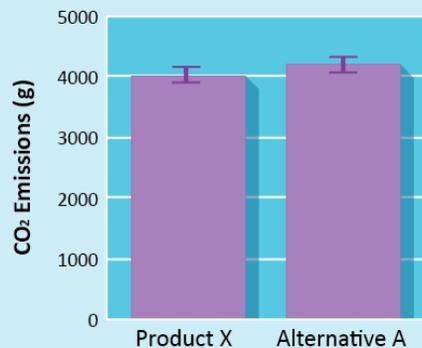


Figure 3a. CO₂ emissions associated with production and disposal during the first stage AA (without considering life expectancy).

In the second stage AA where the responsible entity must consider technical performance, the practitioner determines that the life expectancy of Alternative A is twice as long as Product X. Although this outcome indicates the alternative is technically feasible, it is also likely that the CO₂ emissions associated with production and disposal of Alternative A would be approximately half that of Product X due to the difference in life expectancy (see Figure 3b). Because the responsible entity did not consider CO₂ emission as a relevant factor in the first stage AA, the reduced impact associated with the alternative likely would not be taken into account when comparing Alternative A with Product X. However, if the responsible entity reevaluates the factors eliminated in the first stage during a relevant factor identification in the second stage AA, CO₂ emission could be considered a relevant factor and be included in the ultimate comparison of Product X with Alternative A.

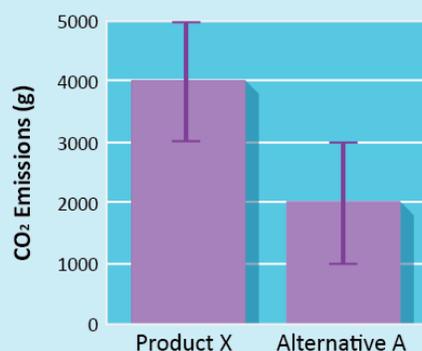


Figure 3b. CO₂ emissions associated with production and disposal during the second stage AA (with consideration of life expectancy).

Figure 3-1 illustrates an iterative process the responsible entity may use while identifying relevant factors. When providing AA Reports, the responsible entity should fully describe any changes in relevant factors, especially those that arise during the multiple iterations of the analysis, and provide supporting information to explain the changes and how they affect the analysis.

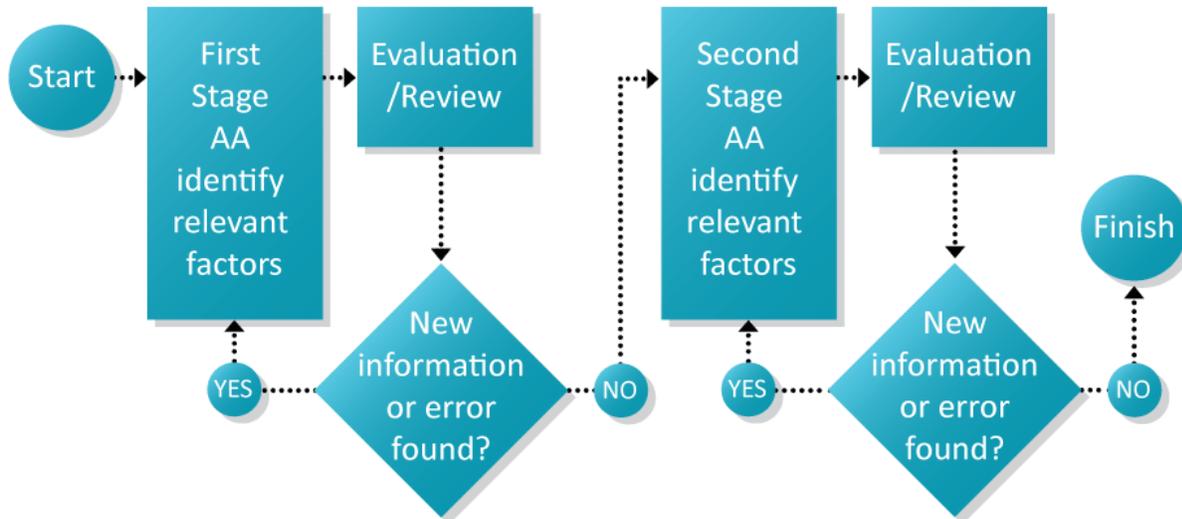


Figure 3-1 An example iterative process to identify and evaluate relevant factors

Incorporating Life Cycle Thinking

When considering the full life cycle impacts it is often easier to identify the potential adverse impacts associated with the use phase, but this does not mean that use phase is more important than other phases. One of the key differences between the AA required by the SCP regulations and other assessments is the requirement to consider all relevant life cycle impacts. Assessing impacts throughout the complete life cycle of a product means considering all inputs including chemicals, materials, water, and energy, and all outputs including emissions and wastes associated with each segment throughout the life cycle from raw materials extraction to end-of-life disposal. In the SCP requirements “life cycle”¹² means the sum of all the following activities:

- raw materials extraction
- resource inputs and other resource consumption
- intermediate materials processes
- manufacture
- packaging

¹² CCR section 69501.1(a)(42)

- transportation
- distribution
- use
- operation and maintenance
- waste generation and management
- reuse and recycling
- end-of-life disposal

Life cycle thinking in the AA focuses on describing changes in the life cycle and associated environmental consequences associated with potential alternatives. Because the responsible entity evaluates only relevant life cycle segments—those where a material contribution and material difference occur—an in depth analysis is not likely to be needed for every life cycle segment. For example, a manufacturer may develop different formulations of a cleaning product, but the packaging might remain the same. In this instance the difference in packaging is not material and may be excluded from further analysis. If the alternative for a water bottle is a switch in raw materials between glass and plastic, most life cycle segments and associated impacts are likely to be relevant due to the differences in resource extraction, production, transportation, and end-of-life management between glass and plastic. The responsible entity must undertake a more extensive analysis to determine which factors actually make a material difference and would be relevant. If the responsible entity is comparing two different types of plastic water bottles, the impacts associated with caps and labels, transportation to user, and the use phase may not differ significantly, but other impacts may vary depending on the materials. For example, a water bottle made from polyethylene terephthalate (PET) has a different life cycle impact profile than the one produced from polylactide (PLA) due to the difference from the production of the two resins, transportation of the resin to fabrication of bottles, and end-of life phase.¹³

In another example, Figure 3-2 shows that a Priority Product and its alternative are comparable for all segments except the use phase for CO₂ emissions. Although CO₂ emissions in the use phase appear to be twice as high for the alternative, the cumulative CO₂ emissions from all life cycle segments show that CO₂ emissions during the use phase contribute less than 3% of the total amount. In this example, the difference in CO₂ emissions during the use phase may constitute a material difference, but may not make a material contribution to adverse air quality impact, and as a result it may be excluded from further analysis.

¹³ Franklin Associates, *LCI summary for PLA and PET 12-ounce water bottles*. Final Report Prepared for PET Resin Association. December 2007, Prairie Village, Kansas.

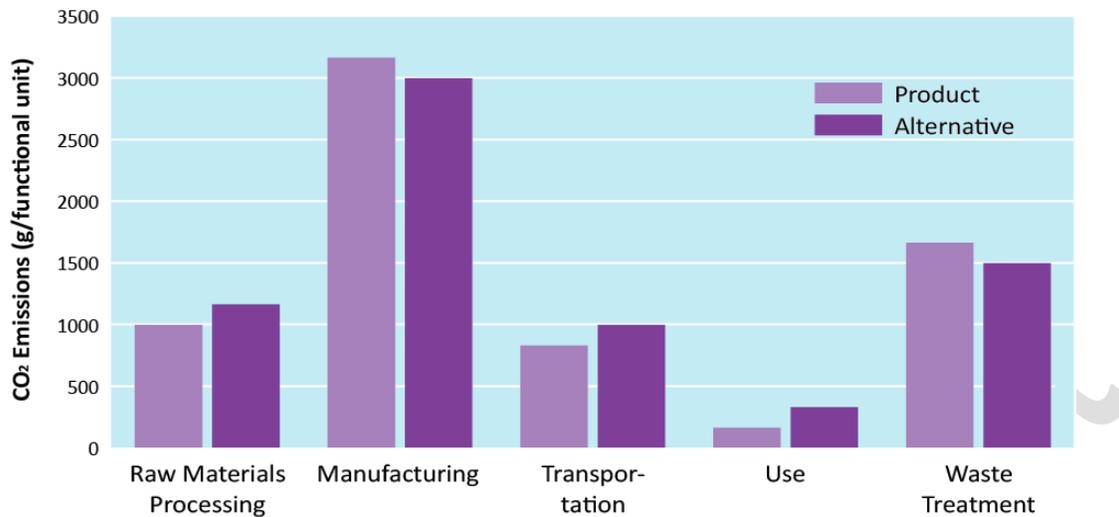


Figure 3-2 Contribution analysis of the life cycle CO₂ emissions for Priority Product and alternative.

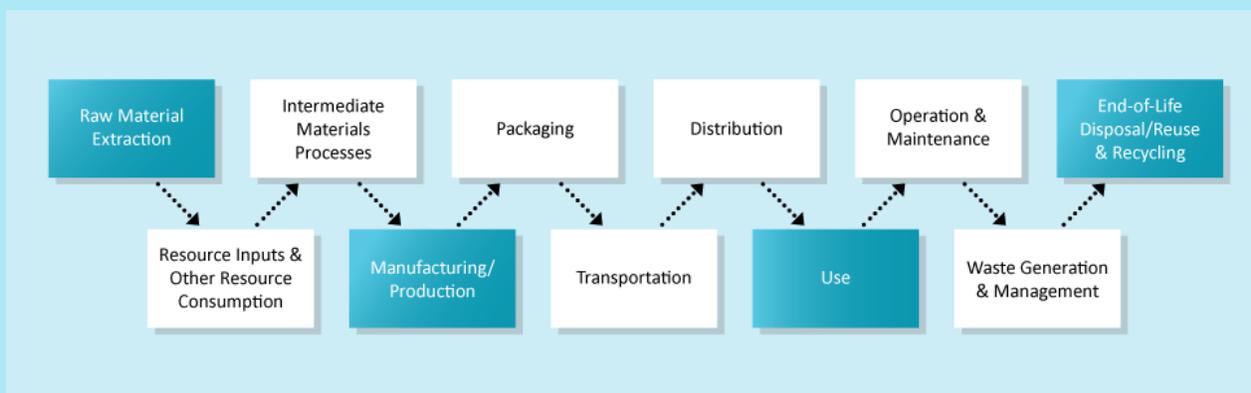
The box below presents some initial questions to help the responsible entity to consider whether particular life cycle segments are potentially relevant. Example 3-2 illustrates a qualitative approach of life cycle thinking at beginning of the process.

Is a life cycle segment potentially relevant?

- What life cycle segments associated with adverse impacts and exposures are identified in the Priority Product profile?
- What life cycle segments will be significantly different given a switch to an alternative?
- How does the Priority Product compare to alternatives with regard to materials and energy consumption for each life cycle segment?
- Can additional or different releases or exposures to humans or the environment occur during any life cycle segment by implementing alternatives?
- Will alternatives affect waste generation or the ways the product would be reused, recycled, or disposed?

Example 3-2: Identifying Relevant Life Cycle Segments

This case study considers a flooring product, designated in this example as “Product,” and its three alternatives: Alternative A, Alternative B, and Alternative C. The three petrochemical plastic-based materials, contained in the Product, Alternative A and Alternative B, result in releases of similar amounts of persistent bioaccumulative toxicants (PBTs), associated with material extraction and refining operations. Hazardous chemicals used in polymerization and solvents and other chemicals required by the production process may result in concerns regarding worker exposure. Comparatively, Alternative C contains higher levels of bio-based content and its production processes release fewer PBTs, and CMRs (carcinogenic, mutagenic, and reprotoxic substances). During the use phase, hazardous additives such as phthalates, flame-retardants, and residual heavy metals in the product may cause user exposure. These potential impacts may require further analysis. The wax used to form an impermeable layer on the flooring products may release VOCs (volatile organic compounds) into surroundings once the layer is worn. If incinerated at end-of-life, a difference in the release of flame-retardants and generation of dioxins and PBTs between the Product and alternatives may be observed. In short, the main concerns from these four flooring options are the differences in persistence and bioaccumulation, toxicity, and exposure from raw material extraction, manufacturing, use, and end-of-life disposal. Impacts from distribution, transportation, and packaging are not materially different. In addition, because operation, maintenance and waste management practice for these products are similar, those life cycle segments are not significant for comparison. In the diagram, relevant life cycle segments are in dark boxes and nonrelevant life cycle segments are in light boxes:



The following diagram summarizes the differences among the Product and the three alternatives that make the life cycle segments potentially relevant.

Product		Alternative A	Alternative B	Alternative C
<ul style="list-style-type: none"> • Uses a small amount of post-consumer recycled content • PBTs, CMRs during petroleum extraction and refining 	Raw Materials Extraction	<ul style="list-style-type: none"> • Some use post-consumer recycled content (may be toxic) • PBTs, CMRs during petroleum extraction & refining 	<ul style="list-style-type: none"> • Some use post-consumer recycled content (may be toxic) • PBTs, CMRs during petroleum extraction & refining 	<ul style="list-style-type: none"> • Some use postindustrial recycled content • Few PBTs, CMRs & pesticides (can be eliminated)
<ul style="list-style-type: none"> • PBTs • Integrated CMRs 	Manu-facturing/ Production	<ul style="list-style-type: none"> • PBTs (can be designed out) • Integrated CMRs 	<ul style="list-style-type: none"> • Optional integrated CMRs • No identified PBTs 	<ul style="list-style-type: none"> • CMRs (can be eliminated) • No PBTs
<ul style="list-style-type: none"> • Heavy Metals, flame retardants, & phthalates • VOCs 	Use	<ul style="list-style-type: none"> • Heavy metals & flame retardants (can be designed out) • VOCs (may be reduced) 	<ul style="list-style-type: none"> • No heavy metals, flame retardant & phthalates • VOCs (may be reduced) 	<ul style="list-style-type: none"> • No heavy metals, flame retardant & phthalates • VOCs (may be reduced)
<ul style="list-style-type: none"> • PBTs • Small experimental recycling available 	End-of-Life Disposal and Reuse/ Recycling	<ul style="list-style-type: none"> • No identified PBTs • No recycling available 	<ul style="list-style-type: none"> • No identified PBTs • No recycling available 	<ul style="list-style-type: none"> • No identified PBTs • Small experimental recycling available

This diagram shows the differences among the Product and the three alternatives; these differences make the four life cycle segments potentially relevant when comparing the alternatives to the Product.

