Alternative Analysis Guide

Version 1.1

DEPARTMENT OF TOXIC SUBSTANCES CONTROL
SAFER PRODUCTS AND WORKPLACES PROGRAM
July 2020

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.

Version Update

Date	Version	Affected section(s)	Description
7/1/2020	1.1	Entire document	Document format was modified to meet ADA accessibility standards

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Acronyms

22 CCR	Title 22 of the California Code of Regulations
AA	Alternatives Analysis
BAHY	biodiversity adjusted hectare years
CMR	carcinogen, mutagen, or reproductive toxicant
CO	carbon monoxide
CO_2	carbon dioxide
DALY	Disability Adjusted Life Year
DTSC	Department of Toxic Substances Control
DfE	Design for Environment*
EC	European Commission
ECHA	European Chemicals Agency
ECOSAR	Ecological Structure Activity Relationships
EIO-LCA	Economic Input Output Life Cycle Assessment
EpiSuite	Estimation Program Interface Suite™
GHG	greenhouse gas
GWP	global warming potential
GREET	Greenhouse gases, Regulated Emissions, and Energy use in Transportation Model

* *Now known as Safer Choice, United States Environmental Protection Agency*

ISO	International Organization for Standardization
ISTAS	Union Institute of Work, Environment and Health (Spain based)
LCA	Life Cycle Assessment
LCCA	Life Cycle Cost Accounting
LCI	Life Cycle Inventory
LCIA	Life Cycle Impact Assessment
LFGE	Landfill Gas to Energy
MSW-DST	Municipal Solid Waste – Decision Support Tool
NAS	National Academy of Sciences
NH_3	ammonia
NMVOC	non-methane volatile organic compound
NOx	nitrogen oxides
NPO	non-profit organization
NREL	National Renewable Energy Laboratory
OECD	Organization for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
PBT	persistent bioaccumulative toxicants
PM	particulate matter
QSAR	quantitative structure activity relationship
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006

SCP	Safer Consumer Products
SEA	Socio-Economic Analysis
SO_2	sulfur dioxide
TRACI	Tool for Reduction and Assessment of Chemicals and other environmental Impacts
US EPA	United States Environmental Protection Agency
VOC	volatile organic compound
VSLY	value of a statistical life year
WRATE	Waste and Resource Assessment Tool for the Environment

Glossary

Any words shown in italics are defined in the Chapter 54 Green Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant Data, Title 22, California Code of Regulations (22 CCR) or Chapter 55 Safer Consumer Products regulations, 22 CCR.

Alternative[1]: means any of the following:

- Removal of Chemical(s) 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 Chemical(s) of Concern in the Priority Product;
- Redesign of a Priority Product and/or manufacturing process to reduce or restrict potential exposures to Chemical(s) of Concern in the Priority Product; or
- Any other change to the Priority Product or a manufacturing process that reduces the potential adverse impacts and/or potential exposures associated with the Chemical(s) of Concern in the Priority Product, and/or the potential adverse waste and end-of-life effects associated with the Priority Product.

Alternatives Analysis **(AA)**[2]: An evaluation and comparison of a Priority Product and one or more alternatives to the product under Article 5.

Alternatives Assessment: a process for identifying and comparing potential chemical and non-chemical alternatives that can replace chemicals or technologies of concern based on their hazards, performance, and economic viability.

Benefit Cost Analysis (BCA): A BCA evaluates the benefits of alternatives and the associated costs. It answers the question of whether the benefits are sufficient for the gainers to potentially compensate the losers (EPA, 2010).

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[1] *Title 22, California Code of Regulations (22 CCR): Chapter 55. Safer Consumer Products section 69501.1(a)(10)*

[2] *22 CCR section 69501.1(a)(11)*

Data: The term "data" is used interchangeably with the term "information" or "reliable information" throughout the Guide. For the purposes of this Guide, the term "data" does not mean the generation of new data or scientific studies. The term "data" is used to describe existing information or the analysis of existing information.

Department: The Department of Toxic Substances Control.

Exposure: The contact between a chemical and a human or ecological receptor for a specific duration of time. Exposure occurs by contact with a chemical through various exposure media (air, water, soil, and food) via exposure routes (inhalation, ingestion, and dermal contact).

Exposure Assessment: Exposure assessment is the process of estimating or measuring the magnitude, frequency, and duration of exposure to an agent, along with the number and characteristics of the population exposed. Ideally, it describes the sources, pathways, routes, and the uncertainties in the assessment.

Exposure Factor[3]: As used in this Guide, this term is associated with potentially relevant factors used to compare a Priority Product with alternatives. It 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 formed the basis for prioritization 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 Pathway: The route a stressor takes from its source to its human or ecological receptor. An exposure pathway is associated with potentially relevant factors used to compare the Priority Product with the alternatives.

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

Green Chemistry (DTSC, 2008): The design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances and toxic chemicals.

Hazard: Generally, in the Alternative Assessment or Risk Assessment framework, hazard usually refers to an intrinsic property of a substance, activity or risk source that enables it to cause harm.

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[3] *22 CCR section 69503.3(b)*

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

Hazard Traits[4]: Properties of chemicals that fall into broad categories of toxicological and environmental exposure potential, and physical hazards that may contribute to adverse effects in exposed humans, domesticated animals, wildlife, or in ecological communities, populations, or ecosystems.

Life Cycle[5]: 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 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, intermediate materials production processes, product manufacture, packaging, transportation, use, operation and maintenance, reuse and recycling, and end-of-life disposal.

Life Cycle Thinking: A decision-support approach in manufacturing or product design 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: An uncertainty analysis technique that approximates the probability of certain outcomes by modeling multiple trial runs, called simulations, using random variables.

Multi-Criteria Decision Analysis (MCDA): A decision-making 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 the decision-making process.

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[4] *Hazard traits as specified in Chapter 54 Green Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant Data, 22 CCR.*

[5] *22 CCR section 69501.1(a)(42)*

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 intended functions. Manufacturers and users set performance requirements either qualitatively or quantitatively.

Physicochemical Properties[6]: Properties of chemicals that 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[7]: The functional, performance, and legal requirements of a product.

Quantitative Structure-Activity Relationship Models: Usually referred as QSARs, are mathematical models that can be used to predict in a quantitative manner the physicochemical, biological (e.g., toxicological), and environmental fate properties of chemicals from a knowledge of their chemical structure.

Read-Across: A technique to predict endpoint information (e.g., physicochemical properties, toxicity, environmental fate, and ecotoxicity) for one chemical based on data associated with 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 chemical in the product throughout its life cycle.

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[6] *22 CCR section 69407.2*

[7] *22 CCR section 69505.5(a)*

Release[8]: An intentional or unintentional liberation, emission, or discharge of a chemical into the environment.

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 chemical stressors. 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 possibility of various outcomes of an analysis to changes in initial conditions or scenarios (i.e., combinations of parameters).

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 specific parameter results in relatively large changes in the outcomes, the outcomes are said to be sensitive to that parameter.

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. Under the REACH* authorization procedure, a SEA is a compulsory part of an application for authorization whenever the risks to human health or the environment from the use of a substance are not adequately controlled.

Uncertainty Analysis: A systematic qualitative or quantitative 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 considered in communicating the outcome.

[8] *22 CCR section 69501.1(a)(56)*

Introduction

California's Safer Consumer Products (SCP) program challenges responsible entities to reduce or eliminate toxic chemicals in the products consumers buy and use. The SCP regulations (DTSC, 2013) establish innovative approaches for both 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 framework regulations are structured to avoid regrettable substitutes, where one harmful chemical is removed from a product only to have it replaced by another harmful chemical. The structure also provides a transparent process with extensive opportunity for stakeholder input and review of manufacturer and Department decisions.

The regulations require a four-step process for evaluating chemicals in products, assessing potential alternatives, and determining how best to limit the potential for harm.

1. Chemicals – The Department identifies chemicals which are potentially hazardous based on the work of authoritative bodies around the world. These are called Candidate Chemicals and may raise serious environmental or health concerns and, in some cases, may present risk of injury to health or the environment.

2. Products – The Department evaluates and prioritizes product-Candidate Chemical combinations to develop a list of Priority Products for which a safer alternative should be sought. The Department must adopt Priority Products via rulemaking to trigger Steps 3 and 4.

3. Alternatives Analysis (AA) – The regulations require responsible entities (manufacturers, importers, assemblers, and retailers) to notify the Department if their product is a Priority Product and to perform an AA to identify, evaluate and compare one or more alternatives to the Priority Product.

4. Regulatory Responses – The Department shall seek to maximize the use of alternatives of least concern when such alternatives are functionally acceptable, technically feasible, and economically feasible. In selecting regulatory responses, the Department shall give preference to regulatory responses providing the greatest level of inherent protection.

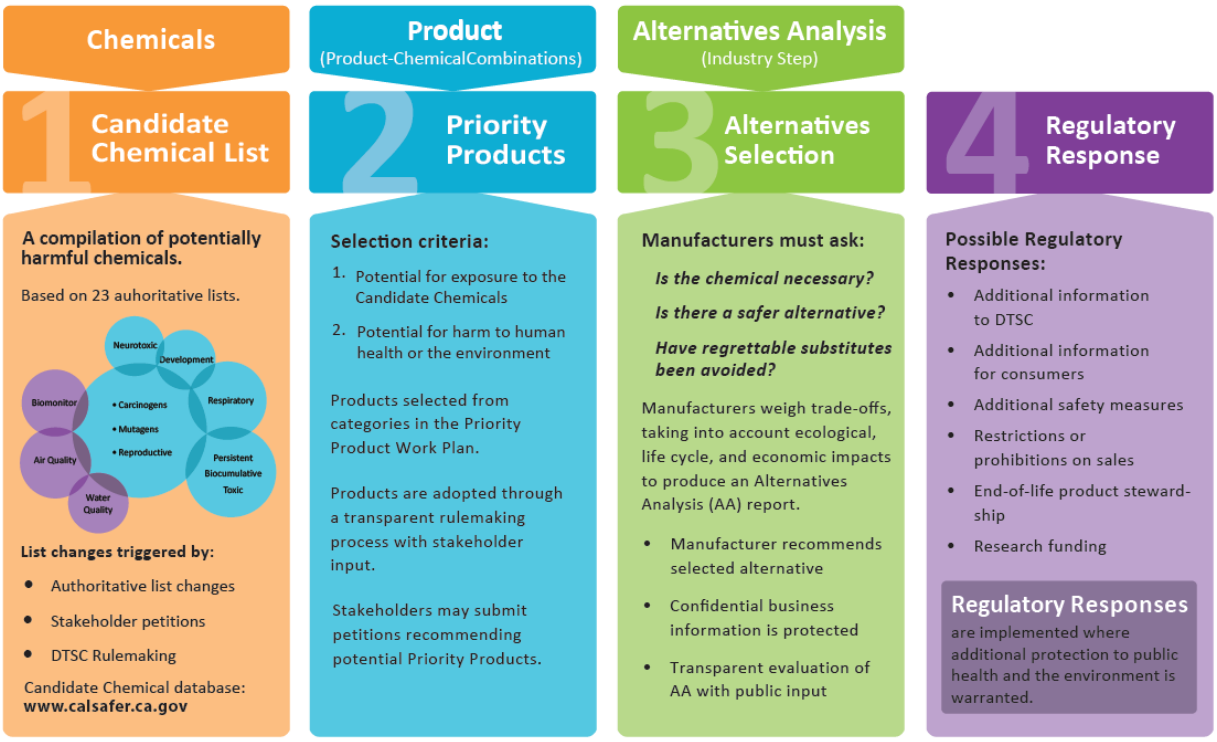

Figure I-1 Major Elements of SCP Regulations

With some exceptions[9], responsible entities for the Priority Product shall conduct an Alternatives Analysis once the Department lists a Priority Product through the rulemaking process. The SCP approach requires an Alternatives Analysis[10] (AA) that considers important impacts of the product throughout its 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 AA and meet the regulatory requirements.

Please note: Before consulting the Guide, the reader should review and be familiar with the Safer Consumer Products regulations in California Code of Regulations, Title 22, sections 69501 through 69510, and 69511 through 69599.

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[9] *22 CCR section 69505.1(a)*

[10] *In the Safer Consumer Product regulations, the term "Alternatives Analysis (AA)" 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.*

Background

When toxic chemicals contained in products present potential harm to consumers or the environment, manufacturers or regulatory agencies typically address the harm on a case-by-case basis and occasionally ban the use of a specific 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 lead to a regrettable substitution. A comprehensive AA with a broad scope will consider a wide variety of effects and avoid shifting the problem from one segment 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 life cycle segments like product design, product manufacturing, and the product's end-of-life management. Considering effects from a life cycle perspective helps manufacturers to create products that are benign by design and that avoid unintended consequences from the outset.

Example of 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.

The Department affirmed this shift in focus when it adopted the 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 AA process to evaluate potential alternatives.

Application of the Guide

The purpose of this guidance document (Guide) is to provide useful approaches, methods, resources, and tools for AAs. 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 the 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.

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 to help AA analysts, preparers, practitioners, and responsible entities by providing methods, tools, information sources, and best practice approaches to help conduct AA. As information about products, chemicals, alternatives, and available data expands over time, future updates of the Guide are likely to highlight more specific details.

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 AAs.
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 geographic location, company size, or product type. Therefore, not all 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, the responsible entity 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 situation. A credible third party may help responsible entities perform or review all or part of the analysis.

When performing an AA, the 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 AAs, the responsible entity 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 – Ensure the assumptions, methods, and data are consistently applied throughout all steps of the AA to support internal consistency and comparability with similar analyses.