**Source: Tom Lent, Julie Silas, and Jim Valette. Resilient Flooring & Chemical Hazards: A Comparative Analysis of Vinyl and Other Alternatives for Health Care. Healthy Building Network, April, 2009.*

Incorporating Exposure Pathways

When developing the scope of relevant factors, the responsible entity must also consider the associated exposure pathways and consider how a sensitive subpopulation's potential use of, or exposure to, the product may be different from other, less sensitive populations.¹⁴ The AA process outlined in the SCP regulations does not require a traditional risk assessment that focuses on quantifying risks using exposure assumptions and modeling. Rather, the AA emphasizes hazard reduction and incorporates exposure pathways to capture trade-offs among alternatives and the Priority Product for risk reduction, using simplified exposure estimates when considering potential impacts. Although the estimates of exposures may be simplified or qualitative, the SCP regulations specify a complete range of exposure considerations. For example, when comparing the differences in human health effects associated with the Chemical of Concern and a replacement chemical, the responsible entity needs to understand not only the hazard of the chemicals, but also where the chemicals might partition into the environment when they are potentially released, how long they remain there, and how and where exposure occurs during the use phase and other life cycle phases.

The responsible entity will first look at the exposure factors identified as the basis for the Priority Product listing. The responsible entity will also gather exposure information from other sources to identify the exposure factors and pathways for the alternatives and to supplement the available information for the Priority Product.¹⁵ Different factors that contribute to adverse impacts, exposure pathways, and life cycle multimedia impacts may interact with one another. Schematic representations, such as conceptual models, may help the responsible entity capture and communicate this interaction.

¹⁴ CCR section 69505.5(c)(3)

¹⁵ CCR section 69503.3(b)

What are associated relevant exposure pathways?

- Are the Chemical of Concern and potential chemical alternatives used in the same relative amounts and in the same manner (such as in a formulated product)?
- At what point during the life cycle could human populations (such as workers or children) or ecological receptors (such as plants or animals) be exposed to the potential releases: raw materials extraction and processing, formulating, manufacturing, distribution, use, storage, transportation, waste treatment, or disposal? Where do these practices occur geographically?
- What are the use patterns for the Chemical of Concern and its alternatives (such as liquids or aerosols)? Does the product have a wide dispersive use or non-dispersive use?
- What are the potential types of use and end-of-life exposure scenarios: potential use or exposure to sensitive subpopulation; workers, customers, clients, and members of the general public who use, or otherwise come in contact with the product or releases from the product in homes, schools, workplaces, or other locations?
- What are the expected differences regarding exposure frequency, extent, level, duration (acute vs. chronic), and routes (oral, dermal, inhalation) for each use scenario and end-of-life scenario for the Priority Product and alternatives? For example, some chemicals may be highly persistent and can bioaccumulate in the environment long after the use and disposal phase.
- What are the differences in how the product contains chemicals, including potential for release during the useful life and at the end-of-life?
- If engineering or administrative controls are used, what avenues of exposure are they intended to reduce for the Priority Product and potential alternatives?
- Are there differences in the physicochemical properties that could substantively affect exposure pathways among the Chemical of Concern and potential alternatives? For example, is it in a size or form that makes it easy to inhale or ingest? Is it likely to escape into the indoor or outdoor environment during use?

The responsible entity may use information from existing exposure assessment studies, especially those that describe a chemical's likelihood to degrade or migrate in the environment or its potential to accumulate and persist in biological or environmental compartments. The responsible entity may also use industrial data, engineering expertise, and other professional judgment to estimate exposure pathways. For example, process engineers may have enough expertise to determine potential releases in the work place by examining manufacturing and processing operations, such as vapors from processing equipment, that could result in worker exposure and releases to the environment.

Appendix 3-3 lists a variety of sources for collecting relevant exposure-related information. For example, an OECD document (2012) summarizes existing models and tools used for exposure assessment.¹⁶ The National Academy of Sciences (NAS) prepared a document, “A Framework to Guide Selection of Chemical Alternatives” (2014),¹⁷ that provides structured approaches for both qualitative (based on physicochemical properties) and quantitative (based on exposure models) comparative exposure assessment, and compiles useful reference materials, databases, and tools.

In particular the 2014 NAS Report describes in detail how critical physicochemical properties (such as molecular size and weight, octanol-water partition coefficient, vapor pressure, aqueous solubility, Frontier orbital energies, bioconcentration factor) may inform an AA with respect to evaluation of physical hazards, environmental fate and transfer, exposure pathways, and potential of bioconcentration and bioavailability. However, there is potential uncertainty associated with the ability of these properties to predict potential exposures. For example, numerous AAs associated with the use of a chemical flame retardant used physicochemical properties to demonstrate that the chemical was not volatile or soluble in water, concluding it was unlikely to distribute into the environment, resulting in little relevant exposure. Based solely upon physicochemical properties, these assumptions were valid. Additional studies, however, found that the chemical was detected throughout the environment including remote locations. It was subsequently learned that, although non-volatile and water soluble, the chemical readily adsorbed onto small particles that were distributed throughout the environment via water and air. Therefore, if physicochemical properties are used to estimate exposure, it is important to review all possible variables and not limit the evaluation to a few, potentially misleading properties. See also Chapter 6 of this Guide for additional information about exposure assessment in the AA.

Finally, the responsible entity may consider using a conceptual model approach to depict the interactions among the exposure pathways and life cycle segments, and to help scope and identify relevant factors. Example 3-3 details a stepwise approach to develop a conceptual model to identify and communicate relevant factors at early stages of AA. This example describes a progression of information that can help identify relevant factors: first step depicts potential exposure and associated impacts, the second step compares impacts, and the third step compares impacts for different life cycle phases.

Conceptual Model:

In the AA context, a conceptual model is a simplified graphical or pictorial depiction of how potential chemical hazard traits, fate and transport, and exposure pathways relate to each other throughout the product’s life cycle. Initially, AA practitioners may use a conceptual model to clarify similarities and differences among the Priority Products and alternatives based on a qualitative analysis of available information.

¹⁶ Organization for Economic Cooperation and Development(OECD). Descriptions of Existing Models and Tools Used for Exposure Assessment. OECD Environment, Health and Safety Publications Series on Testing and Assessment No. 182. Paris, France, 2012.

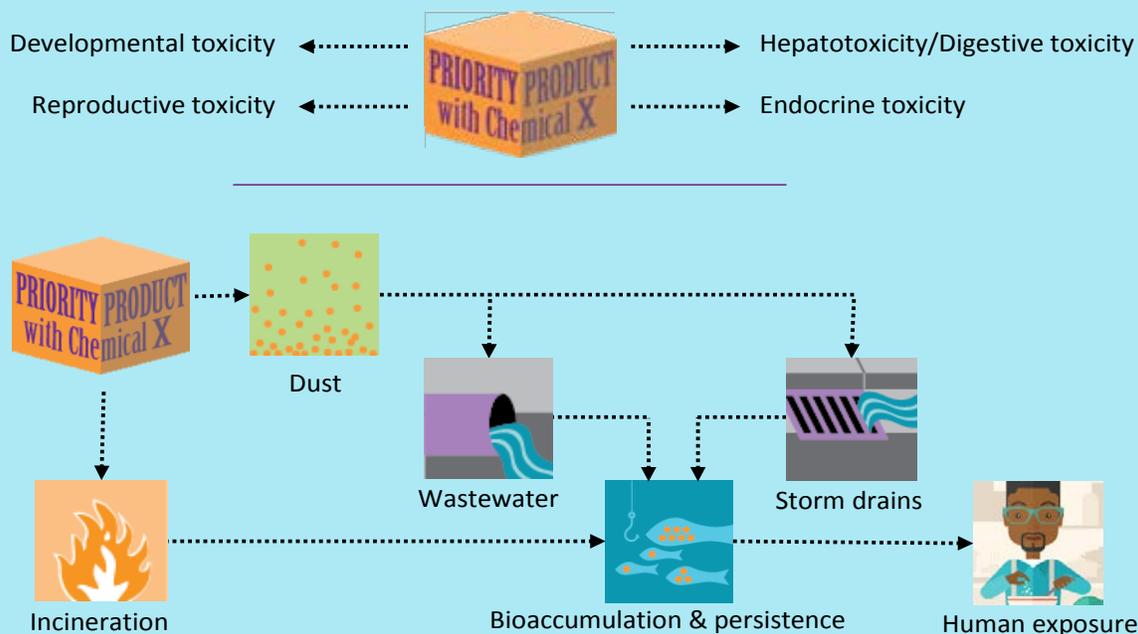
¹⁷ National Academy of Sciences (NAS). A Framework to Guide Selection of Chemical Alternatives. Washington, D.C., 2014

Example 3-3: Applying A Conceptual Model to Communicate Potential Relevant Factors

The following three-step process shows how to build and use a conceptual model to identify potential relevant factors with associated exposure pathways and life cycle segments. Consider a simplified example: a hypothetical Chemical of Concern, “Chemical X,” is a flame retardant used in a device, with a potential flame retardant chemical replacement, “Alternative A,” and a potential material change for the device casing, “Alternative B.”

STEP 1: CREATE A BASELINE CONCEPTUAL MODEL FOR THE PRIORITY PRODUCT CONTAINING THE CHEMICAL(S) OF CONCERN

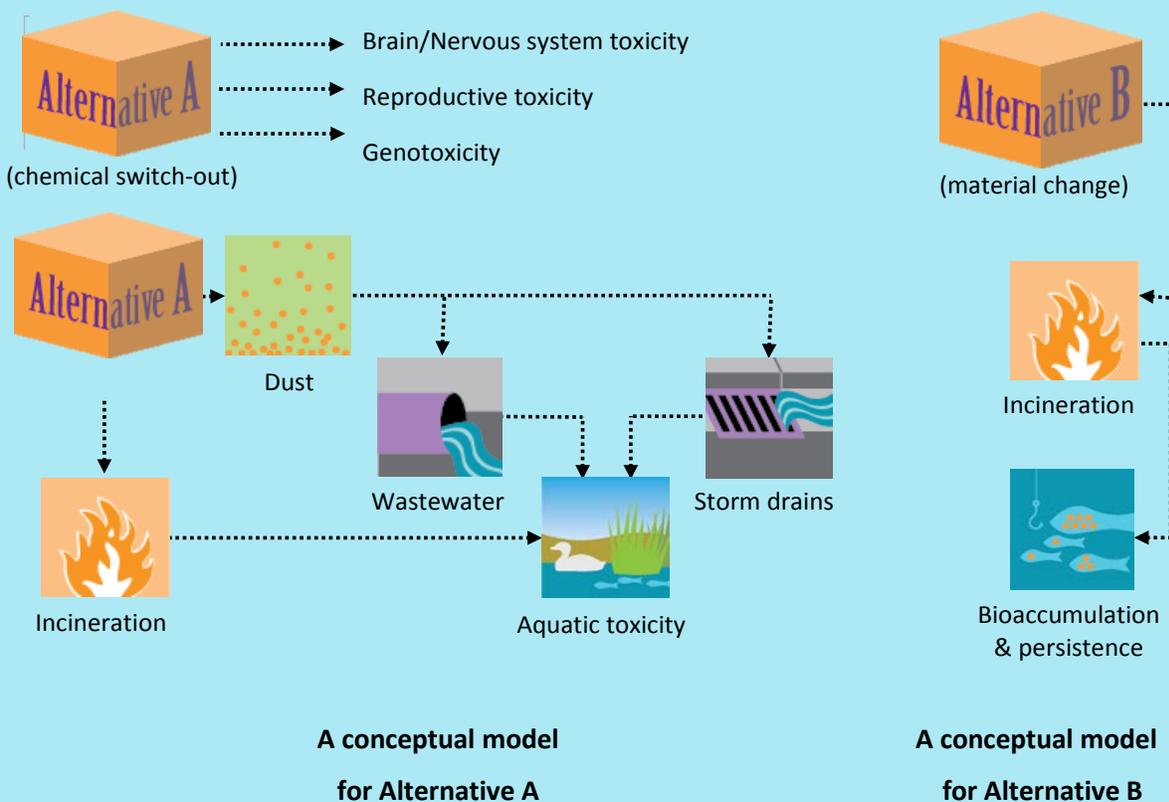
In this example, the Priority Product profile shows the Department listed the Priority Product containing Chemical X due to its developmental toxicity, hepatotoxicity, reproductive toxicity, endocrine toxicity, and bioaccumulation and persistence. To see how humans and the environment are exposed to Chemical X in the Priority Product, the diagram shown below illustrates different potential exposure scenarios for two life cycle segments: the use phase where Chemical X might be released from the device, and an end-of-life phase where the device is incinerated.



A conceptual model for Chemical X in the Priority Product

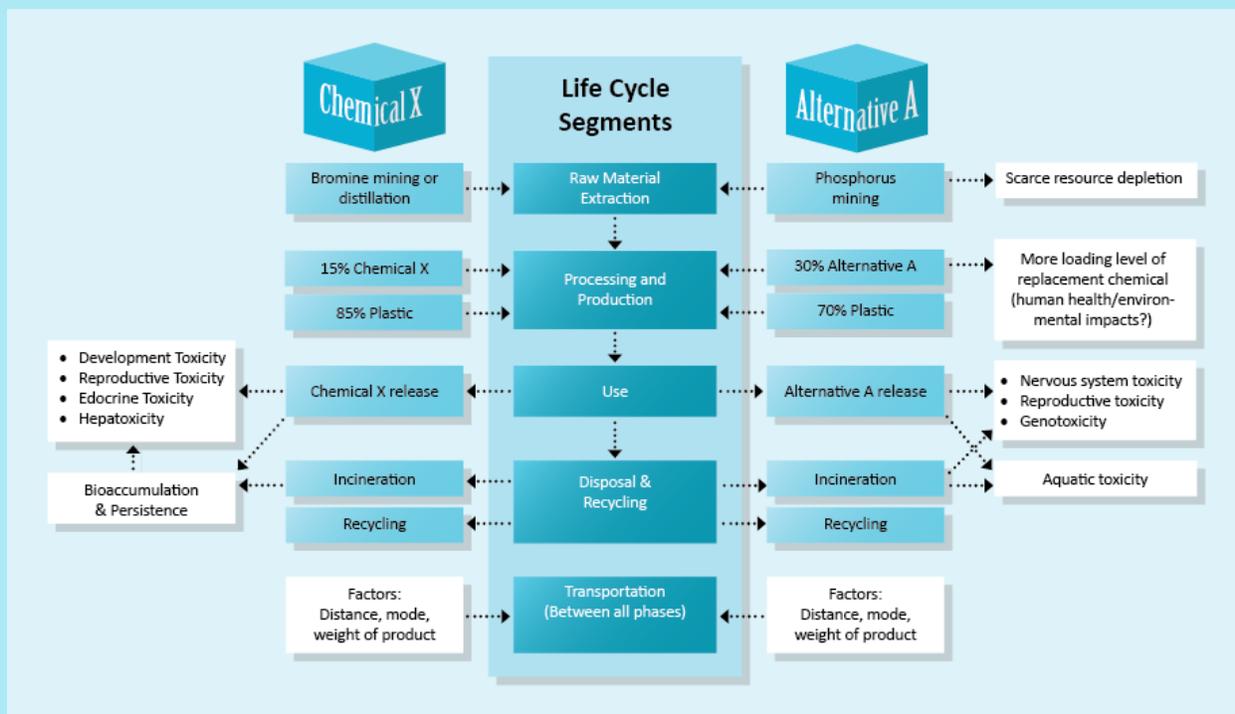
STEP 2: CONSTRUCT CONCEPTUAL MODELS FOR THE ALTERNATIVES UNDER CONSIDERATION

The conceptual models for Alternative A, a chemical switch-out, and Alternative B, a material change, are shown below. The preliminary literature research shows that hazard traits for the replacement chemical in Alternative A include genotoxicity, brain/nervous system toxicity, reproductive toxicity, and aquatic toxicity; and Alternative B does not have any significant human health impacts, but may bioaccumulate and persist in the environment.