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

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 group for data sharing, alternatives assessment and communities of practice. 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. The commons principles complement SCP tenets and are consistent with the goals for the AAs in the SCP regulations. Responsible entities may find these guiding principles helpful when conducting 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 regarding 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.

Confidential Business Information

Responsible entities may wish to assert a claim of trade secret protection with respect to some of the information they are submitting to the Department in their AA documents. The process for asserting this protection is discussed in detail in Article 9 of the SCP regulations. CalSAFER, a data management system maintained by the Department where responsible entities will submit their AA reports, will allow responsible entities to indicate if a submittal contains trade secret information. When that option is selected, CalSAFER will prompt the responsible entity to submit a redacted and unredacted copy of the document and to provide substantiation for the supporting information requested in section 69509(a)(1)-(12). The same substantiation may apply to multiple documents, and the responsible entity should simply use the same information when appropriate. The Department will protect confidential and trade secret information from disclosure to the public if the claim has been properly supported.

The Department will review a trade secret claim and the supporting information for compliance with the requirements of Article 9 when there is a request for disclosure of the information, or at its own discretion. If the Department determines that the information provided in support of a trade secret claim is incomplete or insufficient to support the claim, the Department will not automatically release the information. As described in section 69509.1, the Department will notify the submitter of the determination and identify the specific area(s) for which additional information is needed. If after allowing for submittal of additional information the Department still does not believe it has sufficient information to support a claim, the submitter is given 30-day notice of the Department's intent to release the information. During this time, the submitter may seek judicial review by filing an action for a preliminary injunction and/or declaratory relief. If such review is sought, the Department will not release the information until full resolution of any court challenge.

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 subsequent chapters address specific 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 is a 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 approaches 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 of Alternatives. This chapter presents approaches the responsible entity may use to narrow the list of alternatives that will be thoroughly evaluated in the second stage of the AA.

Chapter 6 Exposure. This chapter describes methods and approaches for collecting information about exposure estimates, exposure-related data sources, and models.

Chapter 7 Life Cycle Impacts. 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 Impacts. This chapter describes the economic analysis needed for the second stage of the AA and methods for collecting and evaluating the needed economic information.

Chapter 9 Informational Needs in AA. This chapter presents approaches to collecting data and addressing data gaps. It also describes ways to evaluate and address uncertainties to support decision-making.

Chapter 10 Selection of Alternatives. 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 Self-Evaluation of AA. This chapter presents a selection of indicators the responsible entity may use to consider the merit and rigor of the information in the AA. It also presents a general evaluation approach the responsible entities may use to evaluate their AAs before submitting the AA Reports to the Department.

Chapter 1 — AA Framework

Figure 1-1 AA Process in the SCP Regulations

This chapter presents the AA framework outlined in Article 5 of the SCP regulations. 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.

1.1 AA Planning

Before undertaking an AA, the responsible entity should perform an initial planning step to identify and coordinate the resources and expertise needed and obtain management support. An 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 skills, experience, and knowledge needed to conduct the AA, such as employees able to provide and evaluate process data, toxicological studies, exposure and risk assessment, engineering and design, project management, technical feasibility, and economic analyses. A responsible entity may hire technical consultants to supplement in-house expertise (TURI, 2011). Any responsible entity, particularly small and medium-sized enterprises (SMEs), may also choose to work with their trade associations or establish a consortium to conduct an AA collectively.

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. (22 CCR section 69501.1(a)(60))

1.2 Two Stage AA Framework

Although the AA framework specifies the elements that the responsible entity must include in the analysis and reports, the methods, approaches, and actions for completing those elements remain flexible. However, 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 the specified, required elements.

To help responsible entities develop an appropriate scope for the AA, the regulations break the analysis down into a two-stage process.

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

- chemistry
- toxicology
- environmental fate & transport
- exposure and risk assessment
- environmental and occupational health & safety
- process engineering
- life cycle thinking and life cycle assessment
- environmental economics
- financial and economic analysis
- public health
- green chemistry
- marketing

During the first stage AA, the responsible entity identifies the goal, scope, legal, functional, and performance requirements of the Priority Product and the Chemical of Concern[11] 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 alternative replacement chemicals that have equal to or greater adverse impacts than the Chemical of Concern.

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 (22 CCR section 69501.1(a)(60)). Chapter 3 of this Guide presents an extensive discussion of relevant factors.

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. Table 1-1 outlines the steps in the first stage AA.

Table 1-1 First Stage AA Process

First Stage AA Steps	Considerations
Step 1: Identify Product Requirements & Function of Chemicals of Concern	• 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, if appropriate
Step 2.: Identify Alternatives	• Identify and consider a broad range of alternatives • Research and evaluate information about existing possibly viable alternatives

[11] *A Chemical of Concern is a Candidate Chemical (identified under 22 CCR section 69502.2) that has been identified as the basis for prioritization a product-chemical combination as a Priority Product.*

First Stage AA Steps	Considerations
Step 3.: Identify Factors Relevant for Comparing Alternatives	• 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	• 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	• May consider other second stage factors such as economic impacts
Step 6.: Preliminary AA Report	• Include AA Work Plan for second stage • See Appendix 1

During the second stage AA (see Table 1-2), the responsible entity follows the approved work plan to compare the Priority Product with the alternatives still under consideration using 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 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 deciding about any applicable regulatory responses. Appendix 1 contains descriptions of the required contents of AA Reports.

Table 1-2 Second Stage AA Process

Second Stage AA Steps	Considerations
Step 1.: Identify Factors Relevant for Comparing Alternatives	• Re-evaluate relevant factors identified in first stage • Consider required relevant factors: • Adverse impacts and multimedia life cycle impacts • Product function and performance • Economic Impacts: • Public health and environmental cost • Cost to government agencies and non-profit organizations • Internal cost
Step 2.: Compare the Priority Product & Alternatives	• 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	• May consider other pertinent information
Step 4.: Alternative Selection Decision	• Select alternative • Support with comparative analysis (step 2 & step 3)
Step 5.: Final AA Report	• See Appendix 1

The SCP two-stage AA framework has some unique characteristics when compared to other alternatives assessments framework:

- considers a broad range of alternatives, and does not limit alternatives to only chemical replacement
- covers comprehensive adverse impacts and multimedia life cycle impacts

- evaluates both external and internal cost impacts
- does not mandate that responsible entities to generate new data during the AA process

Figure 1-2 below shows the steps in the two- stage 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, identifying the relevant factors (Chapter 3) will be a key to the assessment and analysis steps in both stages of the AA, and information needs (Chapter 9) apply throughout the AA.

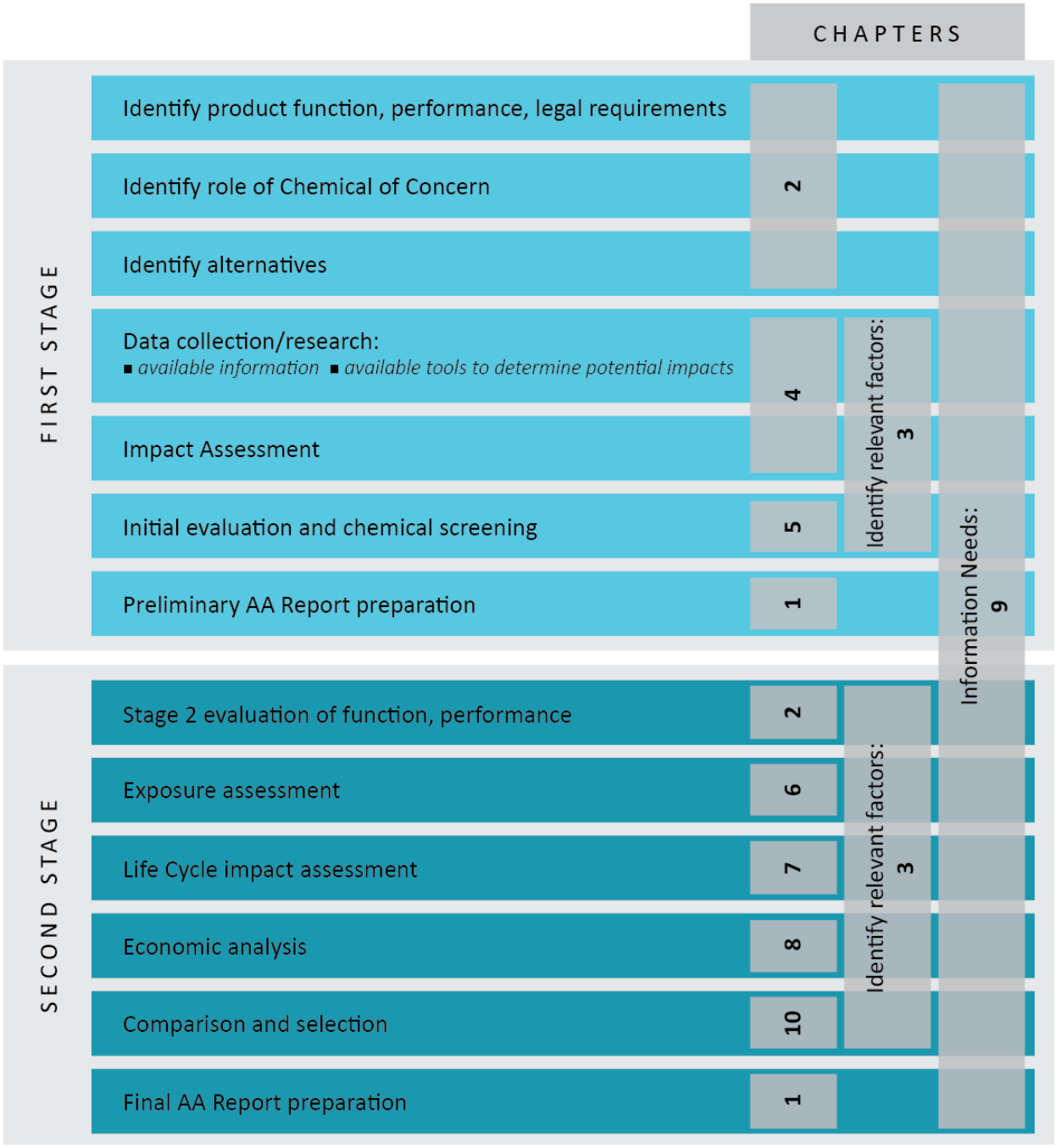

Figure 1-2 Steps in the AA Process with Corresponding Guide Chapters

1.3 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 elect to continue under a separate option. However, changing options does not extend the due date of the AA.

ABRIDGED AA

An Abridged AA 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. More specifically, the responsible entity must identify the factors that are relevant for comparison of the Priority Product and any alternatives (i.e., chemical adverse impacts, exposure pathways, life cycle segments, product function and performance, and economic impacts) and document why the alternatives under consideration are not functionally acceptable and technically feasible. 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. Table 1-3 shows the steps in the Abridged AA and how the first four steps for the Abridged AA are the same as for a first stage AA.

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.

Table 1-3 Abridged AA Process

Abridged AA Steps	Considerations
Step 1.: Identify Product Requirements and Function of Chemicals of Concern	• 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	• Identify and consider a broad range of alternatives • Research and evaluate information about existing possibly viable alternatives
Step 3.: Identify Factors Relevant for Comparing Alternatives	• 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	• Compare Priority Product and alternatives by considering relevant factors • Identify viable alternatives • May eliminate alternatives posing greater adverse than Chemical of Concern
Step 5.: Consider Additional Information	• May consider economic impacts • May consider other relevant information
Step 6.: Abridged AA Report Preparation	• Must have the required elements of an AA Report • Must include an implementation plan for proposed regulatory response[12]

[12] *At a minimum, implementation plan shall address the two required regulatory responses: 1) product information for consumers under 22 CCR section 69506.3, and 2) a research and*

ALTERNATE PROCESS AA

A responsible entity may use an analytical process different from the two-stage AA process if the alternate process—hence Alternate Process AA – contains all the substantive requirements specified in the regulations. When using an Alternate Process AA, the 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 in regulation). The Alternate Process AA 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 Alternate Process AA 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 the Department.

PREVIOUSLY COMPLETED AA

Instead of performing a new AA and submitting Preliminary and Final AA Reports, the 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 it with all missing information specified in the two-stage AA process.

1.4 Regulatory Responses

When the responsible entity completes the AA process and submits all 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 one or more regulatory responses are needed. In selecting and requiring regulatory responses, the Department will maximize the use of alternatives of least concern to protect public health and the environment when such alternatives are functionally acceptable, technically feasible, and economically feasible. The Department will give preference to the regulatory responses that provide the

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development project for the advancement of green chemistry and green engineering under section 69506.8.

greatest level of inherent protection through redesign rather than administrative or engineering controls to limit exposure.

The type of regulatory response for a given situation will depend on the specific circumstances of the analysis. For example, if the 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. Table 1-4 lists the regulatory responses included in Article 6 of the SCP regulations with summaries of the applicable situations. The SCP regulations provide a detailed process specifying the determinations the Department will make and information the responsible entity must provide including reports and notifications for each of the regulatory responses.

Table 1-4 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.

Regulatory Response	Applicability
Product Sales Prohibition	To address a situation when a known safer, viable alternative exists, yet 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.
No Regulatory Response	The Department has deemed that a regulatory response is not necessary to further protect public health and the environment.

1.5 Summary

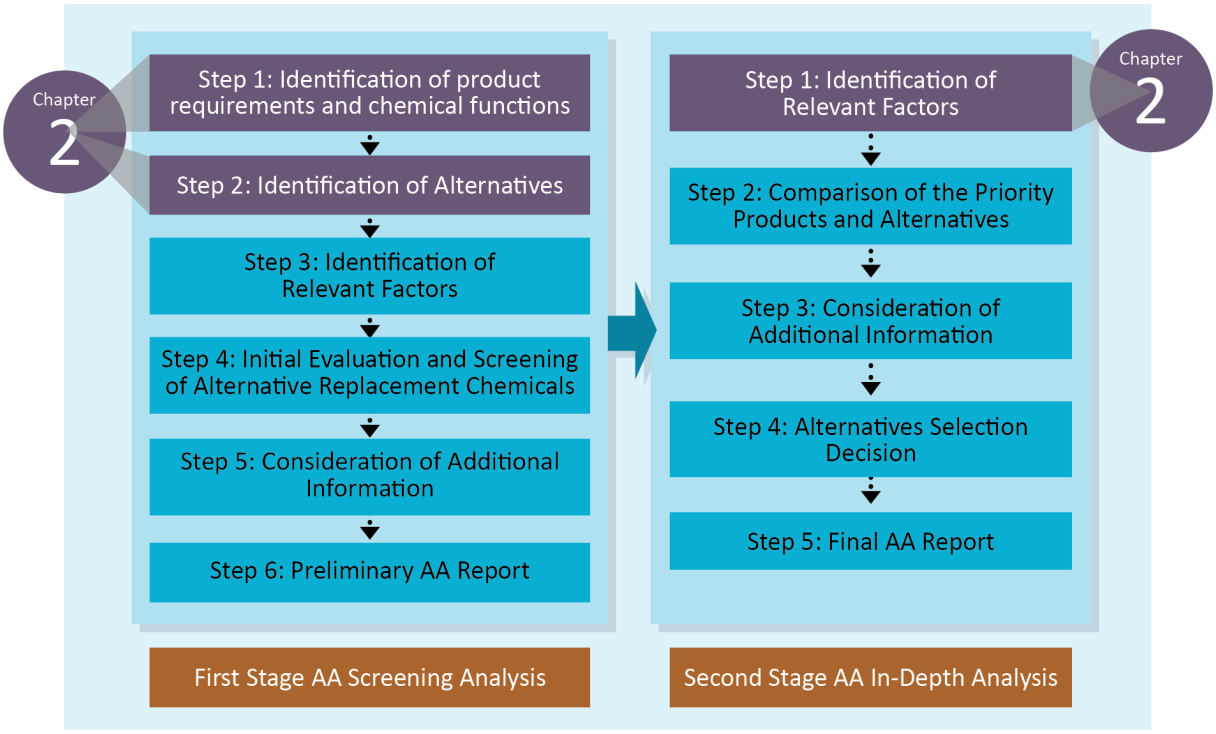
A responsible entity may submit any of the following to comply with the requirements under Article 5 of the SCP regulations:

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

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

Chapter 2 — Product Requirements and Alternatives

This chapter describes the initial steps the 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 Product.[13] 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.



[13] *In the SCP regulations, a Priority Product is a product-chemical combination identified and listed by the Department under 22 CCR section 69503.5. In this Guide the term "product" with a lower-case "p" may refer to a product in a generic sense, which may or may not be determined to be a Priority Product, or it may refer to an alternative under consideration.*

2.1 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 because both can be important when searching for alternatives.

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?

Sometimes these functions are closely related. Surfactants in detergents, for example, lower the surface tension of water, thereby making oil and grease more likely to interact with 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.

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 specific conditions.
- The extent or duration of the function or service, expressed in use frequency or time frame, such as service life.

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 opacity, 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 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).

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.

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.

When evaluating potential alternatives, the responsible entity may consider if the product would remain marketable if its array of attributes or standards changes. Although the Department acknowledges the importance of consumer acceptance, the Department will consider how the responsible entity justifies that a viable alternative was not selected because of consumer resistance by describing how it determined consumer acceptance.

- 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 required to meet legal requirements?

Because of the point in time when potential alternatives are being evaluated, and that no specific alternative has been selected yet for an actual determination of consumer acceptance, responsible entities can use their previous experience to determine if features in the alternative will cause consumer resistance. Responsible entities must consider if the potential alternative has benefits that can outweigh those features that may affect consumer acceptance. If introduced to the market, will educating consumers about the health and environmental benefits of the alternative overcome consumer resistance? Will consumers be willing to accept the new product knowing that it is safer than the product being replaced which causes health or environmental problems?

2.2 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 are generally understood to mean requirements established by action of the legislative, executive, or judicial branches. They may also include judicial or quasi-judicial actions, such as judicially enforceable settlement agreements, and court, executive branch, and regulatory orders.

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 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 as specified in California requirements.

2.3 Role of 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 adding flexibility in plastic products or surfactants reducing surface tension 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.[14]

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: "polyethylene," "polyethylene glycol (PEG)," "polyoxyethylene," "polyethoxyethylene," or "polyoxynolethylene." 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

[14] *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 22 CCR section 69505.2, in lieu of completing the AA and submitting the required AA Reports (see Notification Factsheet).*

(ATSDR, 2012). 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.

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.

(22 CCR section 69501.2(a)(26)(A))

If the Chemical of Concern is present in the Priority Product solely as contaminant, the regulations provide an exemption from the requirements to conduct an AA if the Chemical of Concern does not exceed the applicable AA Threshold [15] which is the Practical Quantitation Limit (PQL) for that chemical. The Department may also opt to specify in the Priority Product list an AA Threshold greater than the applicable PQL for the Chemical of Concern that is a contaminant. [16] Note that degradation products of an intentionally added Chemical of Concern are not considered contaminants nor unintentionally added.

[15] *22 CCR section 69505.3*

[16] *22 CCR section 69503.5(c)*

2.4 Identification of Alternatives

The responsible entity will 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.

(22 CCR section 69501.1(a)(10))

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 Chemicals Clearinghouse (IC2) Alternative Assessment Document (IC2, 2013) and the European Chemical Agency's Guidance for preparing an application for authorization (ECHA, 2011a) can provide suggestions on how to identify alternatives. The following questions, inspired by these sources, can help identify alternatives:

- Are there similar products offered for sale that use an alternative?
- Do other manufacturers advertise their product as free of the Chemical of Concern? What alternative was used?
- Do chemical manufacturers 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 any available 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 concept of functional substitution can be applied when identifying alternatives. Functional substitution is the application of information on function to identify, evaluate, and select safer alternatives that achieve a specific result (Tickner, et.al., 2015). It considers three conceptual levels of substitution: chemical function, end use function, and function as service. At the chemical function level, the focus is on chemical properties needed to achieve a specific chemical function. The end use function level relates to the specific purpose that a chemical serves in a product. For example, low density polyethylene has served as a substitute for polyvinyl chloride food wraps that were once used, serving the same function to protect food products and provide flexible containment features. At the function as service level, the chemical provides a service desired in a product. For example, the chemical provides antimicrobial function in hand soap. It is important to question the need for the function being provided. Is antimicrobial in soap needed? Will the soap without the antimicrobial chemical provide the needed service? Although the responsible entity has the discretion to conclude if

such feature is necessary for their product, it should provide the reasoning for such determination.

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, an 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 SCP regulations as a Candidate Chemical, the manufacturer may be exempt from the AA requirement, or subject only to limited notification requirements.[17] Although responsible entities may be exempt from the AA requirements, the Removal Notifications in lieu of Alternatives Analysis still require responsible entities to provide information about the replacement chemical , concentration in the reformulated product, and hazard traits and environmental or toxicological endpoints known to be associated with the replacement chemical. Having this information may make responsible entities be aware of potential impacts that they consider as replacement chemicals and avoid those that may lead to regrettable substitution.

REFORMULATING OR REDESIGNING A PRIORITY PRODUCT TO ELIMINATE OR REDUCE THE CHEMICAL OF CONCERN

Depending on the product type, the 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, the 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 the responsible entity will consider a dissimilar material will likely

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[17] *22 CCR section 69505.2*

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 (EWG, 2007). 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 may typically not replace or remove the Chemical of Concern, instead the Priority Product is altered or remodeled 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, thereby preventing chemical release.
- A multi-layered design that prevents chemical release.

If the Chemical of Concern remains in the product, altering or remodeling the product to reduce the potential for exposure during use may not address all the potential adverse impacts. The responsible entity must evaluate the adverse impacts of the Chemical of Concern on public health and environment during other relevant life cycle segments, which may include the end-of-life. For example, the responsible entity should consider if the additive to bind the compound within the plastic during use deteriorates and is then released during recycling or disposal of the product. The responsible entity should consider the Chemical of Concern's fate when the product deteriorates and is exposed to disposal or recycling process conditions.

OTHER PRIORITY PRODUCT CHANGES TO REDUCE IMPACTS

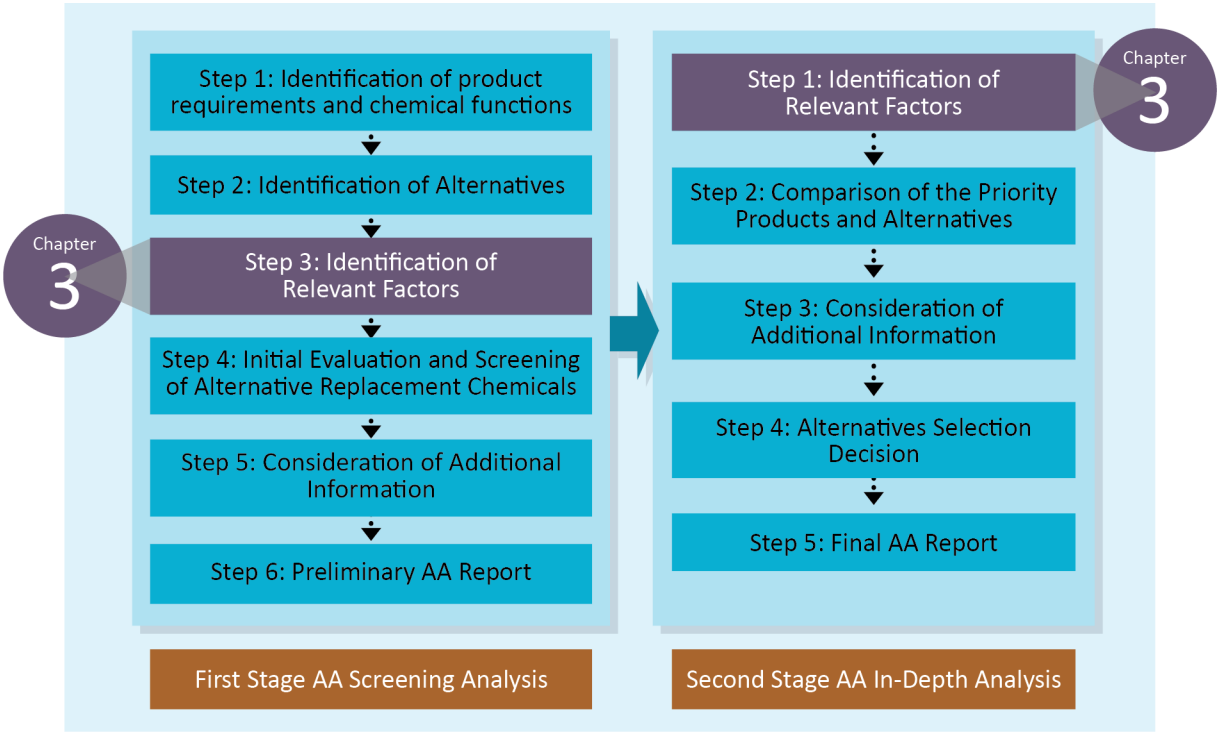
Other types of product reformulation or redesign consider alternatives that address potential adverse impacts not specifically identified in the other categories. For example, a product redesign may consider the end-of-life management of the product that will maximize recycling or control hazardous materials. Responsible entities may consult several 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.

2.5 Summary

When identifying alternatives, responsible entities must clearly describe the Priority Product's 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 usually an iterative process as best practice.

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 impacts associated with the Priority Product and/or one or more alternatives under consideration; and
- There is a material difference in the factor's contribution to impacts between the Priority Product and one or more alternative(s) under consideration and/or between two or more alternatives.

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 (note that this rationale does not need to be in-depth analysis as long as it is well supported).

3.1 What are Relevant Factors?

Beginning with a large pool of potential factors, the responsible entity will identify factors relevant for comparison of alternatives using regulatory criteria,[18] knowledge of the Priority Product and alternatives, and usually an iterative approach that continually refines the relevant factors throughout the analysis. Table 3-1 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 an expanded list of potential factors.

[18] *22 CCR section 69505.5(c)(1)*

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.

Material contribution: relating to a factor that is both meaningful and consequential to an observed outcome or impact.
Material difference: relating to a factor's contribution to an observed impact that is both meaningful and consequential to the comparison of alternatives.

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 example checklists for this purpose. The factors that cannot be quantified by available information should not be overlooked; the regulations also allow the use of available qualitative information and analytical tools. Chapter 9 and Chapter 11 discuss in more details about data gaps, uncertainties, and information quality issues.

Table 3-1 Summary of Potential Factors Requiring Consideration for a Two-Stage AA

FIRST STAGE AND SECOND STAGE AA

Adverse Impacts and Multimedia Life Cycle Impacts	
Adverse environmental impacts	Physical chemical hazards
Adverse public health impacts	Physicochemical properties
Adverse waste and end-of-life effects	Associated exposure pathways and life cycle segments
Environmental fate	
Materials and resource consumption impacts	

SECOND STAGE AA

Product Function and Performance	Economic Impacts
• 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	• 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

3.2 Iterative Process

Identifying relevant factors is usually an iterative and dynamic process that the responsible entity conducts throughout the AA. In the first stage of the AA, the responsible entity may begin with the factors that formed the basis for prioritization of the Priority Product. The responsible entity may also undertake a broad search of databases and published literature for all available information about the potentially relevant factors.[19] The responsible entity may use available quantitative information and analytical tools, supplemented by available 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. During the second stage of the AA, the responsible entity should look again at relevant factors and associated exposure pathways and

[19] *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 US EPA's ChemView (http://www.epa.gov/chemview/, accessed December 1, 2015).*

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 may further evaluate and compare relevant factors related to product function, performance and economic impacts.[20] The responsible entity may also need to reevaluate factors eliminated during the first stage AA, as shown in the Example 3-1.