STEP 3: COMPLETE THE CONCEPTUAL MODEL WITH LIFE CYCLE THINKING

The conceptual model shown as a box diagram below includes five life cycle segments, and some associated impacts, for Chemical X and Alternative A: raw material extraction, processing/production, use, disposal/recycling, and transportation. For example, if the distance and mode of transportation among all phases does not change, and the weight of the product does not change significantly between Chemical X and Alternative A, transportation might not be a relevant life cycle segment for comparison (no material differences). However, when comparing Chemical X with Material B (not shown), the transportation phase might be relevant for comparison, because differences in weight may result in energy consumption and air emission differences during transportation.



A conceptual model of life cycle segments comparison between Chemical X and Alternative A

Summary

The relevant factors identified and evaluated in the AA should take into account the following:

- The identification of relevant factors is an iterative and dynamic process.
- Factors can be quantified by readily available information or based on qualitative information.
- The full life cycle should be considered – it is often easier to identify the potential adverse impacts associated with the use phase, but this does not mean that it is more important than other phases.
- The potential use of a product by a sensitive subpopulation or exposure to the product may be different from other, less sensitive populations.
- Different factors may contribute to adverse impacts, exposure pathways, and life cycle multimedia impacts and may interact with one another.
- Schematic representations, such as conceptual models, may help capture and communicate relevant factor interactions.

Chapter 4 – Impact Assessments

This Chapter describes how to use impact assessments throughout the AA process. It provides approaches and information sources that may be useful for the responsible entity to evaluate impacts at several points in the analysis.

The responsible entity must gather and evaluate information about the human health, ecological, and environmental effects associated with a Priority Product and its alternatives to assess and establish the impacts associated with those endpoints. This chapter describes approaches to impact assessment and some of the data sources that may be useful. The responsible entity will then use this information to identify and verify relevant factors, and compare the Priority Product and alternatives. Because impact assessment is another iterative process, the responsible entity may return to the impact assessments to augment the data and analysis, as needed.

The responsible entity uses information from these assessment steps throughout the AA. For example, a hazard trait assessment forms the scope of the first and second stage, and plays a key role when the responsible entity compares the Priority Product and alternatives at the conclusion of the second AA stage.

The responsible entity will use information from impact assessments for the following specific activities:

- **Identify relevant factors** – Early in the first AA stage, the responsible entity will use information about impacts to identify the initial relevant factors.
- **Verify the relevant factors** – Later in the first stage, as the responsible entity gathers detailed data about the factors initially identified as relevant, impact assessment helps confirm the material contributions and differences associated with those factors.
- **Screen the alternatives** – At the end of the first stage the responsible entity will use impact assessment data to help determine which alternatives are likely to be inferior to the Priority Product so those alternatives may be eliminated from further analysis.
- **Assess life cycle impacts** – During the second AA stage, as the responsible entity performs an in-depth analysis of the life cycle impacts, the responsible entity will typically revisit the initial impact assessment to add more detailed information.
- **Compare alternatives** – The responsible entity will rely on information from the impact assessments to compare the effects and identify tradeoffs associated with the Priority Product and alternatives.
- **Select a preferred alternative or appropriate response action** – Ultimately, the responsible entity will rely on information from the impact assessments to make decisions to either implement an alternative or retain the original Priority Product.

With the large number of hazard traits specified in the SCP regulations¹⁸ and a number of potentially relevant factors to consider, the impact assessments can quickly become complex depending upon the number of alternatives and factors identified. An iterative approach can help make the analysis more manageable.

With an iterative approach, a responsible entity revisits the previously identified relevant factors to determine if they remain relevant. Typically, the responsible entity would use a simplified assessment during the initial stage to identify relevant factors. Once the responsible entity identifies the factors, subsequent iterations will be more in-depth, adding and documenting additional detail. The responsible entity may subsequently identify new relevant factors as it evaluates expanded aspects of the life cycle of the Priority Product and alternatives during the second AA stage.

In addition, a responsible entity may use a variety of tools and methods, such as hazard assessment models or read-across tables, to streamline different aspects of the impact assessments. This chapter presents a typical set of steps a responsible entity may use to conduct its analysis, and describes a selection of general tools and approaches.

Gather Data

Data gathering tasks, as described in this section, form the core of the impact assessments. The responsible entity collects the data and information available to evaluate the properties, hazard traits, and impacts of the Priority Product and its chemical alternatives. Depending upon its position and role in the supply chain, the responsible entity may have proprietary information, which the responsible entity will augment with any additional data it collects or generates.

Information may come from a variety of sources, both privately held and publicly available, and some factors are easier to characterize and quantify than others. Some information may be experimental or measured data accumulated over many years. For instance, many physical properties, such as boiling point or vapor pressure, have been measured by various authorities and collected in commonly available reference publications.

Data for other factors, such as toxicological properties, may be more difficult to apply in a generalized way, and can be difficult to find and interpret. For instance, finding data for some of the factors described in the regulations, such as endocrine disruption, may require specialized skills and expertise to locate, obtain, and interpret original research and findings. Furthermore, since toxicological studies typically focus on specific exposures, species, and endpoints, the responsible entity will need technical expertise to interpret the studies, and enough understanding to know when the information collected for a particular species or set of endpoints can apply to other species or endpoints.

¹⁸ CCR section 69401.2

When experimental or measured data are not available for a particular chemical, responsible entities may elect to estimate data values using models or analog assumptions. Initiatives to reduce reliance on animal studies for toxicological information are rapidly expanding. Alternative approaches such as read-across tables and modeled approaches can be used when empirical data are not available.¹⁹ Chapter 9 provides additional information about addressing data gaps in the analysis.

Alternative non-animal-based approaches often rely on extrapolations from known information about the traits associated with similar chemicals, or from other assumptions. One modeling method, QSAR (quantitative structure activity relationship), uses the relationship between a chemical's molecular structure and its effects on biological systems to predict the activity of other chemicals with similar structures.²⁰

Because modeled and analog data are based on an assumption that a chemical's activity can be predicted, these data will always carry some uncertainty, depending upon the reliability of the assumptions. A responsible entity may consider well-documented, and appropriately controlled, measured or experimental data to be more reliable than modeled or analog data because data derived directly from an original source is more transparent, easier to evaluate, and usually relies less on assumptions.

A responsible entity may find much of the information available to characterize the hazard traits and their impacts to be complex, requiring distinct levels of technical training and expertise to collect and interpret the data. Inexperienced responsible entities may benefit from technical assistance for some portions of the AA. However, depending on the identified relevant factors, the responsible entity may be able to collect enough information to screen the alternatives and proceed to the second stage of the AA, where more extensive data will be required to compare a more focused selection of alternatives.

Table 4-1 lists some of the available information sources for the descriptors and endpoints of the hazard traits. This table is followed by examples of each of the different types of data sources and descriptions of the ways they are useful to the AA. Appendix 4 contains a more comprehensive list of available data sources for hazard assessment.

¹⁹ Read-across tables and categories are resources that use endpoint information for one chemical to predict endpoint information for another chemical based on similarities between the chemicals.

²⁰ QSAR (Quantitative Structure Activity Relationship) models are mathematical models that predict toxicity based on molecular structure. U.S. EPA developed a Toxicity Estimation Software Tool (TEST) to estimate acute toxicity and some physical properties using QSAR methodologies. <http://www.epa.gov/nrmrl/std/qsar/qsar.html>

Table 4-1 - Hazard Trait Data Sources

Reference volumes and literature sources

Data summaries

- Authoritative lists – developed by governmental bodies or expert bodies recognized by expert authorities (such as the Prop 65 list and EC Annex VI CMR list used to identify Candidate Chemicals²¹)
- Databases and data portals to collect and organize available data

Primary research and measurements

- Bioassays
- Independent research and analysis published in peer-reviewed scientific journals
- Expert reports published or sponsored by international, federal, state or local agencies

Proprietary research – not publicly available

Modeling Tools

- Analogs and Structure activity relationships (such as Quantitative Structure Activity Relationships (QSARs) used in REACH²²)
- High throughput assays and analysis (bioinformatics)

REFERENCE VOLUMES:

A variety of references compile values for many intrinsic chemical properties. Desk references such as *Hawley's Condensed Chemical Dictionary* (Sax and Lewis, 1987) and *The Merck Index* (Merck, 1989) provide a good starting point for general information about chemical properties. Although libraries typically maintain copies of such reference volumes, much of this information is also available online. For example, *The Merck Index* has an online version that provides basic information results, but to gain access to the complete monograph, the responsible entity needs to purchase a user account.

Some government agencies also compile reference documents for a limited number of chemicals, such as the toxicological profiles the Agency for Toxic Substances and Disease Registry (ATSDR) maintains for a priority list of 275 substances. These detailed reports summarize toxicological data compiled from available published research and are available at no charge at the ATSDR website.

²¹ Authoritative Lists: <http://www.dtsc.ca.gov/SCP/SourceLists.cfm>

²² http://echa.europa.eu/documents/10162/13655/pg_report_qsars_en.pdf

DATA SUMMARIES:

In addition to general and detailed chemical reference volumes, some organizations compile certain types of hazard trait data into data summaries for quick reference. In the past, such data summaries were most commonly available for occupational uses, such as the National Institute for Occupational Safety and Health (NIOSH) Pocket Guide to Chemical Hazards. While many information sources are still available as documents, data providers are increasingly turning to online platforms that not only make searching for specific information easier, but also make data updates and augmentation easier. For example, although the ATSDR still updates and makes the toxicological profiles available as downloadable documents, to make the information in these profiles easier to use, the ATSDR developed an online toxic substances portal that allows users to search the profiles for specific information.²³ Online data summaries, including lists and portals, will help responsible entities find available information about the relevant factors.

An authoritative list is developed or used by an authoritative body, such as a government agency, non-governmental organization, or an academic institution.

A variety of both governmental and non-governmental organizations are developing authoritative lists and summary tables (also known as “look-up” tables) to categorize the hazard traits of chemicals. The information conveyed in these resources varies widely according to the purpose of the list. Authoritative tables and lists can range from a simple list of single or multiple hazard traits to compilations that provide a summary of traits or additional detail about a chemical or its listing. For example, a list of carcinogens may identify the category of carcinogen for which the chemical is listed or a summary table may group or rank chemicals according to specified preferences or criteria. Authoritative lists are designed to be easily understood and readily accessible to anyone interested in chemicals policy, especially practitioners with limited chemical expertise and experience evaluating chemicals. Usually, the authoritative list will also describe the sources of information the organization used to compile the list and any criteria it developed to classify or rank the chemicals in the list.

Authoritative lists and table summaries can be useful, particularly for identifying alternatives, and screening, or narrowing, the pool of chemical substitute options that would be acceptable or preferable to the Priority Product. However, the breadth and scope of most of these lists are limited, which thereby limits the completeness or thoroughness of the alternative screening. Most lists only provide information for a few chemicals, and a few attributes, while none provide data for all of the attributes contained in the SCP regulations. A responsible entity that uses lists and look-up tables to gather health impacts data will likely need to look to other sources to

List Translator Example – GreenScreen® List Translator

Clean Production Action developed its list translator to automatically screen and rank chemicals through its hazard lists. The translator is free and publicly available.

²³ATSDR Toxic Substances Portal: <http://www.atsdr.cdc.gov/substances/index.asp>.

supplement this information, depending on their relevant factors. The responsible entity also should carefully consider the data sources and criteria for the list in order to interpret it properly and to avoid invalid, misleading, or biased conclusions.

Because different authoritative lists typically address different issues, some responsible entities may need to use several lists to gather a greater variety of information. A list translator simplifies this task by screening a number of hazard traits through multiple lists simultaneously. Currently, most list translators

have only been developed to apply to narrow categories of chemicals or products, such as cleaning products, and are typically designed to be used by practitioners with limited experience or knowledge of chemical hazards. As with the lists themselves, list translators are straightforward to use, but they can be constrained by their narrow focus and limited number of attributes. A responsible entity who uses a list translator tool will need to determine which of its relevant factors the translator considers, and gather independent data for those not included.

Finally, as both the amount of available information about chemicals and demand for that information expands, various governmental, academic, and expert organizations are developing electronic databases and portals to make the available data more useful and accessible. These portals are designed to make it easier for users to search for available data for a particular chemical by collating and linking a variety of information sources with different formats. Because available data are so varied, widespread, and frequently updated, creating and maintaining a useful database can be challenging.

As with chemical lists, chemical databases and portals are typically straightforward to use, but they can be difficult to interpret. Some information portals and databases are curated at some level to return information that is tabulated or summarized so that it can be used immediately. More typically, however, a chemical database will provide a comprehensive collection of raw data or primary study references. Although this type of information is more rigorous and scientifically robust, a responsible entity must have adequate expertise to be able to properly interpret and use this data. Some databases, such as ChemHAT, are specifically intended for non-technical users and contain more generalized qualitative data. Table 4-2 lists some available databases.

Also, as with the chemical lists, the responsible entity will need to examine the databases and portals it uses to identify the data sources, determine the data usability, and identify which of the relevant factors will be addressed by the portal. If a database or portal does

List Example – Prop 65

California's Proposition 65 list contains chemicals identified by the state as carcinogenic or posing reproductive hazard. The list also provides safe harbor levels* when available. Some assessment approaches use the Prop 65 list to identify chemicals of concern.

*No Significant Risk Levels (carcinogens) or Maximum Allowable Dose Levels (reproductive hazards)

Adequate training and expertise for hazard assessment includes training in chemistry, toxicology, the fate and transport of chemicals in the environment, and data quality.

not contain information for all of the relevant factors, the responsible entity may need to use multiple data sources to supplement the information.

Table 4-2 - Examples of Databases and Portals for Impact Assessments

Tools	Type of Information	Contact*
ACToR	Free portal for chemical toxicity data from a collection of U.S. EPA databases with over 500,000 chemicals	U.S. EPA
ToxRefDB	Database of in vivo animal toxicity studies	U.S. EPA
Subsport	Free portal for information needed to substitute for hazardous chemicals, including substitution tools to compare and assess alternative substances and technologies	Kooperationsstelle Hamburg IFE GmbH; ISTAS; ChemSec; Grontmij A/S
RISCTOX	Database of health & environmental risks	European Trade Union Institute and European Environmental Bureau
ChemHAT	Chemical hazard database	GreenBlue Alliance

*Developer or host of online information database or portal

LITERATURE SOURCES:

Scientific literature may provide information useful for impact assessments. For example, researchers may measure, collect or review information for some chemicals or products, reporting the findings in scientific publications. In some instances an existing study may identify relevant factors, hazard traits, and data for a Priority Product and alternatives. These examples often appear in scientific publications and can be useful as a starting point for a subsequent analysis of the same Priority Products, particularly for less experienced practitioners. When using a previously completed analysis, the responsible entity must evaluate whether the existing analysis contains relevant, complete, and up-to-date information, and augment as necessary.