[20] *22 CCR sections 69505.6(a)(2) & 69505.6(a)(3)*

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 segments 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.

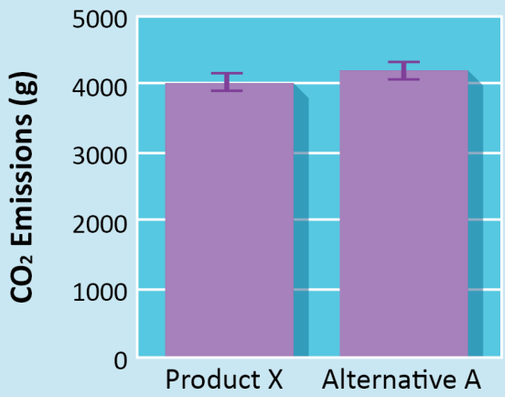


Figure 3a. CO_2 emissions associated with production and disposal during the first stage AA (without considering life expectancy).

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 different 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.

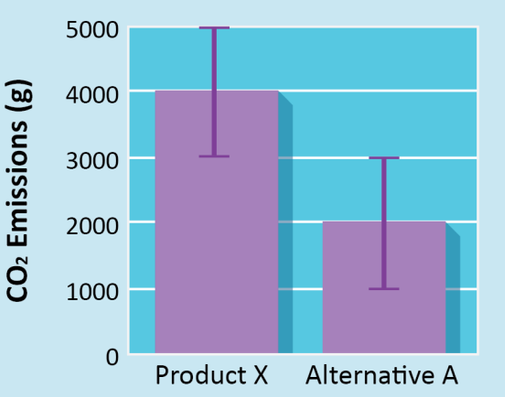


Figure 3b. CO_2 emissions associated with production and disposal during the second stage AA (with consideration of life expectancy).

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

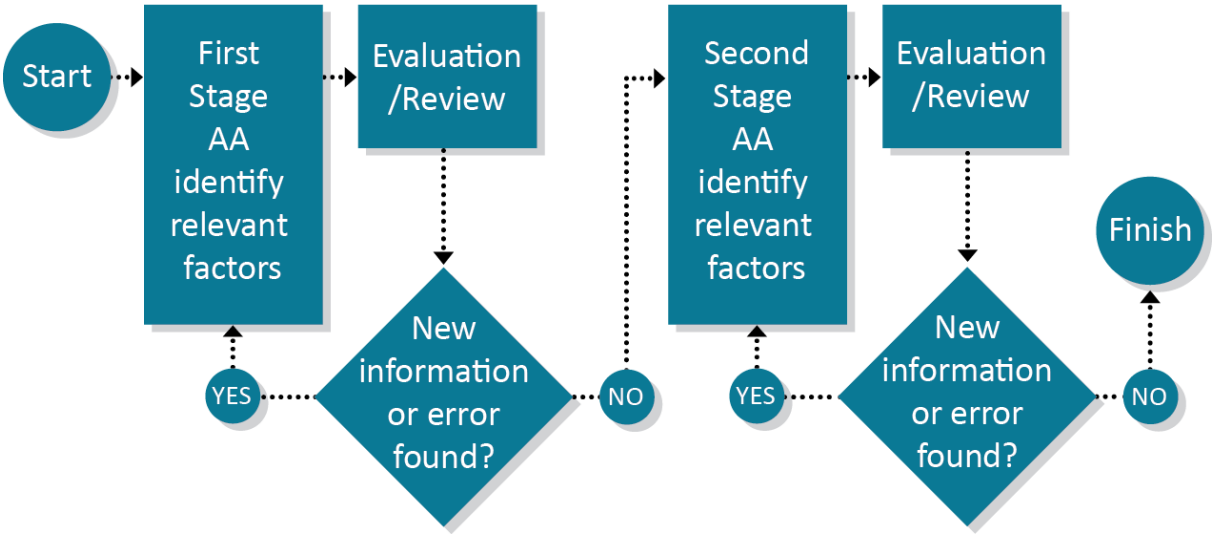


Figure 3-1 An Example Iterative Process to Identify and Evaluate Relevant Factors

3.3 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 segment, but this does not mean that use is the most important segment. One of the key differences between the AA required by the SCP regulations and other Alternative Assessments framework is the requirement to consider all relevant life cycle impacts. Assessing impacts throughout the complete life cycle of a product means considering all the inputs including chemicals, materials, water, and energy, all the outputs including emissions and wastes associated with each life cycle segment from raw materials extraction to end-of-life disposal, and their contribution to adverse public health impact, adverse environmental impacts, adverse waste and end-of-life effects, or materials and resource consumption impacts. In the SCP requirements "life cycle"[21] means the sum of all the following activities:

[21] *22 CCR section 69501.1(a)(42)*

- raw materials extraction
- resource inputs and other resource consumption
- intermediate materials processes
- manufacture
- packaging
- 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 make a material difference and would be relevant. If the responsible entity is comparing a plastic bottle with alternative plasticizers, the packaging and transportation segment may not make material contribution to the total impacts and there is no materials difference between alternatives. The intermediate materials processing, manufacturing, use, and end of life segment may be more relevant for comparison in this case. 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 segment 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 segment (Franklin Associates, 2007).

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

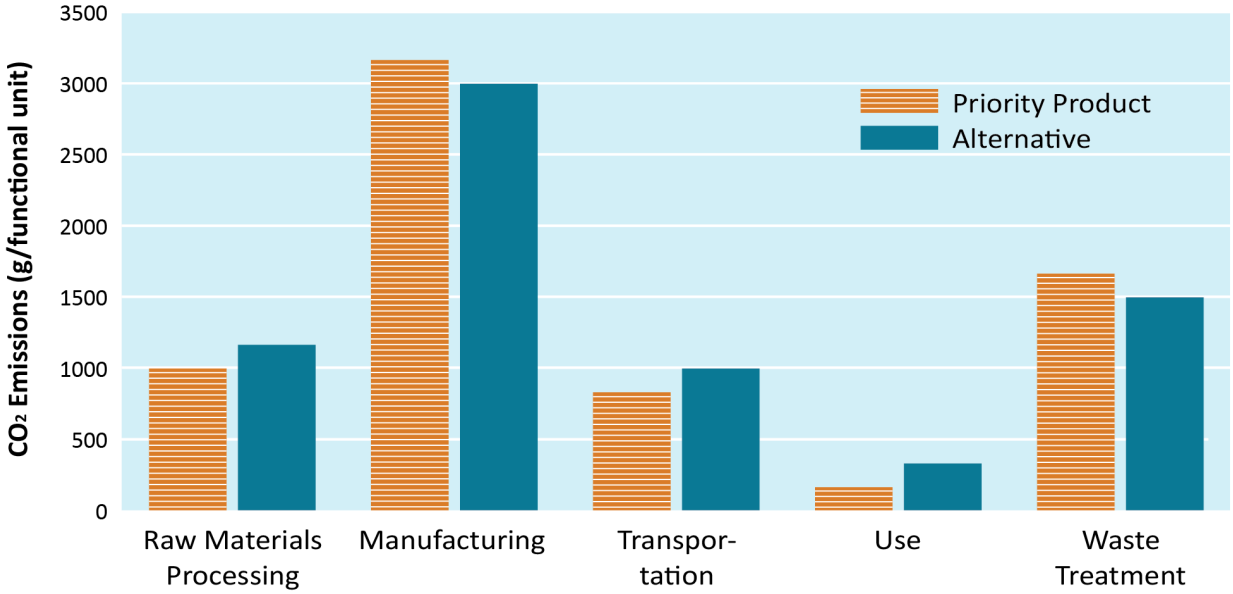


Figure 3-2 Contribution Analysis of the Life Cycle CO_2 Emissions for Priority Product and Alternative

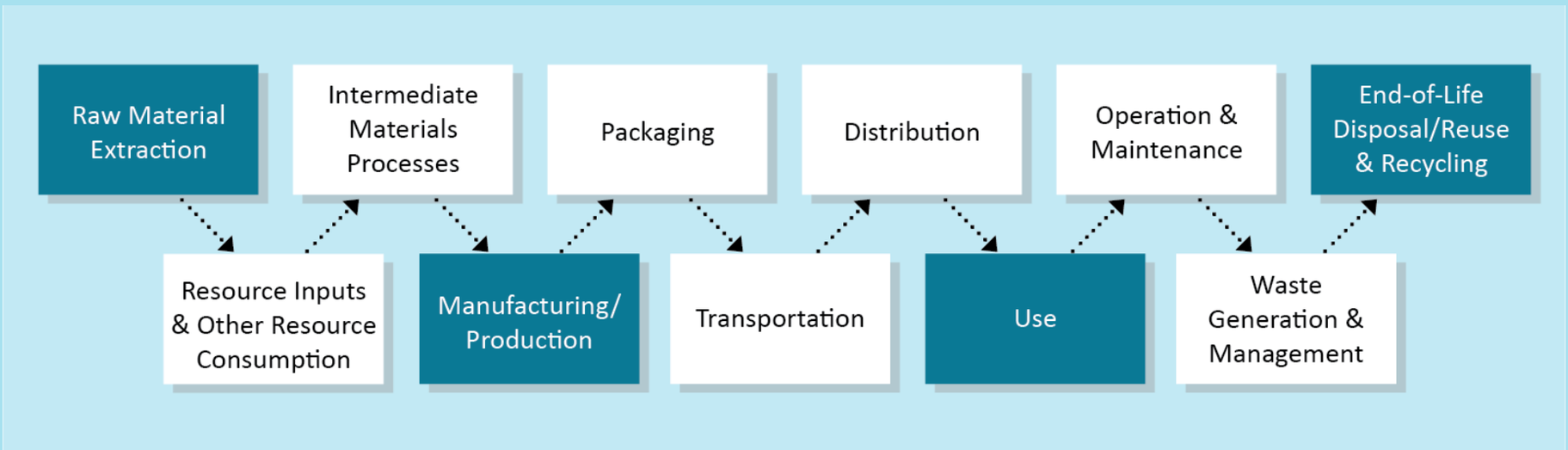
Is a life cycle segment potentially relevant?

- 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 regarding 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?

The box above presents some initial questions to help the responsible entity to consider whether specific life cycle segments are potentially relevant. Example 3-2 illustrates a qualitative approach of life cycle thinking at beginning of the process. The Life Cycle Module in the Interstate Chemical Clearinghouse (IC2) Alternative Assessment Document (IC2, 2013) also provides more information on how to incorporate life cycle thinking when comparing alternatives.

Example 3-2: Identifying Relevant Life Cycle Segments

This case study considers a flooring product, designated in this example as "Priority 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 reproductively toxic substances). During the use segment, hazardous additives such as phthalates, halogenated 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 halogenated 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 non-relevant 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.

Example 3-2 (continued): Comparison of Relevant Life Cycle Segment

Priority Product	Life-Cycle Segment	Alternative A	Alternative B	Alternative C
• A small amount of post-industrial recycled content • PBTs, CMRs during petroleum extraction and refining	**Raw Materials Extraction**	• High post-consumer recycled content (may be toxic) • PBTs, CMRs during petroleum extraction and refining	• Limited post-consumer recycled content • PBTs, CMRs during petroleum extraction and refining	• High renewable content/post-industrial recycled content • Toxic pesticides (may be eliminated) • Eutrophication
• PBTs • CMRs • Heavy Metals • Endocrine disruptors • VOCs and solvents	**Manufacturing and Production**	• PBTs (may be designed out) • CMRs • Heavy metals	• No identified PBTs • Few CMRs (may be eliminated) • Lack of emission data	• No PBTs • CMRs (may be eliminated) • Dust
• Flame retardants • Phthalates • VOCs • Pigments	**Use**	• Flame retardants • Heavy metals • VOCs • Pigments	• One problematic metal (aquatic toxicant) • VOCs • Pigments	• No heavy metals • VOCs and odors (may be reduced) • Pigments
• PBTs • Post-consumer recycling challenging	**End-of-Life, Reuse and Recycling**	• Lack of studies • Limited recycling	• No identified PBTs (except one problematic decomposition product) • Down-grade recycling	• No identified PBTs • Pilot composting program available

This diagram shows the qualitative 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.

*Adapted from: 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.

3.4 Incorporating Exposure Pathways

When developing the scope of relevant factors, the responsible entity must also consider the associated exposure pathways[22] and consider how a sensitive subpopulation's potential use of, or exposure to, the product may be different from other, less sensitive populations.[23] 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 may need 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 segment and other life cycle segments.

The responsible entity should first look at the exposure factors identified as the basis for prioritization of the Priority Product. The responsible entity should also gather exposure information from other sources to identify the exposure factors and pathways for the alternative relevant for comparison with the Priority Product and other alternatives under consideration. It is important to note that exposures occur not only at the point of product use, but also throughout the product's life cycle need to be considered. The following box provides some example questions for the responsible entity to consider product-chemical combined exposure factors through the product's life cycle.

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[22] 22 CCR sections 69505.5(c)(3)B)

[23] 22 CCR section 69503.3(b)(4)(D), one of exposure factor specified in section 69505.3(b).