Primary research found in literature searches about chemicals or products may also provide information for impact assessments. Searching for reliable and useful scientific literature sources typically requires an understanding of sometimes highly technical journals and literature databases. As with primary data collected from chemical databases, a responsible entity that uses research or studies about chemicals must have adequate training and expertise to be able to interpret the data and assess the data quality. Typically, peer-

reviewed literature or studies will be preferable to studies that have not undergone review. The responsible entity must include details about the research relied upon—including the assumptions in the research and any available descriptions of the data quality—in the AA Report.

PROPRIETARY RESEARCH:

Some manufacturers and product developers undertake independent research to identify and characterize various process chemicals and alternatives. Occasionally, this research is a collaborative effort with a public entity like an academic institution or governmental agency, and a responsible entity may find results in public documents. More typically, however, private research occurs within a company's research and development department and only becomes public if the researcher seeks publication or presents findings at a conference or meeting.

A responsible entity may use the results of proprietary research for its hazard assessment. If the proprietary research is not publicly available, the responsible entity will need to include enough detail in the AA Report to describe the research methods and data quality. A responsible entity may claim aspects of its proprietary information to be confidential business information (CBI) and submit a redacted version of the AA Report for posting to the Department's website.

MODELING TOOLS:

As computing options evolve, models and tools that use known information about some chemicals to predict the behavior of other chemicals that lack information are gaining acceptance. When data about a chemical is not available, some scientists will turn to modeling tools to fill the gaps. The scientific community is quickly expanding its use of these models in response to drivers such as increased computing power, increased demand (and associated cost) of developing data, and ethical questions about animal testing procedures.

Modeling approaches typically require extensive knowledge about chemical structure and related groupings to use effectively. A responsible entity that uses data models should document the modeled data in the AA Report and include information about the selected methods and assumptions. While the responsible entity can use the information generated by these models, the AA Report required by the regulations does not require that data gaps be filled in this way. However, a responsible entity that cannot select an alternative because available data are poor may use modeling approaches to generate data. Appendix 4 presents more detailed information about modeling approaches and sources.

Table 4-3 - Examples of Models and Tools for Hazard Assessment

Tools	Type of Information	Regularly Updated?	Contact
TEST (Toxicity Estimation Software Tool)	Uses a mathematical model to estimate toxicity based on molecular structure	Yes	U.S. EPA
ToxCast	Uses high throughput assays to test chemicals for biological activity in cells or isolated proteins to predict toxicity	Yes	U.S. EPA

Comparative Tools and Approaches

As the practice of alternatives assessment becomes an important component of product and process development, those who seek safer alternatives also seek automated methods to evaluate and compare the hazards and impacts associated with the use of chemicals. A number of organizations have developed tools to help summarize and readily compare information about the hazard traits or attributes associated with chemicals in products. For example, U.S. EPA incorporates an assessment similar to GreenScreen® in its Design for the Environment (DfE) assessments for Safer Choice products.

In the AA specified by the SCP regulations, a responsible entity may use a hazard comparison tool in two places in the analysis: as part of the screening step in the first AA stage and as part of the decision step in the second stage. If a responsible entity uses a hazard assessment tool it will need to determine which relevant factors the tool addresses, and supplement the comparison for any factors that are not included.

Table 4-4 contains a summary of hazard comparison tools, and Appendix 4 presents an expanded list of hazard comparison tools with brief descriptions. Many of these comparison tools are designed for specific uses, such as occupational assessments, and some of them are updated on an ongoing basis. All of them consider a limited universe of hazard traits and impacts, which is described in the tool documentation, and none of them include the full array of hazard traits specified in the SCP regulations. It is likely a responsible entity will need to consult multiple tools and sources of information to complete a comparison.

Hazard comparison tools usually specify data requirements for certain hazard traits. The tools then employ a methodology, comprised of criteria and other assumptions, to rank or group the chemicals and alternatives according to the hazard traits. Most of these tools are sensitive to data quality and data gaps; namely, a tool's findings may not be reliable if much of the hazard trait data are missing. Usually a tool's outcomes are also sensitive to the hazard traits, assumptions, and criteria employed for ranking. In most instances hazard comparison tools require users to have considerable technical expertise to collect and summarize the hazard trait data and interpret the results. In 2007, Clean Production Action created GreenScreen®, one of the earliest comprehensive hazard comparison tools, providing training, a free translator tool, and inspiration for other

comparison methods. Since that time, Clean Production Action has updated GreenScreen® and adapted it for a variety of specialized uses and applications, although it remains a technical tool requiring training for effective implementation.

Table 4-4 - Examples of Tools for Comparing Hazards

Tool	Developer
QCAT	Washington St. DEQ
GreenScreen® for Safer Chemicals	Clean Production Action
Safer Choice	U.S. EPA
Column Model	Germany
COSHH Essentials	England
P2OASys	Massachusetts
NIOSH Hazard Banding	NIOSH
Cradle to Cradle	MBDC

Some tools, however, have been specifically developed to be easier to use and more accessible to less technical practitioners. The state of Washington developed the QCAT (Quick Chemical Assessment Tool), based on GreenScreen®, to allow small and medium-sized businesses to perform a simplified hazard analysis. This tool, which allows businesses to screen out alternatives that would be inferior to the Chemical of Concern, incorporates lower data requirements and compares alternatives using a more limited array of hazard traits than the GreenScreen®.

Chapter 5 – Screening Alternatives

In the final step of the first stage AA, the responsible entity prepares for the second stage AA by screening the alternatives. The primary goal of screening is to retain alternatives that would be an improvement over the Priority Product, while eliminating alternatives that present unacceptable impacts or unsatisfactory performance. While the responsible entity will want to consider a complete list of potential alternatives when beginning the AA, it is important to narrow the alternatives list and establish a meaningful scope of alternatives given the considerable data requirements and resources needed for completing the second stage AA. Through alternatives screening a responsible entity will establish a relative ranking of alternatives by eliminating inferior choices and in some cases reserving more marginal options for further consideration during subsequent iterations of the analysis.

Considerations for Screening

Responsible entities may use a variety of approaches to screen the alternatives and select the most promising options for further analysis during the second stage AA. If the responsible entity performs a hazard comparison during the analysis, the responsible entity may use information from that comparison as part of the alternatives screening.

A robust, systematic screening approach will use a series or group of comparisons that considers all of the identified relevant factors. The responsible entity will determine the relative importance of the various factors and use these relationships to determine how to construct a comparison.

A screening approach may take a number of different forms, from a sequential comparison of select factors to a complex simultaneous analysis of multiple factors, with many interim grading schemes in between.²⁴ The regulatory requirements do not specify a particular screening approach for alternatives; however, the regulations indicate that the initial screen may eliminate those chemical alternatives that have the potential to pose greater adverse impacts than the Chemical of Concern when considering the specified impact categories:

- Adverse environmental impacts
- Adverse public health impacts
- Adverse waste and end-of-life effects
- Environmental fate
- Materials and resource consumption impacts
- Physical-chemical hazards
- Physiochemical properties

²⁴ A Framework to Guide Selection of Chemical Alternatives (NAS 2014) and Interstate Chemicals Clearinghouse Alternatives Assessment Guide (IC2 2013) present summaries of similar decision approaches.

Specifically, a responsible entity may consider an alternative to be inferior to the Priority Product when that alternative:

- Exhibits a greater adverse impact to air quality, ecological, soil quality, or water quality.
- Exhibits a greater impact from toxicological hazard traits such as carcinogenicity, developmental toxicity, reproductive toxicity, cardiovascular toxicity, dermatotoxicity, endocrine toxicity, epigenetic toxicity, genotoxicity, hematotoxicity, hepatotoxicity, immunotoxicity, musculoskeletal toxicity, nephrotoxicity, ocular toxicity, ototoxicity, reactivity in biological systems, or respiratory toxicity.
- Generates more material waste or byproducts during its life cycle.
- Is more persistent in the environment, as determined by its environmental fate characteristics.
- Creates a greater consumption burden on society by using a larger volume or amount of renewable and nonrenewable resources throughout its life cycle.
- Poses a greater handling danger, as indicated by its physical chemical hazards.
- Poses a greater reactive or flammability hazard, as indicated by its physicochemical properties.

During the screening step the responsible entity may consider additional information and factors that are not specifically identified in the first stage AA. The responsible entity may also consider performance measures, economic impacts, and other potential impacts. The Preliminary AA Report must describe how the responsible entity used any additional factors in the screening decision. See Chapter 11 for more information about the different types of AA Reports.

Screening Approach

The responsible entity begins screening the alternatives using the data gathered for the relevant factors, comparing the alternatives to the Priority Product and to each other. If one or more of the alternatives are clearly superior, or inferior, to the Priority Product for all of the relevant factors, the screening process is simple. In this instance, the responsible entity may retain the superior alternatives and set aside the other alternatives in case they are needed later for future iterations during the analysis.

More commonly, however, the responsible entity will find some of the alternatives' relevant factors are superior to the Priority Product, and others may not be clearly superior or may be relatively equivalent, making the choice among the alternatives more complex involving trade-offs. Similarly, when the responsible entity cannot find data for some of the relevant factors, comparing the alternatives to the Priority Product may be problematic because the outcome of comparisons of unknown factors cannot be known and the relative merit of alternatives remain uncertain.

Trade-offs

Trade-off assessment is one of the most difficult aspects of decision-making in alternatives assessment. Because most comparisons of alternatives will involve trade-offs, the responsible entity may address such

decisions in a variety of ways, all of which require developing an explicit or implicit hierarchy among the relevant factors.

A hierarchy among the factors identifies which relevant factor the responsible entity determines to be the most important, followed by the next most important factor, and the next. Sometimes the responsible entity describes its hierarchy, and sometimes the hierarchy is embedded in the decision process and only becomes apparent in the order with which the responsible entity considers the factors. For example, if the responsible entity first compares carcinogenicity factors and eliminates some alternatives due to this characteristic, then carcinogenicity becomes the de facto most important factor in that analysis.

Most analyses evolve in a stepwise fashion. The responsible entity breaks down a complex array of comparisons into more manageable decisions. Because the regulations explicitly favor alternatives that are “safer,” most responsible entities will compare health and environmental factors first, placing these factors at the top of the hierarchy.

When the comparison requires a choice between or among impacts that the responsible entity considers to be equally important, the responsible entity may consult additional impacts such as exposure or life cycle effects to influence the choice and act as a tiebreaker. At this early stage in the AA, any additional information is likely to be qualitative. For example, if two chemical alternatives both pose health impacts, but one is an inhalation hazard and one is a skin sensitizer, the potential of the product to be inhaled or result in dermal exposure to the chemicals might provide a deciding factor. Such decisions are likely subjective, dependent upon many, if not all, of the specific conditions of use of the chemical in the product. This means the responsible entity must describe in the AA Report all of the assumptions and rationale for the decisions and trade-offs so the Department understands these choices.

Some decision analyses use mathematical modeling to identify preferences and decide among trade-offs. For example, the simultaneous approaches of multi-criteria decision analysis explicitly express the relative importance of each of the factors in the analysis by weighting them. Because these approaches are complex and resource-intensive, responsible entities will likely use simpler decision logic for the alternative screening. Some responsible entities, however, may use more complex decision approaches later in the analysis. Chapter 10 includes a description of various mathematical decision models²⁵.

Limited Screens

The responsible entity may also adapt screening approaches from some of the existing tools and methods described for impact analysis. As shown in Chapter 4, some assessment approaches use a short list of conservative criteria to screen alternatives, eliminating those choices that are inferior to the original product and Chemical of Concern or that are unacceptable due to inherent hazard traits. Since these tools typically do

²⁵ Chapter 10 of this Guide describes a number of approaches, including multi-attribute decision analysis, that provide systematic methods to use when the responsible entity conducts a decision, or trade-off, analysis at the conclusion of the completed AA.

not include evaluation of the range of factors specified in the regulations, the responsible entity will need to adapt or supplement these approaches rather than applying them directly.

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Resources

The resources listed below provide frameworks and information sources as well as tools and approaches for conducting AAs or for screening alternatives.

BizNGO. [BizNGO Chemical Alternatives Assessment Protocol](#). (PDF) This resource is a decision framework for substituting chemicals of concern to human health or the environment with safer alternatives.

BizNGO. [The Guide to Safer Chemicals](#). This resource is a hands-on guide for downstream users of chemicals that charts pathways to safer chemicals in products and supply chains.

C2C. The [Cradle to Cradle Certified^{CM} Products Standard](#) is a multi-attribute, continuous improvement methodology that evaluates products across five categories of human and environmental health.

Chemical Commons. [Principles for Alternatives Assessment](#). This framework includes six principles for alternatives assessment that guide a process for well-informed decision making that supports successful phase-out of hazardous products, phase-in of safer substitutes, and elimination of hazardous chemicals where possible.

Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ). [Practical Chemical Management Toolkit](#). This toolkit provides a step-by-step process for identifying and assessing chemical hazards, managing the risks associated with the use of chemicals, and planning and preparing for any emergencies involving chemicals.

Ecological Footprint Standards 2009 – [Global Footprint Network](#). This was created to ensure that footprint assessments are produced consistently and according to the community adopted best practices.

European Commission. [Minimizing Chemical Risk to Workers' Health and Safety through Substitution](#). This report presents a systematic, yet flexible, risk-based process for chemical substitution in the workplace.

European Chemicals Agency's various guidance documents such as:

- Guidance on the preparation of an application for authorization
- Guidance on the preparation of socio-economic analysis as part of an application for authorization

European Commission. [Product Environmental Footprint Guide. A guide](#) to provide a method for modeling the environmental impacts of the flows of material/energy and the emissions and waste streams associated with a product throughout its life cycle.

German Federal Environment Agency (Umweltbundesamt). [Guide on Sustainable Chemicals](#). This guide assists in the selection of sustainable chemicals by providing criteria to distinguish between sustainable and non-sustainable substances.

German Federal Institute for Occupational Safety and Health (BAuA). [Technical Rules for Hazardous Substances—Substitution \(TRGS 600\)](#). This guidance provides a framework for identifying and evaluating substitutes and establishes criteria for assessing and comparing the health risks, physicochemical risk, and technical suitability of identified alternatives.

ILCD handbook. [International Reference Life Cycle Data System Handbook](#). This document provides a basis for consistent, robust and quality-assured environmental LCA studies, as required in a policy and market context

[IC2 Alternatives Assessment Guide](#). This document provides background information on how to conduct an alternatives assessment.

ISO 14044 (2006) [Life Cycle Standards](#) This standard specifies requirements and provides guidelines for life cycle assessment (LCA).

Lowell Center for Sustainable Production. [Alternatives Assessment Framework](#). This resource provides a framework for the assessment of safer chemical, material and product alternatives to chemicals of concern that provides for a decision making process and a set of evaluation modules.

Massachusetts Toxics Use Reduction Institute. [Five Chemical Alternatives Assessment Study](#). This study presents a methodology for assessing alternatives to chemicals of concern based on performance, technical, financial, environmental, and human health parameters.

National Academies (2014), A framework to guide selection of chemical alternatives, <http://www.nap.edu/catalog/18872/a-framework-to-guide-selection-of-chemical-alternatives>

National Institute for Occupational Safety and Health. [Prevention through Design \(PtD\)](#). This website describes the concept of Prevention through Design, a framework for addressing occupational safety and health needs in the design process to prevent or minimize the work-related hazards and risks associated with the construction, manufacture, use, maintenance, and disposal of facilities, materials, and equipment.

Ontario Toxics Reduction Program. [Reference Tool for Assessing Safer Chemical Alternatives](#). This reference tool provides support and guidance for government, industry, and other stakeholders to identify and consider safer alternatives.

PAS 2050 (2011), [Specification for the assessment of the life cycle greenhouse gas emissions of goods and services](#) This publicly available standard (PAS) was developed in response to broad community and industry desire for a consistent method for assessing the life cycle greenhouse gas emissions of goods and services.

U.S. EPA Design for the Environment Program (DFE). [Alternatives Assessments](#). This website describes the key steps to conducting an alternatives assessment.

U.S. EPA Design for the Environment Program (DFE). [Cleaner Technologies Substitutes Assessments](#). This publication presents the methods and resources needed to conduct a Cleaner Technologies Substitutes Assessment (CTSA), a methodology for evaluating the comparative risk, performance, cost, and resource conservation of alternatives to chemicals currently used by specific industry sectors.

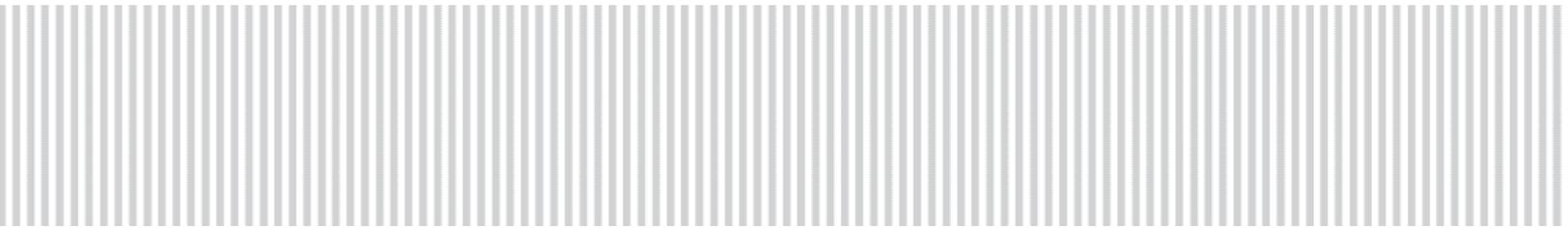
U.S. EPA [Greening Your Purchase of Cleaning Products: A Guide for Federal Purchasers](#). This website highlights guiding principles that provide a framework purchasers can use to make environmentally preferable purchases.

U.S. OSHA [Toolkit for safer chemicals](#). This website presents an overview of the steps involved in alternatives assessment for workplaces and salient resources.

Appendices

Discussion

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Appendix 1 – Required Information for AA Reports

A summary of AA Report contents required by the regulations²⁶.

Executive Summary.

Preparer Information.

- Name and contact information of persons submitting report
- Name and contact information of responsible entities
- Name of other parties involved

Responsible Entity and Supply Chain Information.

- Name and contact information of Responsible Entities
- Name and contact information of manufacturer/importer/distributor
- Name and contact information of direct purchaser
- List and location of retail sales outlets

Priority Product Information.

- Brand Name and Product Name
- Products where component is used (if Priority Product is component)
- Chemical of Concern in Product. Describe role of Chemical of Concern
- Material Safety Data Sheets/ Safety Data Sheets
- Functional, performance, legal requirements, and role of Chemical of Concern in the product

Scope of Relevant Comparison Factors

- Factors for which Priority Product was listed
- Discussion of how relevant factors and associated exposure pathways, life cycle segments were identified.
- Rationale for determination of factors to be not relevant

²⁶ CCR section 69505.7

Scope and Comparison of Alternatives

- Description of alternatives
- Information collected and evaluated to assess potential alternatives
- Rationale for elimination of alternatives from further consideration; describe methods used
- Presentation of data used in evaluation in matrix or other summary format for clear visual comparison

Additionally, for Final AA Report:

- How relevant safeguards provided by federal and California regulatory programs were considered
- Demonstration that the following relevant factors had been evaluated:
 - Adverse impacts and multimedia life cycle impacts
 - Product function and performance
 - Useful life
 - Technical and economic feasibility
 - Economic impacts:
 - Public health and environmental costs
 - Costs to government agencies and non-profit organization
 - Comparison of Internal cost impacts

Methodology.

- Description of analytical tools, models and software, and methodologies that have been used to conduct the AA. Discuss their limitations.

Supporting Information.

- References , sources, and citation of information used to support AA preparation
- Uncertainties in analysis

In addition, for Final AA Report:

- Information that is necessary, but not available, to make an informed decision, validate information used to prepare the AA Report, and address uncertainties.

Selected Alternative(s).*Preliminary AA Report*

- Alternatives selected for further evaluation during the second stage AA
- Rationale for their selection

Abridged AA Report

- Alternatives considered
- Product function and performance for each alternative considered
- Rationale for determination of no feasible alternatives

Final AA Report

- Alternatives selected to replace Priority Product
- Comparative analysis of Priority Product and alternatives
- Product function and performance for selected alternative
- Rationale for decision to select an alternative or not
- As applicable, rationale for retaining Chemical of Concern
- List of known Chemicals of Concern in the selected alternative
- Address applicable information specified in section 69505.7(j)(2)(C)1 through 5.

Work Plan and Implementation*Preliminary Report:*

- Scope and implementation schedule for second stage AA
- Proposed submission date of Final AA Report

Abridged AA Report:

- Due date for the proposed regulatory response

Final AA Report:

- Key milestones and dates for implementing selected alternatives
- Steps to be taken to ensure compliance with federal, state, and local laws
- Implementation plan for any proposed regulatory response

Bibliography/ References

Executive Summary

The Executive Summary must contain sufficient information to convey to the public a general understanding of the scope and results of the AA and the basis for the selection of an alternative, or not. It must be organized in conformance with the format and organization of the AA Report, and include a summary of the information presented in each section of the AA Report. The Executive Summary provides as much information as possible to the public and other interested parties, in a manner that is tailored to those who are not experts in the field. In addition, it must not contain any information for which trade secret protection is claimed.

Preparer Information

AA Reports must include the following information in the event that DTSC needs to contact the responsible entity or its authorized agents:

- The name of, and contact information for, the person submitting the AA Report;
- If applicable, the name of, and contact information for, all responsible entities on whose behalf the AA Report is being submitted; and
- The names of the parties that were involved in funding, directing, overseeing, preparing, and/or reviewing the AA.

Responsible Entity and Supply Chain Information

The AA Report must contain the following information regarding the responsible entity and the rest of the supply chain for the Priority Product:

- The name, contact information, and headquarters location of the manufacturer and importer, if applicable. If the AA Report is prepared on behalf of a consortium of manufacturers or other persons in the product's supply chain, a list of the participants must be provided as well as their corresponding contact information.
- The name of, and contact information for, any persons identified on the Priority Product label as the manufacturer, importer, or distributor.
- The name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the product within the prior twelve (12) months.
- List and location of the manufacturer's and importer's retail sales outlets where the manufacturer and/or importer sold, supplied, or offered for sale the Priority Product in California, if applicable.

Priority Product Information

The AA Report must include information identifying and describing the Priority Product to distinguish the product that is covered by the AA Report from other similar products:

- The brand name(s) and product name(s);
- If the Priority Product is a component of one or more assembled products, a description of the known product(s) in which the component is used;
- Chemical(s) of Concern for the Priority Product;
- Material Safety Data Sheets and/or Safety Data Sheets related to the Priority Product; and
- The Priority Product's functional, performance, and legal requirements, and the role and function of the Chemical of Concern in the product.

Scope of Relevant Comparison Factors

The AA Report must include the factors, and the associated exposure pathways and life cycle segments, determined to be relevant for evaluation and comparison of the Priority Product and its alternatives. The AA Report must also explain the rationale for determining that a factor is not relevant. Provide supporting information for this determination.

Scope and Comparison of Alternatives

The responsible entity must identify and describe the alternatives chosen to be evaluated and compared, and explain the rationale for selecting and screening out specific alternatives at each stage of the alternatives comparison process. For any alternative that is screened out because it is determined that its adverse impacts are equal to or greater than those of the Priority Product, the responsible entity must describe the method used to determine the impacts, including the method used to compare the multiple factors associated with the impacts, and the rationale for any trade-offs made among the factors.

A Preliminary AA Report and Abridged AA Report must include the information collected and the comparison conducted for the Chemical(s) of Concern and the alternative replacement chemical(s). This must include a matrix, or other summary format, that provides a clear visual comparison that summarizes the information collected regarding the relevant adverse impacts, and their associated relevant exposure pathways and life cycle segments, for the Chemical(s) of Concern and each alternative replacement chemical being considered, and the comparative results of evaluating this information.

The Final AA Report must include the information collected and the comparison conducted for the Priority Product and its alternatives, including:

- A matrix, or other summary format, that provides a clear visual comparison that summarizes the information collected regarding the relevant comparison factors, and their associated relevant exposure pathways and life cycle segments, for the Priority Product and each alternative considered, and the comparative results of evaluating this information. This will provide a readily understood format where DTSC and other interested parties can review information presented.
- Identification and description of how any relevant safeguards provided by other federal and California State regulatory programs were considered in the AA.

Methodology

The AA Report must identify and describe the analytical tools, models, and software used to conduct the AA, and discuss any of their limitations. The AA Report must also identify any published methodologies and/or guidelines used, and any deviations from those methodologies and/or guidelines.

Supporting Information

The responsible entity must cite all information used as supporting information to perform the AA and preparation of the AA Reports. The AA Reports must include a brief summary of the information reviewed and considered.

The Final AA Report must identify information that is not currently available but, if it were available, could be used to validate information used and address any uncertainties in the analyses.

Selected Alternative(s)

The Preliminary AA Report must identify and describe the alternatives selected for further evaluation in the second stage of the AA, and explain the rationale for the selection decision.

The Final AA Report must identify and describe the selected alternatives. The description of the selection decision must include an analysis that evaluates and compares the selected alternatives against the Priority Product and a detailed list and explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product. The Final AA Report must also include:

- The product function and performance information for the selected alternative(s). If no alternative is selected, this information must be provided in the Final AA Report or Abridged AA Report, as applicable, for each alternative considered.
- An explanation of the rationale for retaining the Chemical(s) of Concern or using the alternative replacement chemical(s), and one or more selected alternatives retains the Chemical(s) of Concern or uses one or more replacement chemicals.
- A list of all chemicals known, based on available information, to be in the selected alternative(s) that are Chemicals of Concern, that differ from the chemicals in the Priority Product, or that are present in the selected alternative(s) at a higher concentration than in the Priority Product relative to other chemicals in the Priority Product other than the Chemical(s) of Concern. The following information, to the extent available, must be provided for those chemicals:
 - Environmental fate;
 - Hazard trait and environmental and toxicological endpoint information that has not already been provided to the Department under this chapter;
 - Information about the chemical purity, meaning the relative absence of extraneous matter, and identification of known impurities and additives in the chemical;
 - Physicochemical properties; and
 - Substance identification information [see section 69505.7(j)(2)(C)5].

Work Plan and Implementation

PRELIMINARY AA REPORT:

The responsible entity must specify the proposed submission date for the Final AA Report and include a work plan for the second phase AA effort.

FINAL AA REPORT:

The Final AA Report will be submitted to the Department no later than twelve months after the Department issues a notice of compliance for the Preliminary AA Report. It must include a detailed plan for implementing any selected alternative(s). The implementation plan must include key milestones and dates for implementing the selected alternative(s), if applicable, and identify steps that will be taken to ensure compliance with applicable federal, state, and/or local laws. The implementation plan may also include the identification of and implementation plan(s) for any regulatory response(s) that the responsible entity wishes to propose that would best limit exposure to, or reduce the level of adverse impacts or adverse waste and end-of-life effects posed by, any Chemical(s) of Concern or replacement Candidate Chemical(s) that will be in the selected alternative(s) or the Chemical(s) of Concern that is/are in the Priority Product if the decision resulting from the AA is to retain the Priority Product.

Appendix 2 – Data Sources for Identification of Alternatives

- **Ariel WebInsight** (<http://3ecompany.com/products-services/regulatory-research/ariel-webinsight>)
An online chemical regulatory compliance reference product for accessing global EH&S compliance information.
- **CleanGredients®** (<http://www.cleangredients.org/>)
An online database of chemical products used primarily to formulate cleaning products that have been pre-approved to meet the U.S. EPA's Safer Choice Standard.
- **CLEANTOOL Database** (www.cleantool.org)
A Europe-wide database for parts cleaning, metal surface cleaning, component cleaning and degreasing.
- **Green Chemical Alternatives Purchasing Wizard** (<http://ehs.mit.edu/site/content/green-chemical-alternatives-purchasing-wizard>)
A publicly available tool aimed at reducing hazardous waste by replacing hazardous chemicals with greener substitutes. Greener chemicals can be identified by searching by the chemical or process that needs replacing or by known alternative chemicals or processes.
- **Institute for Research and Technical Assistance Reports** (<http://www.irta.us/>)
This website provides links to completed alternatives assessments on a variety of topics.
- **Interstate Chemicals Clearinghouse (IC2)** (<http://theic2.org/>)
This website has database on:
 - **State Chemicals Policy:** a searchable database of passed and pending state-level chemicals legislation
 - **States' Chemicals of Concern:** a searchable database that provides hazards and toxicity characteristics of various states' chemicals of concern.
 - **Chemical Hazard Assessments:** a tool that promotes awareness of assessments conducted on chemicals of high concern by enabling users to search for GreenScreen and Quick Chemical Assessment Tool (QCAT) assessments
- **IUCLID (International Uniform Chemical Information Database)** (<http://iuclid.eu/>)
A software application maintained by the European Chemicals Agency (ECHA) intended to capture, store, maintain and exchange data on intrinsic and hazard properties of chemical substances.
- **Massachusetts Institute of Technology Green Chemical Alternatives Purchasing Wizard** (<http://ehs.mit.edu/site/content/green-chemical-alternatives-purchasing-wizard>)

This database is designed to provide easy and quick access to information about available chemical alternatives to hazardous solvents.