What are relevant exposure factors?

- Are the Chemical of Concern and potential chemical alternatives used in the same relative amounts and in the same manner?
- 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?
- 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 segment.
- 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?

EXPOSURE DATA AND CONCEPTUAL MODELS

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 identify exposure pathways. For example, industrial hygienists may have expertise to determine potential releases in the workplace 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 (OECD, 2012b). The National Academy of Sciences (NAS) prepared a document, "A Framework to Guide Selection of Chemical Alternatives" (2014 NAS Report) (NAS, 2014), 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. The Interstate Chemical Clearinghouse (IC2) Alternative Assessment Document (IC2, 2013) has recently updated its Exposure Module to align with the NAS comparative exposure assessment and provide additional guidance on this method.

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, a Responsible Entity may use a conceptual model to clarify similarities and differences among the Priority Products and alternatives based on a qualitative analysis of available information.

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 neither volatile nor 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. Furthermore, it is important to combine physicochemical properties of chemicals with the product related factors (such as use profile, form and delivery type, frequency and duration of use, expected exposure routes, concentration of ingredient, volume of ingredient use, the accessibility of the ingredient in the product life cycle, and the method of disposal) to complete a holistic analysis of potential exposure. See also Chapter 6 of this Guide for additional information about exposure assessment in the AA.

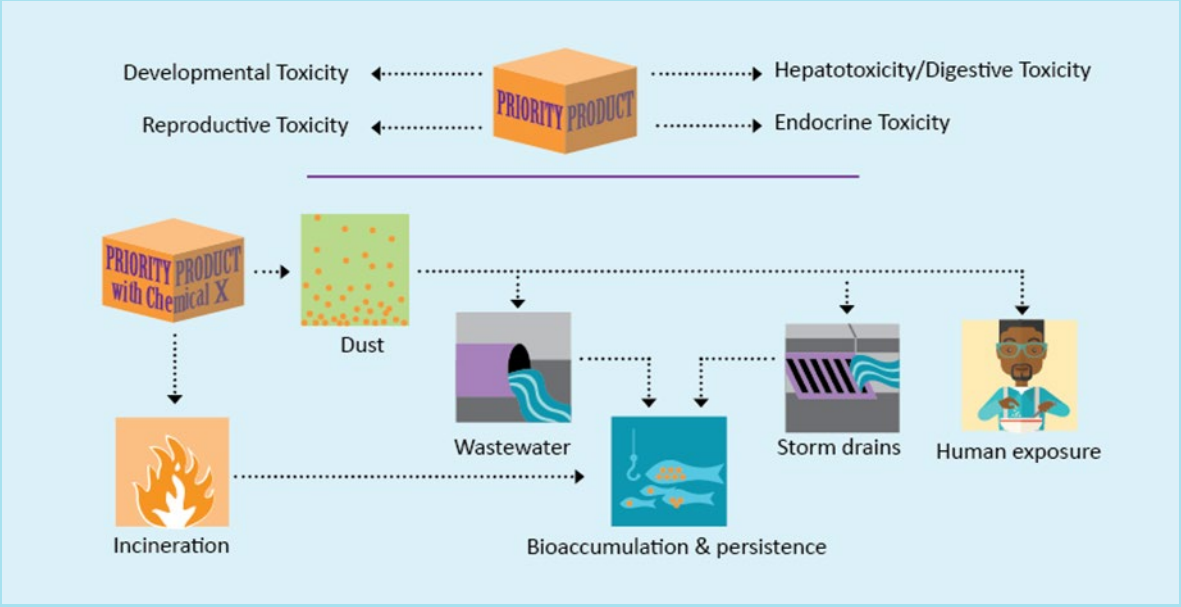
Finally, the responsible entity may consider using a conceptual model approach to depict the interactions among the exposure pathways and life cycle segments, and to help scope and identify relevant factors. Example 3-3 details a stepwise approach to develop a conceptual model to identify and communicate relevant factors at early stages of an AA. This example describes a progression of information that can help identify relevant factors: the first step depicts potential exposure and associated impacts, the second step compares impacts, and the third step compares impacts for different life cycle segments. More detailed conceptual model examples to show human and environmental exposure pathways and receptors for the chemicals are available in several publications from the U.S. Environmental Protection Agency (EPA) (EPA, 2015a; EPA, 2014).

Example 3-3: Applying a Conceptual Model to Communicate Potentially Relevant Factors

The following three-step process shows how to build and use a conceptual model to identify potentially 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

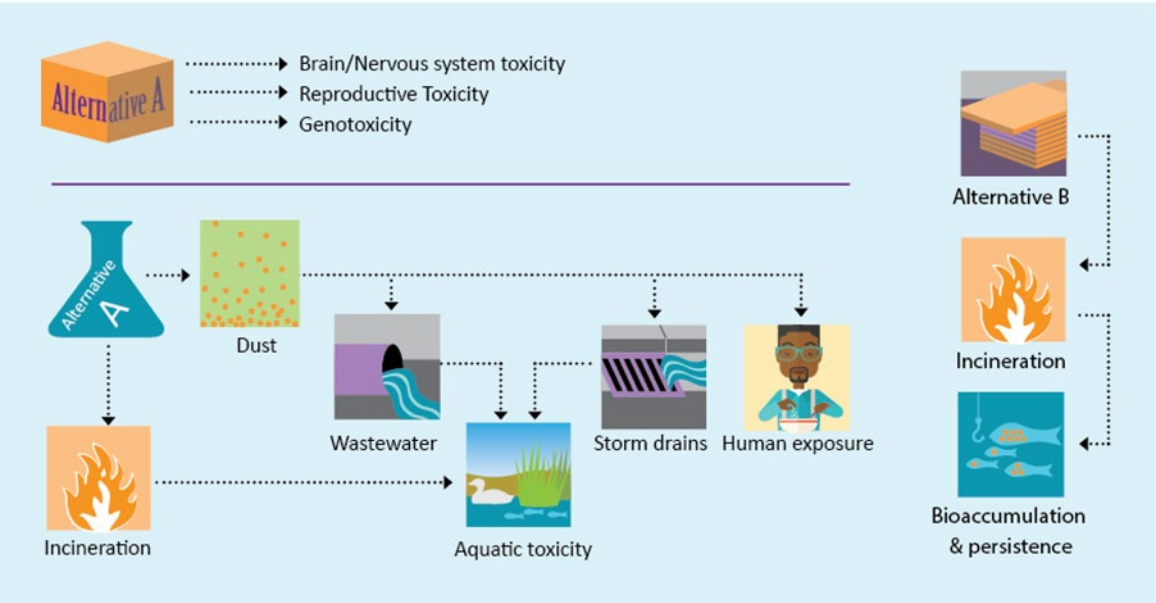
In this example, the Priority Product profile shows the Department listed the Priority Product containing Chemical X due to its developmental toxicity, hepatotoxicity, reproductive toxicity, endocrine toxicity, and bioaccumulation and persistence. To see how humans and the environment are exposed to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

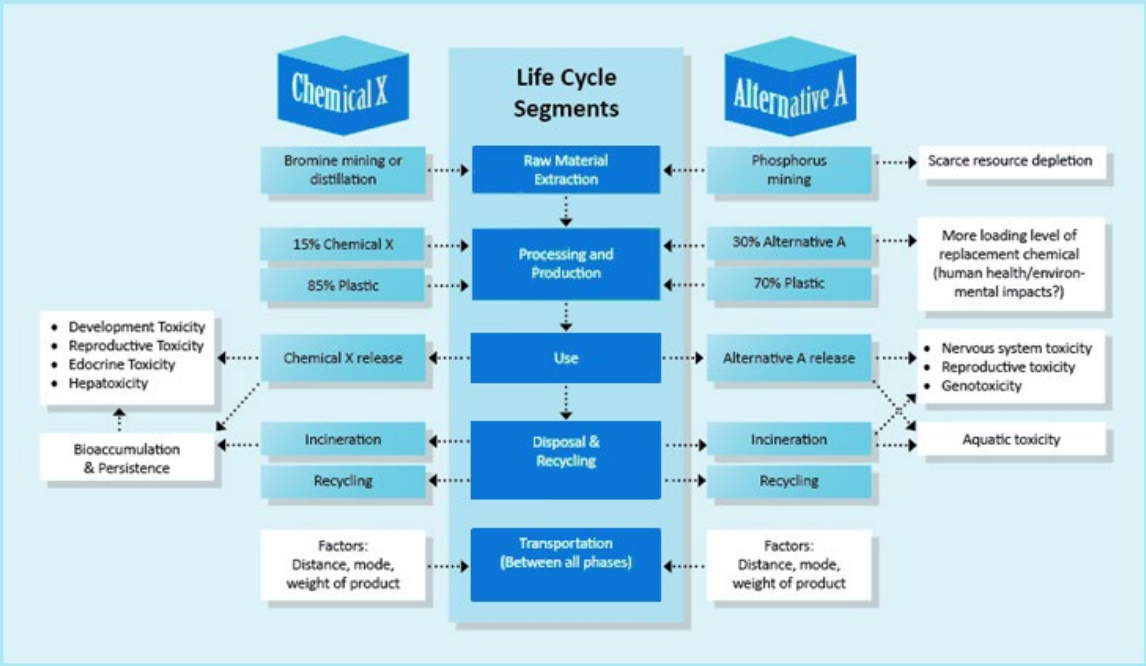
The conceptual models for Alternative A, a chemical switch-out, and Alternative B, a material change, are shown below. The preliminary literature research shows that hazard traits for the replacement chemical in Alternative A include genotoxicity, brain/nervous system toxicity, reproductive toxicity,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



A Conceptual Model for the Alternatives Under Consideration

STEP 3: COMPLETE THE CONCEPTUAL MODEL WITH LIFE CYCLE THINKING

Life Cycle Thinking fits into the first stage AA to identify relevant factors with associated exposure pathways and life cycle segments for further analysis. 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

3.5 Summary

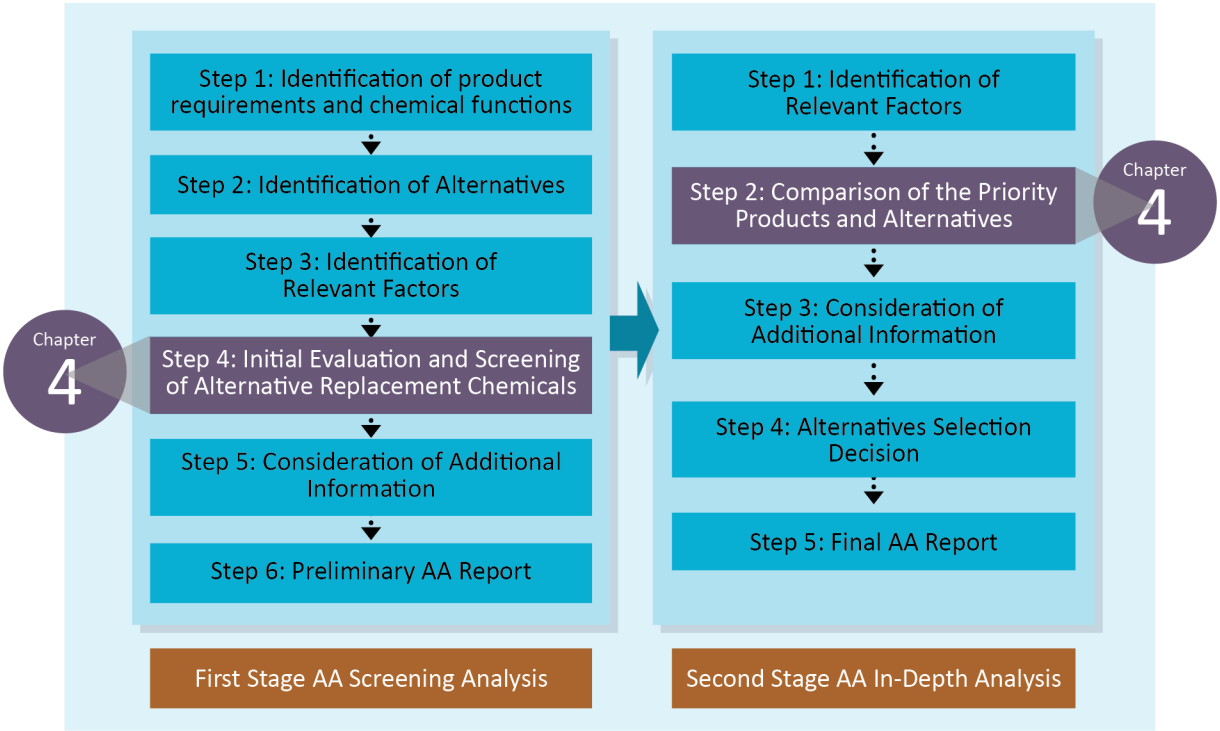
The relevant factors identified and evaluated in the AA should consider the following:

- The identification of relevant factors is an iterative and dynamic process.
- Factors can be quantified by 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 segment, but this does not mean that it is more important than other segments.
- 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 existing assessment methodologies to establish adverse impacts throughout the AA process. It also 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. 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 the 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 that 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 details.
- **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 regulations[24] and several 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, the 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, the 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

[24] *22 CCR section 69401.2*

assessments. This chapter presents a typical set of steps the responsible entity may use to conduct its analysis and describes a selection of general tools and approaches.

4.1 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.