- **Massachusetts Toxics Use Reduction Institute** (<http://www.turi.org/About>)
 - **CleanerSolutions Database.**
(http://www.turi.org/Our_Work/Cleaning_Laboratory/Does_It_Clean/CleanerSolutions_Database)
This database provides information about safer alternatives to hazardous solvents for surface cleaning.
 - **Chemical Databases.**
(http://www.turi.org/Our_Work/Research/Alternatives_Assessment/Databases)
A list of databases on chemical characteristics, preferred products, undesirable materials, and other related databases.
 - **Finding Environmental, Health and Safety Information.**
(http://www.turi.org/Our_Work/Toxic_Chemicals/Finding_Environmental_Health_and_Safety_Information)
Provides links to resources on environmental, health and safety data on chemicals.
 - **Examples of Assessments.**
(http://www.turi.org/Our_Work/Research/Alternatives_Assessment/Examples)
Provides examples of assessments for a variety of chemicals and uses.
- **Pharos Project** (<http://www.pharosproject.net/>)
A database for identifying health hazards associated with building products.
- **Prospector** (<https://www.ulprospector.com/en/na>)
A search engine from UL that offers technical information on products and provides the ability to connect with suppliers.
- **SOLV-DB** (<http://solvdb.ncms.org/>)
A database containing a wide variety of data on solvents. It was developed by the National Center for Manufacturing Sciences (NCMS).
- **SUBSPORT** (<http://www.subsport.eu/>)
An internet portal database that offers information on chemical substitution. It was created to support companies in fulfilling substitution requirements of EU legislation. The website also has a feature that allows one to search multiple related websites and databases outside of SUBSPORT.
- **U.S. EPA Safer Choice Program:**
 - **Safer Chemical Ingredients List** (<http://www2.epa.gov/saferchoice/safer-ingredients>)
A list of chemical ingredients that EPA's Safer Choice Program determined to be safer than traditional chemical ingredients.
 - **Design for the Environment, Alternatives Assessments** (<http://www2.epa.gov/saferchoice/design-environment-alternatives-assessments>)
This website provides links to completed alternatives assessments on a variety of topics.

Appendix 3-1 – List of Factors for Consideration in the Alternatives Analysis

Table 3-1a in this Appendix consists of several tables that summarize the scope of factors required for consideration in the AA. The responsible entity should refer to CCR section 69501.1 and cited references for definitions of the terms used in the tables. In the definitions of the factors contained in CCR section 69501.1, many of the factors are nested within other definitions, and in some instances, other chapters of the California Code of Regulations. In these tables, the highest level of the nested definition begins in the left-hand column of the table, with subsequent detail for each of the definitions in each of the additional columns to the right.

Table 3-1a - Scope of Factors Required for Consideration in the AA

Factor Category	Factors
Life cycle ¹ segments	Raw material extraction
	Resource inputs and other resource consumption
	Intermediate materials production processes
	Product manufacture
	Packaging
	Transportation for all phases
	Distribution
	Use
	Operation and maintenance
	Waste generation and management
	Reuse and recycling
	End-of-life disposal

Factor Main Category	Factor Sub-category	Factors	Subfactors	
Adverse impacts and multimedia life cycle impacts	Adverse environmental impacts ²	Adverse air quality impacts ³	California Toxic Air Contaminants ⁴	
			Greenhouse gases ⁵	Carbon dioxide
				Hydrofluorocarbons
				Methane
				Nitrogen trifluoride
				Nitrous oxide
				Perfluorocarbons
				Sulfur hexafluoride
			Other global warming potential gases ⁶	
			Nitrogen oxides	
			Particulate matter ⁷	
			Stratospheric ozone depletion substances ⁸	
			Sulfur oxides	
		Tropospheric ozone forming compounds ⁹		
		Adverse ecological impacts ¹⁰	on aquatic, avian or terrestrial animal, plant organisms, or microbes	
			on aquatic and terrestrial ecosystems	
		Adverse soil quality impacts ¹¹	Compaction or other structure changes	
			Erosion	
			Loss of organic matter	
			Soil sealing	
		Adverse water quality impacts ¹²	Increase in biological oxygen demand	
			Increase in chemical oxygen demand	
			Increase in temperature	
Increase in total dissolved solids				
Introduction/Increase in California CWA priority pollutants ¹³				
Introduction/ Increase in California CWA pollutants ¹⁴				
Introduction/ Increase in chemicals with MCLs ¹⁵				
Introduction/Increase in chemicals with Notification Levels ¹⁶				
Introduction/Increase in chemicals with public health goals for drinking water under California Safe Drinking Water Act ¹⁷				
Exceedance of an enforceable California or federal regulatory standard relating to the protection of the environment				

Adverse human health impacts ¹⁸	Carcinogenicity
	Developmental toxicity
	Reproductive toxicity
	Cardiovascular toxicity
	Dermatotoxicity
	Endocrine toxicity
	Epigenetic toxicity
	Genotoxicity
	Hematotoxicity
	Hepatotoxicity and digestive system toxicity
	Immunotoxicity
	Musculoskeletal toxicity
	Nephrotoxicity and other urinary system toxicity
	Neurodevelopmental toxicity
	Neurotoxicity
	Ocular toxicity
	Ototoxicity
	Reactivity in biological systems
	Respiratory toxicity
Exceedance of an enforceable California or federal regulatory standard relating to the public health	
Adverse waste and end-of-life effects ¹⁹	Volume or mass generated
	Any special handling needed
	Effects on solid waste and wastewater disposal and treatment
	Discharge to storm drains or sewer adversely affecting wastewater treatment facilities
	Release into the environment
Environmental fate ²⁰	Aerobic and anaerobic half-lives
	Aqueous hydrolysis half-life
	Atmospheric oxidation rate
	Bioaccumulation
	Biodegradation
	Mobility in environmental media
	Persistence
Photodegradation	
Materials and resource consumption impacts ²¹	Renewable resources ²² consumption
	Nonrenewable resources ²³ consumption

Physical chemical hazards ²⁴	Combustion facilitation
	Explosivity
Physicochemical properties ²⁵	Flammability
	Physical state
	Molecular weight
	Density
	Vapor pressure and saturated vapor pressure
	Melting point
	Boiling point
	Water solubility
	Lipid solubility
	Octanol-water partition coefficient
	Octanol-air partition coefficient
	Organic carbon partition coefficient
	Diffusivity in air and water
	Henry's Law constant
	Sorption coefficient for soil and sediment
	Redox potential
	Photolysis rates
	Hydrolysis rates
	Dissociation constants
	Reactivity including electrophilicity

Discussion

Exposure pathways ²⁶	Chemical quantity information ²⁷	Quantities necessary to manufacture the Priority Product			
		Volume/mass placed into stream of commerce in California			
	Exposure factors ²⁸	Market presence of product	Statewide sales by volume		
			Statewide sales by number of units		
			Intended product uses, types, age group of targeted customer base		
		Occurrence or potential occurrence of exposure to Candidate Chemical(s) in product			
		Household and workplace presence of the product			
		Potential exposure to Candidate Chemical(s) in the product during life cycle	Manufacturing, use, storage, transportation, waste, end-of-life management practices and locations of practices		
			Manufactured, stored or transported through California solely for use outside California		
			Intermediate product solely for manufacture of exempted consumer product		
			Types of uses	Household and recreational use	
				Sensitive subpopulation potential use or exposure	
				Workers, customers, clients and members of general public in homes, schools, workplaces or other locations	
			Frequency, extent, level and duration of exposure potential for each use and end-of-life scenario		
		Containment of Candidate Chemical(s) within the product			
Engineering and administrative controls that reduce exposure concerns					
The potential of Candidate Chemical(s) and degradation products to release into and accumulate & persist in the environment					

Additional factors required for the second stage of AA	Product function and performance ²⁹	The principal manufacturer-intended use(s) or applications for the Priority Product
		The functional and performance attributes for the Priority Product
		The applicable legal requirements for the Priority Product
		The useful life of the Priority Product, and that of the alternatives under consideration
		The function and performance of each alternative relative to the Priority Product and other alternatives under consideration
		Whether an alternative exists that is functionally acceptable, technically feasible, and economically feasible
	Economic impacts ³⁰	Public health and environmental costs
		Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality and wildlife
		Internal cost impacts including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs

¹ California Code of Regulation (CCR) section 69501.1(a)(42)

² CCR section 69501.1(a)(4)

³ CCR section 69501.1(a)(2)

⁴ CCR section 69501.1(a)(2)(A). California Toxic Air Contaminants: <http://www.arb.ca.gov/toxics/id/taclist.htm>

⁵ CCR section 69501.1(a)(2)(B)

⁶ As specified in CCR section 69405.4

⁷ As specified in CCR section 69405.7

⁸ As specified in CCR section 69405.8

⁹ As specified in CCR section 69405.1

¹⁰ CCR section 69501.1(a)(3)

¹¹ CCR section 69501.1(a)(7)

¹² CCR section 69501.1(a)(9)

¹³ Under section 303 (c) of the federal Clean Water Act (CWA)

¹⁴ Under section 303(d) of the federal Clean Water Act

¹⁵ The primary Maximum Contaminant Levels (MCL) have been established and adopted under section 64431 or section 64444 of chapter 15 of CCR

¹⁶ As specified under Health and Safety Code section 116455

¹⁷ Commencing with Health and Safety Code section 116270

¹⁸ CCR section 69501.1(a)(6)

¹⁹ CCR section 69501.1(a)(8)

²⁰ CCR section 69501.1(a)(32)

²¹ CCR section 69501.1(a)(45)

²² CCR section 69501.1(a)(45)(B)

²³ CCR section 69501.1(a)(45)(C)

²⁴ CCR section 69501.1(a)(48), as specified in article 6 of chapter 54

²⁵ CCR section 69501.1(a)(49), as specified in section 69407.2

²⁶ CCR section 69505.5(c)(3)

²⁷ CCR section 69505.5(c)(3)(A)

²⁸ CCR section 69505.5(c)(3)(B), as specified in section 69503.3(b)

²⁹ CCR section 69505.6(a)(2)

³⁰ CCR section 69505.6(a)(3)

Appendix 3-2 – Checklists for Identification of Relevant Factors

This Appendix includes several example checklists. Responsible entities may use checklists to present identification of relevant factors during the first stage and second stage of the AA, and to document why certain factors, in conjunction with associated exposure pathways and life cycle segments, are either relevant or not relevant. Substantial supporting information that is not listed on this form should also be presented. The sample questions in this form are intended to encourage thoughtful consideration of factors for comparison. If the responsible entity chooses to use these example checklists in the AA Reports, it should refer to the SCP Regulations for the complete scope of factors required for the AA.

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Table 3-2a - Example Checklist for Identification of Relevant Life Cycle Segments

Life cycle segments to be considered – Changes between the Priority Product and the alternative being considered	Likely to be a relevant life segment that requires further assessment? Yes/No/unknown	If “no”, reason why the certain life segment not relevant.
Would the alternative impact raw materials extraction and processing (e.g., process involved, energy used, resources consumed, and discharge to air/water/soil)?		
Would the alternative impact intermediate materials production processes (e.g., process involved, raw materials used, energy used, resources consumed, and discharge to air/water/soil)?		
Would the alternative impact product manufacture (e.g., process involved, energy used, resources consumed, and discharge to air/water/soil)?		
Would the alternative impact distribution and transportation for all phases (e.g., mode of transportation, energy used, and discharge to air/water/soil)?		
Would the alternative impact use, including operation and maintenance, if applicable (e.g., process involved, energy used, resources consumed, and discharge to air/water/soil)?		

Table 3-2b - Example Checklist for Identification of Relevant Adverse Impacts and Multimedia Life Cycle Impacts Factors

Factors to be considered	Changes between the Priority Product and the alternative being considered	Likely to be a relevant factor that requires further assessment? Yes/No/unknown	If “no”, reason why factors not relevant.
Adverse air quality impacts	Would it bring any changes to emissions of California Toxic Air Contaminants (e.g., Benzene, Cr (VI))?		
	Would it bring any changes to the emissions of greenhouse gases (e.g., CO ₂ , methane) into the atmosphere?		
	Would it bring any changes to emissions of compounds that might lead to ozone formation (e.g., NO _x , CO)		
	Would the product be expected to be burned or subjected to combustion (e.g., butane)?		
	Is the product or any of the alternatives intended to be used in particulate form (e.g., talc)?		
Adverse ecological impacts	Would the product, its constituents, or its likely breakdown products have any acute or chronic toxicity to impact aquatic, avian, or terrestrial animal or plant organisms or microbes?		
	Would it bring changes in population size, reduction in biodiversity, or changes in ecological communities?		
	Would it bring changes to abilities of an endangered or threatened species to survive or reproduce?		

Factors to be considered	Changes between the Priority Product and the alternative being considered	Likely to be a relevant factor that requires further assessment? Yes/No/unknown	If “no”, reason why factors not relevant.
	Would it bring changes to deterioration or loss of environmentally sensitive habitats?		
	Would it bring changes that contribute to or cause vegetation contamination or damage?		
Adverse soil quality impacts	Would it impact soil compaction or other soil structure changes?		
	Would it impact soil erosion?		
	Would it cause the impact of loss of organic matter in soil?		
	Would it cause the effect of soil sealing?		
Water quality impacts	Would the product be expected to enter a Publicly Owned Treatment Works (POTW) through municipal sewage (e.g., personal care products down the drain)?		
	Would the product be expected to directly enter the municipal storm sewer systems (e.g., car wash detergents)?		
	Would it bring any increase in biological oxygen demand within the water system?		
	Would it bring any increase in chemical oxygen demand within the water system?		
	Would it bring any increase in temperature of water systems?		

Factors to be considered	Changes between the Priority Product and the alternative being considered	Likely to be a relevant factor that requires further assessment? Yes/No/unknown	If “no”, reason why factors not relevant.
	Would it bring any increase in total dissolved solids in water systems?		
Public health impacts	Would any discharge/release during life cycle or any of its likely breakdown products exhibit carcinogenicity?		
	Would any discharge/release during life cycle or any of its likely breakdown products exhibit developmental toxicity?		
	Would any discharge/release during life cycle or any of its likely breakdown products exhibit reproductive toxicity?		
	Would any discharge/release during life cycle or any of its likely breakdown products exhibit endocrine toxicity?		
	Would any discharge/release during life cycle or any of its likely breakdown products exceed an enforceable California or federal regulatory standard relating to the protection of public health?		
Waste and end-of-life effects	Would it bring any change to the volume or mass of the waste materials and byproducts generated during the life cycle?		
	Would it need any special handling to mitigate adverse impacts resulted from the waste materials generated during life cycle?		