When experimental or measured data are not available for a specific 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 may be used when empirical data are not available.[25]

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, quantitative structure activity relationship (QSAR), uses the relationship between a

[25] *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.*

chemical's molecular structure and its effects on biological systems to predict the activity of other chemicals with similar structures.[26]

Because modeled and analog data assume that a chemical's activity can be extrapolated, these data will carry some uncertainty that depends 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. Use of surrogate and read-across approaches are increasingly common, but the level of rigor involved in doing such analyses varies considerably. Chapter 9 provides additional guidance about addressing such uncertainties.

A responsible entity may find much of the information available to characterize the hazard traits and their impacts to be complex, requiring 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 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.

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[26] *QSAR (Quantitative Structure Activity Relationship) models are mathematical models that predict toxicity based on molecular structure. U.S. Environmental Protection Agency (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 (Accessed November 20, 2015).*

Table 4-1 Hazard Trait Data Sources

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 Chemicals) (DTSC, 2016) • 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 REACH (ECHA, 2016)) • 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; however, 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.

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

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 (ATSDR, 2015). Online data summaries, including lists and portals, will help responsible entities find available information about the relevant factors.

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)

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

Because different authoritative lists typically address different issues, responsible entities may need to use several lists to gather a greater variety of information. A list translator simplifies this task by screening several 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 that 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 expand, 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 specific 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, the 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 and web portals for hazard information of chemicals. Appendix 4 presents an expanded list of databases with brief descriptions. 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 not contain information for all the relevant factors, the responsible entity may need to use multiple data sources to supplement the information.

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

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

Tools	Type of Information	Developer or Host
ACToR	Free portal for chemical toxicity data from a collection of US EPA databases with over 500,000 chemicals	US EPA
ECOTOX	Database for single chemical environmental toxicity data on aquatic life, terrestrial plants, and wildlife	US EPA
SUBSPORT	Free portal for information needed to substitute for hazardous chemicals, including substitution tools to compare and assess alternative substances and Alternative Assessment case studies reports.	Kooperationsstelle Hamburg IFE GmbH; ISTAS; ChemSec; Grontmij A/S

Tools	Type of Information	Developer or Host
RISCTOX	Database of health & environmental risks	Trade Union Institute for Work, Environment & Health (Institúto Sindical de Trabajo, Ambiente y Salud, ISTAS), commissioned by the European Trade Union Institute (ETUI) and supported by the European Environmental Bureau (EEB)
ChemHAT	Chemical hazard database	BlueGreen Alliance

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, the 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 the 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 propriety 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 may turn to modeling tools to fill the gaps. Table 4-3 provides examples of such models to predict potential toxicity of a chemical (see Appendix 4 for an expanded list). 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.

Modeling approaches typically require extensive knowledge about chemical structure and related groupings to be used 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. A responsible entity that cannot select an alternative because available data are poor may use modeling approaches to generate data (see more information about tools and databases in Appendix 4). However, using modeling approach to address data gaps should be a screening step to direct the focus of further analysis because modeling approach tends to oversimplify.

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

Tools	Type of Information	Regularly Updated?	Contact
Toxicity Estimation Software Tool (TEST)	Uses a mathematical model to estimate toxicity based on molecular structure	Yes	US EPA
EpiSuite	Provides physicochemical property estimates	Yes	US EPA
ECOSAR	Provides aquatic toxicity estimates	Yes	US EPA

4.2 Comparative Tools and Approaches

As the practice of alternatives assessment becomes an important component of product and process development, those who seek safer alternatives prefer automated methods to evaluate and compare the hazards and impacts associated with the use of chemicals. Several organizations have developed tools to help summarize and readily compare information about the hazard traits or attributes associated with chemicals in products.

A responsible entity may use hazard comparison tools for the screening of alternatives step in the first stage AA and the comparison of alternatives step in the second stage AA. If the 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 examples of hazard comparison methods, and Appendix 4 presents an expanded list of hazard-comparison methods 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 are described in the tool documentation, and none of them include the full array of hazard traits specified in the SCP regulations. Furthermore, some benchmarks or categories obtained from these comparison tools may have hidden weighting factors that do not align with the responsible entity's priority to reach an AA decision. It is likely responsible entities will need to consult multiple tools and sources of information to complete a comparison to meet their AA needs.

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.

Table 4-4 Examples of Methods for Comparing Hazards

Tool	Developer	Capacity
Quick Chemical Assessment Tool (QCAT)	Washington State Department of Ecology	A simple chemical hazard assessment tool
GreenScreen® for Safer Chemicals	Clean Production Action	A method for comparative chemical hazard assessment
Safer Choice	US EPA	A comprehensive program to find safer products that also perform well, including Design for Environment (DfE) Alternative Assessment
Column Model for Chemical Substitutes Assessment	Germany	A practical tool to make a preliminary comparison for alternative substances
NIOSH Occupational Hazard and Exposure Banding	NIOSH	A method to guide workplace risk assessment by assigning chemicals into "categories" or "bands" based on their health outcomes and potency considerations

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 Quick Chemical Assessment Tool (QCAT), which is based on GreenScreen® method developed by Clean Production Action, 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®.

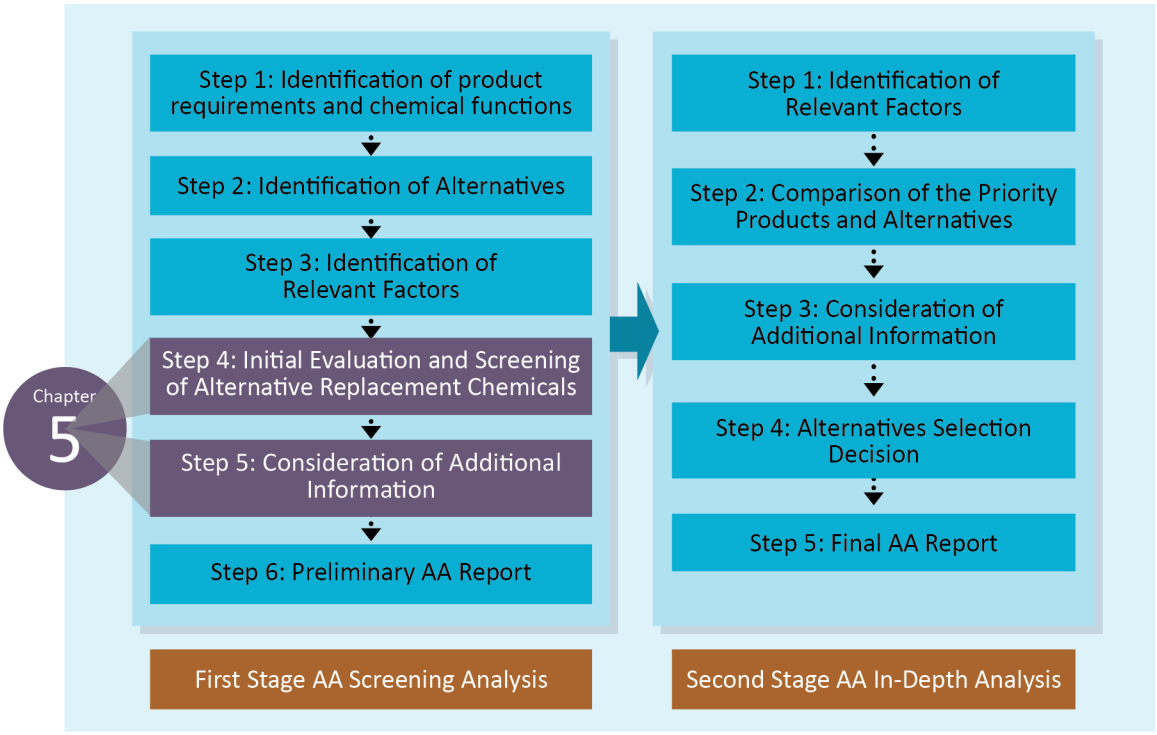
4.3 Summary

- Data gathering forms the core of impact assessments.

- Information sources can be found in reference volumes, data summaries compiled by authoritative bodies and others, scientific literature, proprietary research, and modeling tools.
- Publicly available tools exist to evaluate and compare impacts associated with chemicals in products, although most address only hazard traits.

Chapter 5 — Screening Alternatives

In the final step of the first stage AA, the responsible entity screens the alternatives in preparation for the second stage AA. The primary goal of this screening is to retain alternatives that would be an improvement over the Priority Product, while eliminating alternatives that present unacceptable impacts or performance. In the first stage AA, the responsible entity identifies a list of potential alternatives. However, before beginning the second stage AA, it is important to narrow the number of alternatives to a scope which is manageable given the considerable data requirements and resources needed for the second stage AA. Through alternatives screening, the responsible entity will eliminate inferior choices and reserve the remaining potential alternatives for further consideration during the next stage of the analysis.



5.1 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 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 making the choice among the alternatives more complex. For a given alternative, the impacts associated with some relevant factors may be more favorable than those impacts from the Priority Product yet impacts associated with other factors may not be clearly superior. One or more factors may be relatively equivalent necessitating resolving 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 comparisons of data-less factors cannot be made. It may be hard to avoid regrettable substitutes when the relative merit of alternatives remains highly uncertain.

The responsible entity may use a variety of screening approaches or methodologies. These may take several different forms, from a simple and sequential comparison of selected relevant factors to a more complex and multifaceted simultaneous analysis of multiple factors. Screening may be done using a combination of one or more methods. For example, a responsible entity may employ the following:

- Evaluations to ensure alternatives under consideration meet the product function, performance, or legal requirements,
- Systematic screening approaches that use a series or group of comparisons to evaluate relevant factors (Malloy, et.al., 2011),
- Chemical hazard assessment tools to screen chemical alternatives that are unacceptable due to inherent hazard traits,[27]
- Impact assessment tools and methods, or
- Life cycle thinking.

One approach is to first use chemical hazard assessment tools to rapidly assess and compare the inherent hazards of the Chemical of Concern and replacement chemicals. Hazard assessment tools classify the chemical's hazard level for each human health and ecotoxicological endpoints according to the tool's hazard-ranking criteria. The responsible entity can then compare alternative replacement chemicals against each other and screen out those replacements that are worse than the Chemical of Concern. Figure 5-1 is an example of a

[27] *These assessment tools classify hazard levels and put primary emphasis on carcinogens, mutagens, and reprotoxic (CMR) chemicals as well as those that are persistent, bioaccumulative, and toxic (PBT).*

GreenScreen® For Safer Chemicals' matrix for hazard assessment showing high, moderate, or low hazard levels on various human health and ecotoxicological endpoints.

Group I Human						Group II and II* Human								Ecotox		Fate		Physical	
C	M	R	D	E	AT	single	repeat*	single	repeat*	SnS*	SnR*	IrS	IrE	AA	CA	P	B	Rx	F
DG	*L*	*L*	**M**	**H**	DG	*L*	*L*	**M**	**M**	L	L	L	L	*L*	*L*	*vH*	*M*	*L*	*L*

Abbreviations:

C = Carcinogenicity	SnR = Respiratory sensitization	SnS = Skin sensitization
M = Mutagenicity	IrS = Skin irritation	CA = Chronic aquatic toxicity
R = Reproductive Toxicity	IrE = Eye irritation	P = Persistence
D = Developmental Toxicity	AA = Acute aquatic toxicity	B = Bioaccumulation
E = Endocrine activity	ST = Systemic toxicity	Rx = Reactivity
AT = Acute mammalian toxicity	N= Neurotoxicity	F= Flammability
DG = Data Gap	L = Low	M = Moderate
H = High	vH = Very High	

Note: Hazard levels L, M, H, vH in *italics* reflect lower confidence values. Hazard levels in **BOLD** font reflect higher confidence values.

Figure 5-1 Hazard Summary Table (Clean Production Action, 2016a)

The tabular format provides a snapshot of the hazards assessed and gives a visual indication of areas of concern. The GreenScreen® table expedites comparison of multiple chemicals during the screening process. Since these tools typically do not include evaluation of all the factors specified in the regulations, the responsible entity will need to adapt or supplement these approaches to cover the entire range of factors.

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. As the screening proceeds, other relevant factors are then evaluated and compared. When the comparison requires a choice between impacts, the responsible entity determines which relevant factors are most important – and uses them to come up with safer alternatives.

A well-organized presentation of the analysis can include a visualization of data and facilitate decision-making. Table 5-1 illustrates the life cycle segments and adverse impacts or factors that may potentially become relevant and be used to screen alternatives. Information for each alternative would be included to populate the matrix depending on data availability. Only viable alternatives that demonstrate an improvement will advance for further evaluation during the second stage.

Table 5-1 Relevant Life Cycle Segments and Factors

Life Cycle Segment	Factors or Impacts	Priority Product	ALT 1	ALT 2	ALT 3-10
	Environmental Impacts	H	O	O	O
	Public Health Impacts	H	O	O	O
	Waste and End-of-Life	H			
	Environmental fate	H	M	M	
Raw Materials Extraction	Materials & Resource Consumption Impacts				
	Physical Chemical Hazards				
	Physicochemical Properties				
	Environmental Impacts				
	Public Health Impacts				
	Waste and End-of-Life				
	Environmental fate				
Intermediate Process	Materials & Resource Consumption Impacts	M	H	L	H
	Physical Chemical Hazards				
	Physicochemical Properties				
	Environmental Impacts	H			
	Public Health Impacts	M			
	Waste and End-of-Life				
Manufacturing	Environmental fate	H			
	Materials & Resource Consumption Impacts				
	Physical Chemical Hazards				
Manufacturing	Physicochemical Properties				
Packaging & Transportation		NA	NA	NA	NA
Distribution		NA	NA	NA	NA
	Environmental Impacts	H	L	H	M
	Public Health Impacts	H	M	M	M
	Waste and End-of-Life				

Life Cycle Segment	Factors or Impacts	Priority Product	ALT 1	ALT 2	ALT 3-10
Use	Environmental fate	M	H	L	H
	Materials & Resource Consumption Impacts				
	Physical Chemical Hazards				
	Physicochemical Properties				
Operation & Maintenance		NA	NA	NA	NA
	Environmental Impacts	H	O	M	
	Public Health Impacts	L	O	L	
	Waste and End-of-Life	H		M	
Reuse & Recycling	Environmental fate	H	H	M	
	Materials & Resource Consumption Impacts				
	Physical Chemical Hazards				
	Physicochemical Properties				
End-of-Life		NA	NA	NA	NA

H = High Impact observed
M = Medium Impact observed
L = Low Impact observed

NQ - Data not available (impact not quantifiable)
O - Data not available
NA - Not Applicable

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, human health and ecological endpoints, 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 waste 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 physicochemical hazards.
- Poses a greater reactive or flammability hazard, as indicated by its physicochemical properties.

At this stage in the AA, information is likely to be qualitative. The resulting comparison may indicate similar magnitudes of impact for different factors. 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 all the assumptions and rationale for the decisions and trade-offs in the AA report, so the Department understands these choices.

In addition to a clear lack of a superior alternative, a responsible entity may encounter additional challenges during the screening of alternatives, such as data gaps or conflicting information. The lack of available or accessible data may limit the initial screening of the relative importance of some factors over others. The degree to which the data gaps are filled, or conflicts are resolved will determine the degree to which a decision can be supported. The responsible entity may find it beneficial to conduct new research, use additional tools, or use best professional judgment to address these issues. Ideally, more data should resolve or minimize uncertainty and allow for a more streamlined comparison of alternatives. Another advantage of collecting data during the first stage is that they can inform a decision whether to carry over the alternatives to the second stage for further evaluation, or to narrow the range of alternatives that must be subsequently evaluated—thus potentially reducing the cost of conducting the AA.

5.2 Consideration of Additional Information

The responsible entity may consider additional information and factors that are not specifically required in the first stage AA. These factors may include performance measures, consumer acceptance, economic impacts, and other potential adverse impacts. For instance, prioritizing alternatives based first on performance can help narrow the scope to those that have the potential to be effectively implemented while maintaining product quality (OSHA, 2016).

A responsible entity can use additional information to dismiss from further consideration any alternative that it believes is economically or technically infeasible. The Preliminary AA Report must describe how the responsible entity used any such additional factors in the screening decision. The Department does not encourage premature discarding of alternatives that may be viable upon further evaluation.

5.3 Next Steps

The responsible entity bases its selection of the alternatives on its goals and policies and the results will help determine the next steps. Depending on the screening outcome, various options for completing the AA may become apparent. A responsible entity may decide to iterate and refine the first stage analysis before submitting the Preliminary AA Report, gather additional information, or submit an Abridged AA Report.

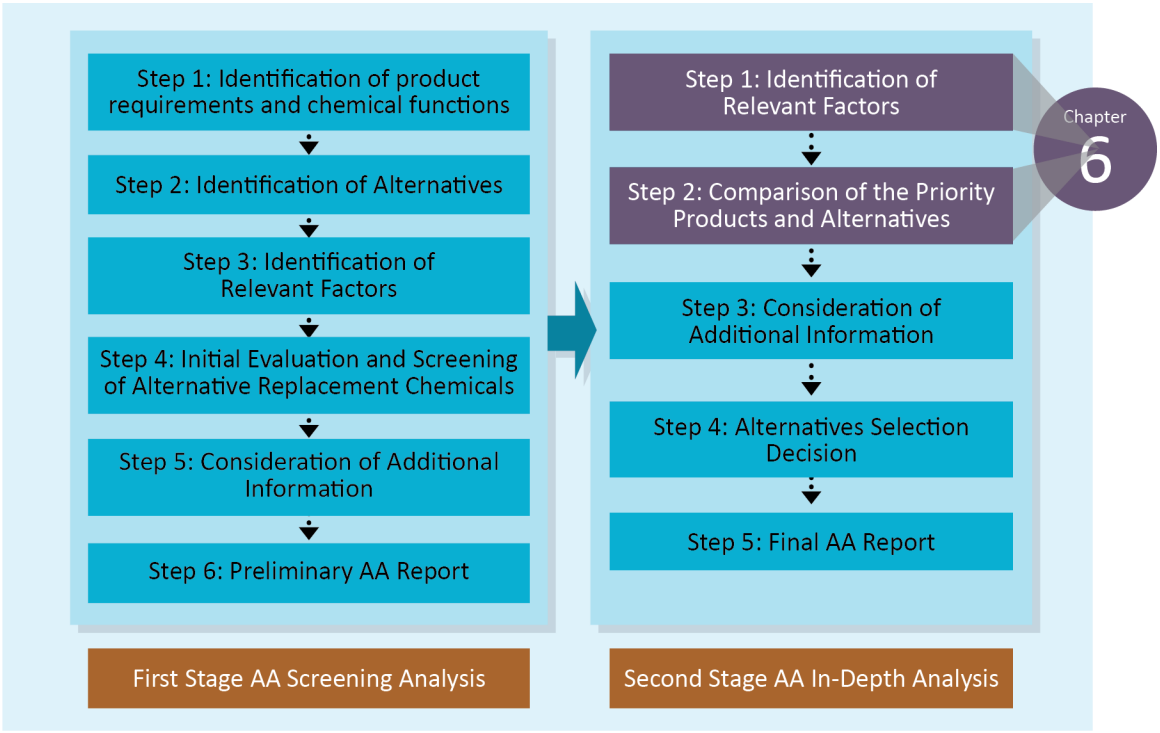
If the responsible entity successfully selects alternatives for further consideration, a Preliminary AA report will provide a work plan for completing the second stage AA. On the other hand, if the responsible entity cannot identify any viable alternatives, it may complete an Abridged AA. When there are too many alternatives at the end of the first stage, a responsible entity may choose to either reassess the alternatives using additional information or use a more refined comparison to reduce the number of alternatives further.

5.4 Summary

- Presently, no universally accepted method for screening alternatives exists. Each responsible entity develops its own approach or uses a combination of approaches.
- No existing tool includes an evaluation of the entire range of factors specified in the regulations. The responsible entity will need to adapt or supplement existing approaches to cover the entire range of factors.
- A well-defined and focused first stage AA may reduce the overall costs of conducting an AA and avoid unnecessary research and evaluation.
- Relevant life cycle segments, factors, and alternatives are carried forward into the second stage.

Chapter 6 — Exposure

This chapter describes methods to assess potential exposures related to the Chemical of Concern, and the alternatives being considered. In addition, the chapter addresses how to use the information from these assessments throughout the AA process. As described earlier in this guide, the SCP regulations do not require a traditional risk assessment that quantifies hazards and exposures to estimate risk. Instead, the AA uses potential exposure to identify relevant factors and compare alternatives. Exposure assessment evaluates whether alternatives have the same, higher, or less exposure level than the Chemical of Concern. Otherwise, similar exposure levels to people, animals, and the environment are assumed.



6.1 Scope of the Exposure Assessment

The potential for exposure plays a crucial role during both stages of the AA. Exposure factors4 documented in the Department's Priority Product listing regulations must be assessed. During the first stage, the responsible entity considers the potential exposure pathways to identify relevant factors and establish the scope for the AA. Also, during the first stage, the responsible entity may dismiss one or more alternatives that have the potential to cause greater adverse impacts resulting from exposure to the Chemical of Concern.

The scope of the exposure pathway assessment for the second stage depends on the results of the first stage. Exposure factors documented in the Priority Product listing regulations are among the things to be considered as relevant factors for the comparisons. In the second stage of the AA, the responsible entity re-evaluates the exposure pathways with associated life cycle segments to confirm the selected relevant factors and to assess if a more detailed exposure assessment is needed for a comprehensive comparison between the Priority Product and the alternatives considered.

This chapter focuses on the methods and resources to evaluate exposure directly associated with the Chemical of Concern and any alternative replacement chemicals. Exposures and impacts occurring at different life cycle segments, for example, exposures to precursor chemicals used in manufacturing, should also be evaluated.

Exposure
Exposure is the contact between a chemical and a human or ecological receptor for a specific duration of time. Exposure occurs by contact with a chemical through various exposure media (air, water, soil, and food) via exposure routes (inhalation, ingestion, and dermal contact).

Chapter 10 will discuss how the information across life cycle segments should be brought together to support the decision made.

6.2 Exposure Assessment Considerations

The SCP regulations specify the types of exposure factors that must be considered. The responsible entity evaluates the following, at a minimum, when identifying relevant factors and associated exposure pathways and life cycle segments: [28]

- Chemical quantity information; and
- Exposure factors used in the Priority Product listing

After the responsible entity identifies the exposure pathways and scenarios as described in section 3.4, the next step is to estimate the impact associated with the exposures, either qualitatively or quantitatively. A variety of methods and models for gathering and evaluating data can be adapted and applied to qualify or quantify exposure and are provided in the subsequent sections.

[28] *22 CCR section 69505.5(c)(3)*

6.2.1 CHEMICAL QUANTITY

The SCP regulations require responsible entities to estimate the amount of the Chemical of Concern and any alternative chemicals needed to manufacture the product, and provide an estimated volume or mass of the Chemical of Concern or alternative chemicals that consumers may potentially be exposed based on the statewide sales of the Priority Product by volume or number of units. [29]

To provide a meaningful comparison, the responsible entity should use consistent units and performance standards for quantity, volume, and mass calculations for both the Priority Product and the alternatives being considered. For instance, significant quantities of a replacement chemical may be needed to provide the same level of performance as the Priority Product with the Chemical of Concern. The change in quantities may affect the potential for exposure.

Chemical quantity in a product and in commerce may serve as a surrogate for exposure potential when exposure data are not available, but the responsible entity cannot rely on this information alone to evaluate exposure effects. The potency of a smaller chemical quantity may still pose a greater potential for adverse effect than another alternative depending on the characteristics of the chemical.

6.2.2 EXPOSURE FACTORS RELEVANT FOR COMPARISON OF ALTERNATIVES

The Department is required to determine and evaluate exposure factors in its process for selecting and listing a product-chemical combination as a Priority Product. The Department's rulemaking files, including the Final Statement of Reasons and supporting technical documentation provide the Department's rationale and basis for identifying the Priority Product. The responsible entity must consider the initial exposure factors DTSC has identified in the Priority Product listing. These factors serve as a starting point for the exposure assessment. Furthermore, the responsible entity must consider whether there are any exposure factors associated with alternatives that make a material contribution to one or more adverse public health impacts and adverse environmental impacts. Additionally, the responsible entity must evaluate whether there will be a material difference in the factor's contribution to adverse

[29] *22 CCR section 69505.5(c)(3)(A)*

public health impacts and adverse environmental impacts between the Priority Products and alternatives or between alternatives.

The responsible entity considers exposure at a variety of levels, including an individual level, an environmental level, and a community level. At the individual level,[30] the responsible entity considers the types and extent of direct exposures that workers or consumers may encounter during the manufacture, use, and disposal of the Priority Product and alternatives. At the environmental level,[31] the responsible entity considers exposure pathways that may result from the manufacture, use, and disposal of the Priority Product and alternatives. Community exposure implications are derived from the prevalence of the Priority Product and alternatives in the marketplace in California.

In addition to the market presence of the Priority Product and alternatives, the responsible entity should consider the exposure factors relevant for comparison of alternatives including:[32]

- Potential occurrence of exposures to the hazardous chemical(s) in the product
- Household and workplace presence of the product
- Potential exposures to the hazardous chemicals during the product's life cycle.

Potential Occurrence of Exposure

Examples of the types of information that the Department considers when identifying a Priority Product are monitoring data that indicate the presence of the chemical in California solid waste, wastewater or storm water streams, environmental media data (e.g., water quality data, dust studies, or air monitoring results), biomonitoring data in humans, or bioaccumulation data for biological organisms. A responsible entity can include measurements of exposure to chemicals in the environment (air, water, or soil), at the point of contact, after contact, or after chemical entry into the human body has occurred.

The Organization for Economic Cooperation and Development (OECD) has developed the Guidance Document for Exposure Assessment Based on Environmental Monitoring (OECD, 2013). The general objective of this document is to derive representative media concentrations using monitoring, modeling, or other approaches for exposure assessment purposes.

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[30] *See near-field discussion in section 6.3.*

[31] *See far-field discussion in section 6.3.*

[32] *22 CCR section 69503.3(b)*

Household and Workplace Presence

The responsible entity considers where and how the product is used and develops scenarios which reflect the range of uses — household, workplace, outdoors, etc. If a product has broad applicability and can be used in the household and in the workplace, the responsible entity includes both intended scenarios in its analysis of exposure potential. The exposure potential must consider intended exposures and reasonably foreseeable uses in either the household or workplace.

Product's Life Cycle Considerations for Exposure Pathways

Exposure due to releases of the Chemical of Concern or the replacement chemicals during life cycle stages, including manufacturing, transportation, storage, use, waste, and end-of-life management[33] must be included in the analysis. These life cycle segments are a subset of the entire lifespan of the product.

The exposure potential during a product's life cycle will be influenced by the types of uses of a Priority Product or its alternatives. The responsible entity considers and evaluates the potential for exposure to sensitive subpopulations, 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, ecologic environment or other locations.

The adverse impacts resulting from the Chemical of Concern or its alternatives are influenced by the frequency, extent (number of exposure pathways), level (concentration of the Chemical of Concern or replacement chemical), and duration (amount of time) of potential exposure. The responsible entity must consider all these factors for each life cycle segment. The exposure duration may vary greatly for a human receptor depending on the product used. For example, the home use of all-purpose cleaners may be in the minutes range versus a custodial worker exposed during an 8-hour workday.