Factors to be considered	Changes between the Priority Product and the alternative being considered	Likely to be a relevant factor that requires further assessment? Yes/No/unknown	If “no”, reason why factors not relevant.
	Would it bring any change to the ability to reuse or recycle materials resulting from the treatment of solid waste and/or wastewater?		
	Would it bring any change to discharge(s) or disposal(s) to storm drains or sewers that adversely affects operation of wastewater or storm water treatment facilities?		
Environmental fate	Would it bring any change to aerobic and anaerobic half-lives, of the product, its constituents, and/or its likely breakdown products?		
	Would it bring any change to aqueous hydrolysis half-life, of the product, its constituents, and/or its likely breakdown products?		
	Would it bring any change to bioaccumulation, of the product, its constituents, and/or its likely breakdown products?		
	Would it bring any change to biodegradation, of the product, its constituents, and/or its likely breakdown products?		
	Would it bring any change to mobility in environmental media, of the product, its constituents, and/or its likely breakdown products?		

Factors to be considered	Changes between the Priority Product and the alternative being considered	Likely to be a relevant factor that requires further assessment? Yes/No/unknown	If “no”, reason why factors not relevant.
	Would it bring any change to persistence, of the product, its constituents, and/or its likely breakdown products?		
Materials and resource consumption	Would it bring any change to consumption of renewable resources, including solar and wind energy, timber, agriculture and water, throughout the life cycle?		
	Would it bring any change to consumption of nonrenewable resources, including petroleum, coal, metals, minerals and other finite resources, throughout the life cycle?		
Physical chemical hazards	Would any discharge/release during life cycle or any of its likely breakdown products exhibit oxidizing properties that facilitate combustion?		
	Would any discharge/release during life cycle or any of its likely breakdown products exhibit explosivity?		
	Would any discharge/release during life cycle or any of its likely breakdown products exhibit flammability?		
Physico-chemical properties	Would it bring any change to vapor pressure and saturated vapor pressure, of the product, its constituents, and/or its likely breakdown products?		

Factors to be considered	Changes between the Priority Product and the alternative being considered	Likely to be a relevant factor that requires further assessment? Yes/No/unknown	If “no”, reason why factors not relevant.
	Would it bring any change to water solubility and lipid solubility, of the product, its constituents, and/or its likely breakdown products?		
	Would it bring any change to octanol-water partition coefficient and octanol-air partition coefficient, of the product, its constituents, and/or its likely breakdown products?		
	Would it bring any change to sorption coefficient for soil and sediment, of the product, its constituents, and/or its likely breakdown products?		

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Table 3-2b - Example Checklist for Identification of Relevant Adverse Impacts and Multimedia Life Cycle Impacts Factors

Factors to be considered	Changes between the Priority Product and the alternative being considered	Likely to be a relevant factor that requires further assessment? Yes/No/unknown	If “no”, reason why factors not relevant.
Chemical quantity information	Would it change the quantities of the Chemical(s) of Concern or alternative replacement chemicals necessary to manufacture the product?		
	Would it change the quantities of the Chemical(s) of Concern or alternative replacement chemicals placed into the stream of commerce in California?		
Market presence of product	Would it change statewide sales of the product by volume?		
	Would it change statewide sales of the product by number of units?		
	Would it change the intended product use(s), and types and age groups of targeted customer base(s)?		
Occurrence or potential occurrence of exposure	Has the Chemical(s) of Concern or alternative replacement chemical(s) been found in biomonitoring studies?		
	Has the Chemical(s) of Concern or alternative replacement chemical(s) been identified on Toxics Release Inventory (TRI) as a chemical with substantial releases (1 million pounds or 10% of production/importation)?		

Factors to be considered	Changes between the Priority Product and the alternative being considered	Likely to be a relevant factor that requires further assessment? Yes/No/unknown	If “no”, reason why factors not relevant.
Household and workplace presence	Has the Chemical(s) of Concern or alternative replacement chemical(s) been found to be present in household dust, outdoor soil, indoor air, drinking water, or other places of contact?		
	Has the Chemical(s) of Concern or alternative replacement chemical(s) been identified to have occupational health effects?		
Potential exposure	Would there be potential dermal, ingestion, or inhalation contact during the product’s life cycle?		
	When during life cycle could people be exposed to the chemical of concern and what are locations of potential exposures?		
	Is the product sold for household and recreational use?		
	Whether the product is used by sensitive subpopulation, including infants, children, pregnant women, elderly individuals, or sensitive receptors due to history of illness or nature of occupation?		
	Would workers, customers, clients, or the public come in contact with the product or releases from the product in homes, schools, workplaces, or other locations?		

Factors to be considered	Changes between the Priority Product and the alternative being considered	Likely to be a relevant factor that requires further assessment? Yes/No/unknown	If “no”, reason why factors not relevant.
	Would it bring any change to frequency, extent, level and duration of potential exposure for each use scenario and end-of-life scenario?		
	Would it bring any change to engineering and administrative controls that reduce exposure concerns associated with the product?		
	Would it bring any change to the potential of chemicals to accumulate and persist in biological systems or environmental compartment?		

Table 3-2d - Example Checklist for Identification of Additional Relevant Factors in the Second Stage of the AA

Factors to be considered	Changes between the Priority Product and the alternative being considered	Likely to be a relevant factor that requires further analysis? Yes/No/unknown	If “no”, reason why factors not relevant.
Product function and performance	Would it change the useful life of the product?		
	Would it change function and performance the product?		
	Would it change the functional acceptability of the product?		

Factors to be considered	Changes between the Priority Product and the alternative being considered	Likely to be a relevant factor that requires further analysis? Yes/No/unknown	If “no”, reason why factors not relevant.
	Would it change the technical feasibility of the product?		
Economic impacts	Would it change the public health and environmental costs for any relevant exposure pathway or life cycle segment?		
	Would it change the costs to manage waste or oversee environmental cleanup and restoration efforts to governmental agencies and non-profit organizations?		
	Would it change the costs to governmental agencies and non-profit organizations charged with protecting natural resource, water quality, and wildlife?		
	Would it change manufacturing costs?		
	Would it change the marketing costs?		
	Would it change the materials and equipment acquisition costs?		
	Would it change any additional internal or external costs?		

Appendix 3-3 – Potential Information Sources for Identification of Relevant Factors

This Appendix compiles potential information sources for AA practitioners to identify relevant factors, and the associated exposure pathways and life cycle segments. These resources provide a wealth of information from government agencies, as well as industry, academia, nonprofit, international, and other sources. Note that the list included in this Appendix is not meant to be exhaustive, and inclusion of any specific information source on the list does not constitute an endorsement by the Department. AA practitioners should review the additional information on a database or tool to decide if a database or tool fits for purpose by looking at the database or tool website. Given the emerging and evolving nature of AA, it is likely that the Department will periodically update the list (e.g., through future stakeholder consultations and public workshops).

Table 3-3a - Potential Information Sources for Identification of Relevant Factors

Name	Relevant Factors Groups				
	Life Cycle	Hazard	Exposure	Function	Economic
ATSDR (Agency for Toxic Substances and Diseases Registry) Toxicological Profiles Characterization		X	X	X	
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)		X	X		
California Wildlife Biology, Exposure Factor, and Toxicity Database (Cal/Ecotox)		X	X		
CAMEO Chemicals		X	X		
Carcinogenic Potency Database (UC Berkeley/LBNL)		X	X		

Name	Relevant Factors Groups				
	Life Cycle	Hazard	Exposure	Function	Economic
CCRIS (Chemical Carcinogenesis Research Information System)		X	X		
CDC NHANES Biomonitoring Summaries			X		
CHE Toxicant and Disease Database		X			
ChemHAT (Chemical Hazard and Alternatives Toolbox)		X	X		
Chemical Data Access Tool (EPA)		X	X		
ChemIDplus		X			
ChemSpider		X	X		
ChemView		X			
CHRIP (Chemical Risk Information Platform)		X	X		
Comparative Toxicogenomics Database (CTD)		X			
DART/ETIC (Developmental and Reproductive Toxicology/Environmental Teratology Information Center)		X			
DTSC Toxics Information Clearinghouse		X	X		
ECHA Information on Chemicals	X	X	X		
eChemPortal		X			
ECOSAR (Ecological Structure Activity Relationships)	X		X		
ECOTOX Database		X			
Endocrine Disruption Exchange, Inc. (TEDX) List of Potential Endocrine Disruptors		X		X	

Name	Relevant Factors Groups				
	Life Cycle	Hazard	Exposure	Function	Economic
EnviChem (Data Bank of Environmental Properties of Chemicals, Finnish Environment Institute)		X	X	X	
EPA ACToR (Aggregated Computational Toxicology Resource - U.S. EPA)		X	X		
EPA HPVIS (High Production Volume Information Service) Chemical Hazard Characterization		X	X		
EPA PBT Profiler	X	X			
EPA SRS - Substance Registry Services (System)		X	X		
EPI Suite		X			
European Chemicals Agency's Dissemination Portal	X	X	X	X	
GENE-TOX (Genetic Toxicology Data Bank)		X			
GESTIS Substance Database		X	X		
Global Products Strategy (GPS) Chemical Portal		X	X		
Green Chemistry Assistant		X			
Green Screen		X			
Hazardous Chemicals in Schools Database		X	X		
Hazardous Substances Data Bank (HSDB)		X	X		
Haz-Map		X	X		
High Production Volume Information System (HPVIS)		X			

Name	Relevant Factors Groups				
	Life Cycle	Hazard	Exposure	Function	Economic
Household Products Database		X			
HSNO CCID (New Zealand Hazardous Substances and New Organisms Chemical Classification Information Database)		X	X		
Integrated Risk Information System (IRIS)		X	X		
IPCS INCHEM		X	X		
PRIO		X	X		
National Report on Human Exposure to Environmental Chemicals			X		
NICNAS (Australian National Industrial Chemicals Notification and Assessment Scheme)		X			
NIOSH Health Hazard Evaluations		X			
OECD SIDS		X	X		
OSHA Occupational Chemical Database		X	X		
Persistent, Bioaccumulative, and Toxic (PBT) Profiler		X			
Pharos		X			
PubChem		X	X		
Quick Chemical Assessment Tool (QCAT)		X			
RISCTOX		X			
Substitution Support Portal (SUBSPORT)		X		X	X
SIN List and SINMILARITY Tool		X			

Name	Relevant Factors Groups				
	Life Cycle	Hazard	Exposure	Function	Economic
ToxCast Database		X	X		
Toxicity Criteria Database		X			
TOXLINE		X	X		
EIO-LCA	X	X		X	X
NREL U.S. Life-cycle Inventory	X	X			
TRACI	X	X			
BEES	X	X			X
Gabi	X	X		X	X
SimaPro	X	X		X	X
Eco Materials Advisor (Granta)	X	X		X	
Sustainable Minds	X	X			

Appendix 4 – Tools and Methods for Chemical Hazard Assessment

A chemical hazard assessment requires collecting and evaluating all available and relevant information about a chemical. Inherent chemical properties consists of the physical, chemical, fate and material properties of a chemical—for example, the structure, composition, size, and solubility that arise from a particular chemical formulation. These properties may determine how mobile, persistent, or bioavailable the chemical is in the environment. They also influence the ability of a chemical to interact with biological processes that lead to human disease or adverse outcomes in wildlife species. A hazard assessment includes the following:

A. Information gathering and evaluation:

- All relevant available information on the intrinsic or inherent properties of a chemical should be collected, including all human and environmental toxicological information, fate physicochemical properties, and details of its molecular identity (CCR section 69501.1(a)(20)(B)). This includes available existing test data (in vivo or in vitro testing), data generated by non-testing methods [e.g., Quantitative structure activity relationship (QSAR), grouping, read-across, and weight of evidence]] and human epidemiological data. Literature searches for gathering information on hazard/toxicity of chemical alternatives should be comprehensive and reliable to give confidence that potential chemical hazard is characterized properly. Existing data (both experimental and estimated data) may be evaluated for its quality (reliability, relevance, and adequacy) using tools such as the EPA's High Production Volume (HPV) Challenge Program and Organization for Economic Co-operation and Development (OECD) data adequacy guidelines (<http://www.epa.gov/hpv/pubs/general/datadfin.htm>).
- Chemical hazard information can be obtained from: 1) publicly available empirical data about the chemical being evaluated; 2) estimated data from appropriate computer models (e.g., quantitative SAR-based estimations from EPA's predictive models; and 3) in the absence of measured data (in vivo and in vitro), hazard predicted on measured data from a suitable chemical analog.
- Data sources can include primary scientific literature, databanks and databases of compiled data, existing assessments such as Cal/EPA health effects assessments, U.S. EPA assessments (Integrated Risk Information System), publicly available chemical toxicity profiles developed by Health Canada and Environment Canada under the Canadian Environmental Protection Act (CEPA), and agreed data sets such as the Organization for Economic Co-operation and Development (OECD) High Production Volume (HPV) Chemicals Program, and Voluntary Children's Chemical Evaluation Program (VCCEP).

B. Hazard evaluation:

- Identifying the physicochemical hazards (flammability, explosivity, and oxidizing properties) will require evaluating the capacity of the substance to produce a dangerous event (e.g., explosion and/or fire).
- Hazard traits and human health toxicological and environmental endpoints for creating hazard profiles are discussed in Title 22, California Code of Regulations, Chapter 54. Green Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant Data (http://oehha.ca.gov/multimedia/green/pdf/GC_Regtext011912.pdf). These hazard traits are categories of multiple toxic endpoints defined by mode of action (e.g., carcinogenicity), target organ system (e.g., neurotoxicity), susceptible population (e.g., toxicity to domestic animals), and/or components of exposure (e.g., bioaccumulation). The following are the major categories of hazard traits defined in the California Office of Environmental Health Hazard Assessment (OEHHA) Regulations:
 1. Toxicological Hazard Traits- Human Health Effects: carcinogenicity, developmental toxicity, reproductive toxicity, cardiovascular toxicity, dermatotoxicity, endocrine toxicity, epigenetic toxicity, genotoxicity, hematotoxicity, hepatotoxicity, immunotoxicity, musculoskeletal toxicity, nephrotoxicity, neurodevelopmental toxicity, neurotoxicity, ocular Toxicity and respiratory toxicity.
 2. Environmental Hazard Traits: domestic animal toxicity, eutrophication, impairment of waste management organisms, loss of genetic diversity including biodiversity, phytotoxicity, wildlife developmental impairment, wildlife reproductive impairment and wildlife survival impairment.
 3. Exposure Potential Hazard Traits: ambient ozone formation, bioaccumulation, environmental Persistence, global warming potential, lactational or transplacental transfer, mobility in environmental media and particle size or fiber dimension.
 4. Physical Hazard Traits: Combustion facilitation, exclusivity, and flammability.

Methods and Tools for Hazard Assessment:

A number of tools and methodologies are available for conducting hazard evaluation of alternatives at the product, material, and chemical level. The following list describes some of the approaches and tools designed to compare alternatives and, in some cases, provide a decision tool to select a safer alternative. Since the science and toxicological information are subject to change and are continually updated, the newest version of the tools and methods should always be used for HA.

- European Union – REACH: REACH requires that firms wishing to use Substances of Very High Concern (SVHC -Annex XIII) that cannot be adequately controlled must assess suitable alternatives and, if suitable alternatives are available, may prepare a substitution plan. The European Chemicals Agency published Guidance on Alternatives Assessment for Restrictions (Annex XV). REACH regulation calls for comparison of risks, in addition to other attributes including economic feasibility and technical feasibility.
<http://echa.europa.eu/support/guidance;jsessionid=7486850544608729C37A20774C935623.liv>
[e2](#)
- U.S. EPA’s Design for the Environment (DfE) Program Alternatives Assessment Criteria for Hazard Evaluation: The DfE program has developed a methodology for chemicals alternative assessment (CAA) to identify safer alternatives to toxic chemicals. The DfE tool uses existing primary data and predictive computerized modeling to determine human health and environmental hazards of chemical of concern. Life cycle thinking is used to consider chemical hazards throughout manufacture, use and disposal. DfE’s alternative assessment hazard evaluation criteria use hazard thresholds to classify hazards as high, moderate, or low. In assigning a designation of high, moderate, or low hazard, DfE uses the best available experimental data (data generated from U.S. EPA’s Data Adequacy Guidelines) and modeled information. The GHS criteria and data evaluation approach, and EPA risk assessment guidance are applied in the review of dose descriptors (NOAEL/NOAEC and LOAEL/LOAEC).
- DfE’s chemical alternative hazard assessments combine information from five sources, in the following order of preference: (1) publicly available empirical/measured data on the chemical being evaluated; (2) confidential empirical data received at EPA under TSCA regulations; (3) structure–activity relationship (SAR)-based estimations from EPA’s Pollution Prevention Framework and Sustainable Futures predictive methods; (4) professional judgment of EPA staff, often predicated on experimental data for chemical analogues; and (5) confidential empirical data on experimental studies supplied by the chemical manufacturers for the alternatives assessment. CAA is an analytic methodology that requires expertise in toxicology and chemistry to interpret the scientific data.
http://www.epa.gov/dfе/alternative_assessments.html
- Massachusetts Toxics Use Reduction Institute: *Five Chemicals Alternatives Assessment Study*. The Toxic Use Reduction Institute of University of Massachusetts Lowell (TURI) Pollution Prevention Options Analysis System (P2OASys): The TUR Institute developed this systematic tool that assists companies in identifying potential hazards associated with chemicals and processes and helping to choose the alternative that is most protective of worker health and environment. The P2OASys tool provides

numerical hazard scores for a company's current process and identified options, which can then be combined with other information sources and professional expertise to make decisions on adoption of alternatives. Companies input both quantitative and qualitative data on chemical toxicity, ecological effects, and physical properties of the chemical being evaluated and of the potential alternatives. For each hazard category, the tool provides side-by-side comparisons of the data calculated for current processes/chemicals and the potential alternatives. An important distinction of the P2OASys tool is that it does not rank alternatives, but instead provides information that will allow users to make informed decisions for selecting safer alternatives. One unique characteristic of this tool is that it includes data associated with the process in which the chemical is used, to help determine potential occupational exposures. Exposure potential is estimated as low, medium, or high for each alternative. The chemical under evaluation receives a score for each type of hazard that indicates very low to very high risk. P2OASys converts data for each hazard category into a numeric hazard score with the lowest score representing a lower hazard and the highest score representing a higher hazard. Users of this tool must have expertise in occupational and environmental health and in researching chemical databases including toxicological and chemical hazard databases.

[http://www.turi.org/Our Work/Research/Alternatives Assessment/Chemical Hazard Comparison Tools/P2OASys Tool to Compare Materials](http://www.turi.org/Our_Work/Research/Alternatives_Assessment/Chemical_Hazard_Comparison_Tools/P2OASys_Tool_to_Compare_Materials)

- Interstate Chemicals Clearinghouse (IC2): The Guidance was developed through the State's designated Technical Alternatives Assessment Guidance Team, which includes representatives from the seven states who are members of the Interstate Chemicals Clearinghouse. The Guidance is based on the Environmental Protection Agency's (EPA) Design for the Environment (DfE) principles. The IC2 guidance is quite detailed and structured using a modular approach. It covers 11 scoping and assessment modules that assess a number of topics including hazard, exposure, cost and availability, performance, life-cycle concerns, etc. Each module also contains several levels of complexity ranging from a basic assessment to a more complete and technically robust review. The intent behind the guidance is to be flexible enough to meet a wide range of needs by organizations that have very different resources and expertise. It is also intended to be flexible enough to meet a wide range of evaluation needs, as no one method will work in every situation. The guidance document also includes a Decision Module that pulls together all of the individual modules and provides a range of recommended approaches designed to address a variety of needs, from a minimum approach to a preferred assessment with greater requirements.
<http://www.newmoa.org/prevention/ic2/aaguidance.cfm>.
- Stockholm Convention on Persistent Organic Pollutants: The guidance provides a general description of the issues to be considered in identifying and evaluating alternatives to listed persistent organic pollutants and candidate chemicals included in the Stockholm Convention on Persistent Organic Pollutants. <http://www.subsport.eu/substitution-tools/stockholm-convention-alternatives-guidance>.
- Clean Production Action's GreenScreen for Safer Chemicals (GreenScreen): The GreenScreen is a comparative chemical hazard assessment tool that uses the DfE criteria with a scoring system. Like the

DfE CAA method, the GreenScreen tool includes threshold values to determine a hazard level for each hazard trait or toxicological endpoint. The GreenScreen method aggregates criteria and related thresholds into four benchmarks. A set of environmental, safety, and human health criteria exist at each benchmark, and an alternative must meet all the criteria for a given benchmark to qualify for inclusion in that benchmark. GreenScreen hazard criteria and benchmarking system were developed to align with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), OECD testing protocols and the European REACH legislation, while also ensuring that new and emerging science can be incorporated into the hazard assessment process. GreenScreen includes four Benchmarks. Each Benchmark includes a set of criteria that a chemical, along with its known and predicted transformation products, must pass. To progress from Benchmark 1 to Benchmark 2, a chemical (including transformation products) must pass all the criteria specified under Benchmark 1. Likewise, to advance from Benchmark 2 to Benchmark 3, the chemical (and its transformation products) must pass all of the criteria in Benchmark 2, etc. By benchmarking the alternatives, the GreenScreen tool provides a decision framework to identify and screen out the chemicals (and their metabolites/predicted breakdown products) with the least safety, human health, and environmental concern.

<http://www.cleanproduction.org/Greenscreen.php>.

- German Guide on Sustainable Chemicals and Substitution Support Portal (SubsPort): The German Federal Environment Agency has developed criteria for the selection of sustainable chemicals to make it easier for chemical producers, developers and final users to opt for sustainable chemicals. The guide provides a tool for assessing the risks posed by substances step by step and for distinguishing non-sustainable chemicals from sustainable ones. The goal of the SUBSPORT project is to develop an internet portal that constitutes a state-of-the-art resource on safer alternatives to the use of hazardous chemicals. The portal is intended to support companies in fulfilling substitution requirements of EU legislation, such as those specified under the REACH authorisation procedure, the Water Framework Directive, or the Chemical Agents Directive. Furthermore, other stakeholders like authorities, environmental and consumer organizations, as well as scientific institutions will benefit from the portal.
<http://www.subsport.eu/guide-on-sustainable-chemicals> and <http://www.subsport.eu/about-the-project>.
- Quick Chemical Assessment Tool (QCAT): The State of Washington Department of Ecology has developed QCAT, a simplified version of the GreenScreen hazard assessment methodology. It is not intended as a replacement for the GreenScreen, it can be useful to small and medium size companies that find the GreenScreen too complicated and expensive to implement. It can also function as an introduction to the hazard assessment process and has been used to prioritize chemicals for a more detailed review. The QCAT includes detailed information on where to find data and how to interpret what is found. The primary goal of the QCAT is to assign an appropriate grade to a chemical using both a refined group of high priority hazard endpoints identified in the EPA's Design for the Environment (DfE) Program and fewer data sources. A copy of QCAT can be found at the following website:

<http://www.ecy.wa.gov/programs/hwtr/chemalternatives/documents/QCAT2012-03-20final.pdf>.

- U.S. EPA Screening-Level Tools: The U.S. EPA has developed a series of screening-levels models and tools for evaluating the safety of existing and new chemicals. These tools are developed as part of EPA's Sustainable Futures Initiative to assist chemical developers to evaluate toxicity of the chemicals in the design phase and find safer substances if hazards are identified. Most of these tools require knowledge of toxicology and chemistry <http://www.epa.gov/opptintr/sf/tools/methods.htm>. These tools include:
 - Analog Identification Methodology (AIM): An on-line tool to identify publicly available experimental data on structurally related chemicals to help users determine the potential hazards of untested chemicals.
 - EPI Suite: A software program that provides screening-level estimates of physical/chemical properties and environmental fate properties.
 - PBT Profiler: An online tool that screens chemicals for their potential to persist, bioaccumulate and be toxic to aquatic life
 - Oncologic: A software program designed to predict the potential cancer causing effects of a chemical by applying Structure Activity Relationship (SAR) analysis
 - Non-Cancer Screening Protocol: A five step process for screening chemicals for non-cancer health effects in the absence of data.
 - ECOSAR: A software program that predicts toxicity of industrial chemicals released into water to aquatic life. The model estimated acute and chronic toxicity by using SAR analysis.

Selected Data Sources for Collecting and Evaluating Chemical Data

European Chemical Agency (ECHA) <http://echa.europa.eu/information-on-chemicals>

OECD eChem Portal http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en

An internet gateway with information about properties of chemicals, hazard and risk assessments

National Library of Medicine [NLM] Toxicology Data Network (TOXNET) <http://toxnet.nlm.nih.gov/index.html>

A compilation of 13 toxicology-related databases maintained by NLM. TOXNET includes several databases on toxicology, hazardous chemicals, environmental health and toxic releases curated from open literature including ChemIDPlus, HDSB and CCRIS (listed below).

PubChem Substance database <http://pubchem.ncbi.nlm.nih.gov> Identifies the chemical structures of small organic molecules and information on their biological activities including pharmacology, biomedical effects and toxicity, environmental fate and exposure potential, biomolecular interactions and pathways biological test results monitoring and analysis methods, literature, safety and handling.

National Toxicology Program (NTP) <http://ntp.niehs.nih.gov>

U.S. EPA High Production Volume Information System (HPVIS) <http://www.epa.gov/hpvis>

Toxicity Reference Database (ToxRefDB) <http://www.epa.gov/NCCT/toxrefdb>

Integrated Risk Information System (IRIS): Data from the EPA in support of human health risk assessment, focusing on hazard identification (carcinogen classifications) and dose-response assessment (oral RfDs, inhalation concentrations & slope factors). Over 500 chemical records.

U.S. EPA Aggregated Computational Toxicology Resource (ACToR) <http://actor.epa.gov> ACToR is EPA's online warehouse of publicly available chemical toxicity data. ACToR comprises five interacting databases: core ACToR (chemical identifiers and structures, and summary data on hazard, exposure, use, and other domains), DSSTox, ToxRefDB, ExpoCastDB and ToxCastDB.

Carcinogenic Potency Database (CPDB) <http://potency.berkeley.edu> It is a compilation of data on chemical carcinogens compiled from NTP reports and the open literature. The CPDB provides access to the bioassay literature, with qualitative and quantitative analyses of both positive and negative experiments that have been published over the past 50 years in the general literature through 2001 and by the National Cancer Institute/National Toxicology Program through 2004.

Chemical Carcinogenesis Research Information System (CCRIS). It has carcinogenicity and mutagenicity information on over 8000 chemicals. Data provided by the National Cancer Institute (NCI). Over 9,000 chemical records <http://www.nlm.nih.gov/pubs/factsheets/ccrisfs.html>.

Pubmed <http://www.ncbi.nlm.nih.gov/pubmed/>

Catalogue of Somatic Mutations in Cancer (COSMIC)
<http://www.sanger.ac.uk/resources/databases/cosmic.html>

Gene-Tox: genetic toxicology data bank. Peer-reviewed genetic toxicology test data
<http://toxnet.nlm.nih.gov/newtoxnet/genetox.htm>.

Distributed Structure-Searchable Toxicity (DSSTox) <http://www.epa.gov/ncct/dsstox> - *Structure Searchable*

Chemical Effects in Biological Systems (CEBS) <http://cebs.niehs.nih.gov>

Comparative Toxicogenomics Database (CTD) <http://ctd.mdibl.org>. Elucidates molecular mechanisms by which environmental chemicals affect human disease. Data describing the relationship between chemicals, genes and human diseases.

Epigenome database <http://www.epigenome.org/>

International HapMap Project (HapMap) <http://hapmap.ncbi.nlm.nih.gov/abouthapmap.html>

International Cancer Genome Consortium (ICGC) <http://www.icgc.org/>

Databank of Environmental Properties of Chemicals (EnviChem)
<http://www.ymparisto.fi/default.asp?contentid=141944&lan=en>

Hazardous Substances Data Bank (HSDB): Peer-reviewed studies covering a broad scope of human and animal toxicity, safety and handling, environmental fate, physical properties, manufacturing /use, synonyms and more. HSDB is peer-reviewed by the Scientific Review Panel (SRP), a committee of experts in the major subject areas within the data bank's scope. Over 5000 individual chemical records
<http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB>.

U.S. EPA Substance Registry System- Regulatory listings of Chemicals

http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/substancesearch/search.do

(Q)SAR models <http://www.oecd.org/env/ehs/oecdquantitativestructure-activityrelationshipsprojectqsars.htm>

DART: Developmental and Reproductive Toxicology and Environmental Teratology Information Center - literature on developmental and reproductive toxicology

<https://nsdl.oercommons.org/courses/developmental-and-reproductive-toxicology-and-environmental-teratology-information-center-database>.

ChemIDPlus: ChemIDPlus covers much more than just test data, including chemical synonyms, structures, authoritative hazard listings and regulatory list information, physical properties and links to other databases containing information about the chemicals. It also has classification codes that may be useful in functional use work. Over 390,000 chemical records <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>.

International Toxicity Estimates for Risk (ITER): Chronic human health risk values and cancer classifications for over 680 chemicals of environmental concern from multiple organizations worldwide. A product of the Cincinnati based Toxicology Excellence for Risk Assessment, it presents chemical risk information from authoritative groups worldwide, including the U.S. Environmental Protection Agency, the U.S. Agency for Toxic Substances and Disease Registry, Health Canada, the Dutch National Institute of Public Health and the Environment, the International Agency for Research on Cancer, as well as independent parties whose risk values have undergone peer review <http://www.tera.org/iter/>.

ChemHat (Chemical Hazard and Alternatives Toolbox): Occupational health database designed for health and safety professionals and for consumers seeking information about the health effects of exposure to chemicals and biologicals at work. Haz-Map links jobs and hazardous tasks with occupational diseases and their symptoms, Haz-Map shows diseases linked to each agent and agents linked to each disease. Information from textbooks, journal articles, Documentation of the Threshold Limit Values (published by ACGIH), and electronic databases such as NLM's Hazardous Substances Data Bank is classified, summarized, and regularly updated to create the database <http://chemhat.org/>.