The responsible entity may compile quantitative or qualitative information for different exposure scenarios in a matrix. Table 6-1 illustrates human exposures from asbestos releases in brake pads; ecological impacts are not considered in this example.

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[33] *22 CCR section 69505.5(b)(4)(A)*

Table 6-1 Exposure Scenarios by Life Cycle Segments for Asbestos in Brake Pads

Life Cycle Segment	Exposure Frequency	Exposure Level	Exposure Duration	Exposure Location
Manufacturing	Continuous during a workday	PEL: < 0.1 fiber/cm^3 of air EXL: 1.0 fiber/cm^3	PEL: 8-hr TWA EXL: TWA over 30 min.	Brake friction material manufacturing facility[1]
	Continuous during a workday	PEL: < 0.1 fiber/cm^3 of air EXL: 1.0 fiber/cm^3	PEL: 8-hr TWA EXL: TWA over 30 min.	Brake friction material manufacturing facility[1]
Use	EMFAC assumption[2]	Modeling results[3]	EMFAC assumption[2]	Roadway use[4]
Storage	Minimal[5]	Minimal[5]	Minimal[5]	Distribution centers
	Minimal[5]	Minimal[5]	Minimal[5]	Warehouses
	Minimal[5]	Minimal[5]	Minimal[5]	Retail stores
	Minimal[5]	Minimal[5]	Minimal[5]	Freight trucks
Transportation	Continuous during a workday	PEL: < 0.1 fiber/cm^3 of air EXL: 1.0 fiber/cm^3	PEL: 8-hr TWA EXL: TWA over 30 min.	Auto repair shops[1]
	Continuous during a workday	PEL: < 0.1 fiber/cm^3 of air EXL: 1.0 fiber/cm^3	PEL: 8-hr TWA EXL: TWA over 30 min.	Brake repair shops[1]
Waste	Minimal[5]	Minimal[5]	Minimal[5]	Waste broker
	Minimal[5]	Minimal[5]	Minimal[5]	Household hazardous waste facilities
	Minimal[5]	Minimal[5]	Minimal[5]	Waste facilities

Life Cycle Segment	Exposure Frequency	Exposure Level	Exposure Duration	Exposure Location
End-of-life Management	Continuous during a workday	PEL: < 0.1 fiber/cm^3 of air EXL: 1.0 fiber/cm^3	PEL: 8-hr TWA EXL: TWA over 30 min.	Brake remanufacturing facility[1]
	Minimal[5]	Minimal[5]	Minimal[5]	Household hazardous waste facility
	Continuous during a workday	PEL: < 0.1 fiber/cm^3 of air EXL: 1.0 fiber/cm^3	PEL: 8-hr TWA EXL: TWA over 30 min.	Auto repair shops[1]
	Continuous during a workday	PEL: < 0.1 fiber/cm3 of air EXL: 1.0 fiber/cm^3	PEL: 8-hr TWA EXL: TWA over 30 min.	Brake repair shops[1]
	Minimal[5]	Minimal[5]	Minimal[5]	Auto salvage yard

Use type: Occupational (raw ingredient mixing and forming steps)

Exposed population: General population, mechanics, workers at raw ingredient mixing and forming steps in a brake friction material facility, workers that remove, reapply and form used brakes at a brake manufacturing facility

Exposed environmental compartments: air, water near highways and urban area, soil near highways and urban areas

[1] Based on the PEL and excursion limit (EXL) established in 29CFR section 1910.1001(c)(1) and (c)(2)

[2] Based on assumptions outlined in the EMFAC 2011 Technical Documentation and the EMFAC 2014 Volume III - Technical Documentation.

[3] Based on EMFAC results used to model traffic conditions in a specific air basin, county, or major thoroughfare.

[4] Brake use on California roads is based on the California Air Resources Board EMFAC model. This model incorporates vehicle data from DMV and public road data maintained by CalTrans.

[5] Exposure to asbestos in the brake pad or shoe is minimal since asbestos is released during braking. When the brake is used, the brake friction material (containing asbestos) on the brake grinds against the rotor plate to create friction to stop a vehicle.

The responsible entity must take into account the potential for the Chemical of Concern, alternatives, or their degradation products to be released into, migrate from, or distribute across environmental media during different life cycle segments and their potential to

accumulate or persist in biological or environmental compartments. How the Chemical of Concern is contained or bound during the use of the product and the degree to which the containment is sustainable at end-of-life should also be considered. In addition, engineering and administrative controls that reduce exposure concerns associated with the product should be considered. An administrative control, for example, would be warning labels intended to reduce the potential exposures during use and/or end-of-life. An example of an engineering control would be the use of specialized ventilation equipment where the product is used. Engineering and administrative controls are included in the hierarchy of controls used in minimizing or eliminating exposure to occupational hazards but are not considered to be as effective as elimination or substitution controls (NIOSH, 2015). Elimination and substitution are the most effective at reducing hazards.

In evaluating these potential exposures throughout the product's life cycle, the department shall give preference to the greatest level of inherent protection,[34] which refers to avoidance or reduction of adverse impacts, exposures, and/or adverse waste and end-of-life effects that is achieved through the redesign of a product or process, rather than through administrative or engineering controls designed to limit exposure to, or the release of, a chemical of concern or replacement candidate chemical in a product.

Consideration of the life cycle and potential exposure pathways of a product and alternatives would avoid potential regrettable substitutions. For example, methyl tertiary butyl ether (MTBE) was used by the petroleum industry since the late 1970s as an octane enhancer to replace lead. Approximately 4.5 billion gallons of MTBE were used each year in gasoline (275,000 barrels per day out of a total of 8.2 million barrels/day of gasoline), and increased to more than 3 times the amount when Congress mandated its use as a fuel oxygen additive in 1990. MTBE was added to make a cleaner burning gasoline for use in areas of the country with the worst ozone smog problems. Some companies elected to use MTBE to address air pollution. However, since MTBE is very soluble in water and does not "cling" to soil well, it tended to migrate much more quickly into water than other components of gasoline (EPA, 2000). The increased use of MTBE to improve air quality inadvertently polluted another environmental medium, the groundwater.

Another example is the reformulation of vehicle brake pads to remove asbestos, a carcinogen, with copper, a water pollutant. Asbestos exposure occurred during installation of brakes, while copper release to surface waters occurred as the brakes were used. Until the early 1980s, asbestos was a key ingredient used in vehicle brake pads. Asbestos was used in brakes to

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[34] 22 CCR section 69506(b)

control the high heat generated when the brakes were used to slow or stop a vehicle. Vehicle mechanics, who performed maintenance on braking systems, inhaled asbestos from brake dust that collected in the braking system. When asbestos was found to be hazardous to human health, the US EPA banned nearly all products containing asbestos including vehicle brake pads in 1989. This ban was challenged in the courts and overturned in 1991. Since 1991, the brake pad manufacturers have voluntarily discontinued the use of asbestos in vehicle brake pads. While phasing out asbestos, brake manufacturers switched to copper as a safer alternative to control extreme heat produced during braking (AASA/BMC, 2016). Since replacing asbestos with copper in brake pads, increasing copper concentrations in water bodies near highways and urban areas have been observed. These higher copper concentrations affect fish in these water bodies by preventing them from smelling their predators thus reducing their chances of survival.

6.3 Methods and Tools for Exposure Potential Evaluation

There are various methods and tools available to help complete the exposure assessment for the AA in the second stage. The discussions below present some of these concepts.

COMPARATIVE EXPOSURE ASSESSMENT APPROACH

The 2014 National Academy of Sciences (NAS) Report (NAS, 2014) on alternatives assessment provides structured approaches for both qualitative and quantitative comparative exposure assessment. The method includes the use of key physicochemical properties, available exposure models, use and disposal scenarios, chemical properties, and material properties to identify potential exposures and categorize the results. Alternatives are determined to be 1) substantially equivalent, 2) inherently preferable, or 3) potentially worse than the Chemical of Concern. These categories then help determine the evaluation needed to complete the exposure assessment. For instance:

- If alternatives are substantially equivalent in their expected exposure, the assessment can be mainly hazard based.
- If alternatives would be expected to have higher potential for exposure but have toxicological or other advantages over the Chemical of Concern, a more detailed exposure assessment may be appropriate.
- If alternative has less potential for exposure because of its inherent properties, this should be noted and considered when making the selection of alternatives.

The following steps, adapted from the 2014 NAS Report and illustrated in Figure 6-1, can be used when conducting exposure assessments. These are discussed in more detail in the report.

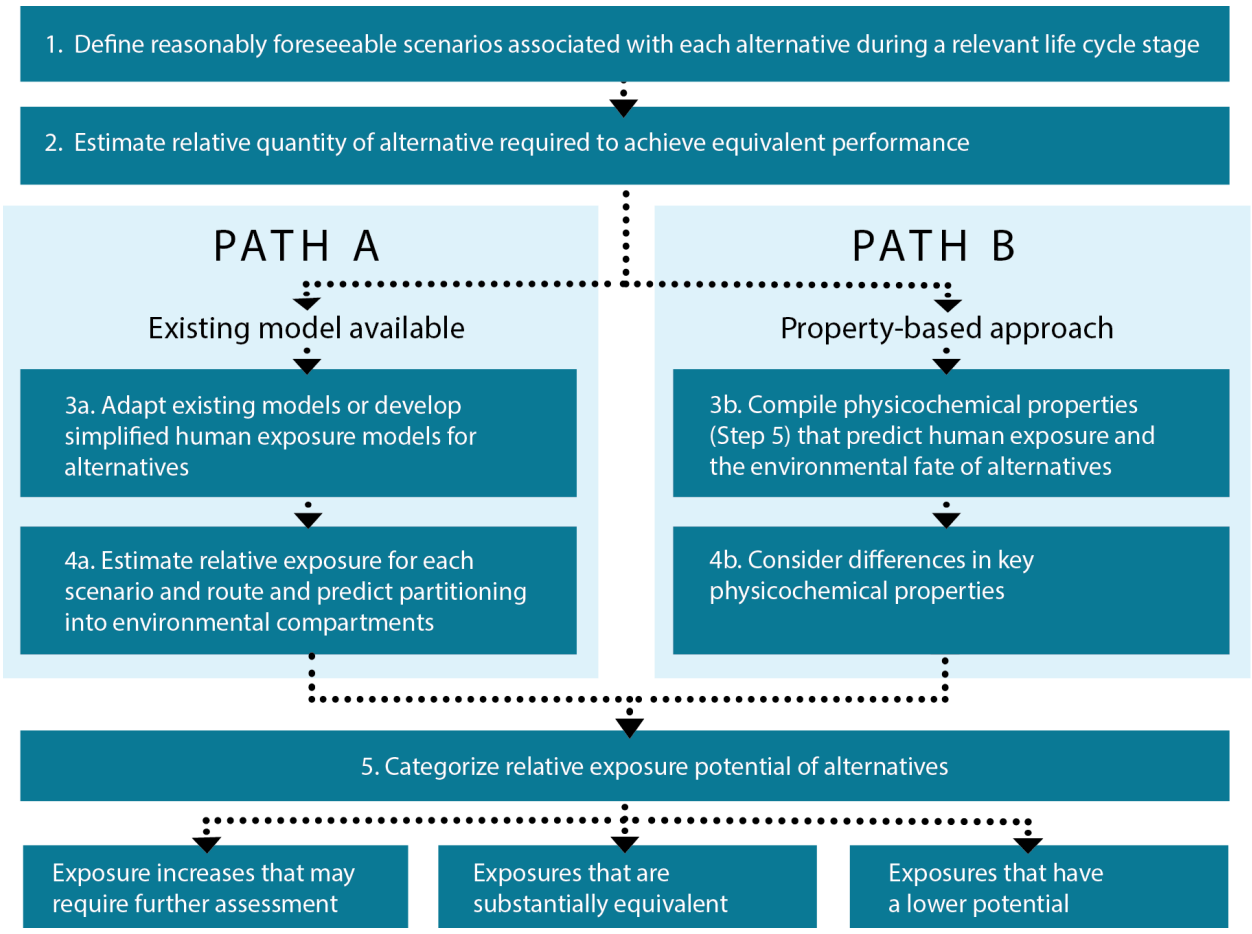


Figure 6-1 An Approach to Comparative Exposure Assessment for Human Exposure Adapted from: National Academy of Sciences (NAS). A Framework to Guide Selection of Chemical Alternatives. Washington, D.C., 2014.)

Physicochemical properties in combination with predictive models can be useful for:

- Identification of the potential direct physical hazards posed by the chemical
- Determination of environmental compartment(s) into which the chemical will partition.
- Estimation of potential for bioconcentration and bioavailability.
- Estimation of likely routes of mammalian exposure and bioavailability, and the likelihood for high aquatic toxicity.
- Estimation of potential for inducing human toxicity.

The IC2 Guide is a good source on implementing the NAS exposure assessment. Additional exposure assessment tools and approaches are discussed below.

CONCEPTUAL MODEL – EXPOSURE

The responsible entity may develop a conceptual model to organize or present all the information gathered. The conceptual model is a graphic representation of the potential relationships between people, wildlife, or the environment, and the chemicals to which they may be exposed, including both direct and indirect exposure pathways. Figure 6-2 (DTSC, 2015) shows various exposure pathways between a consumer product and different receptors. A '•' in the grid indicates a complete exposure pathway via an ingestion, inhalation, or dermal exposure route. Exposure pathways will be assessed using appropriate tools or models depending on available data and the exposure scenarios. Additional discussion of conceptual models can be found in Chapter 3.

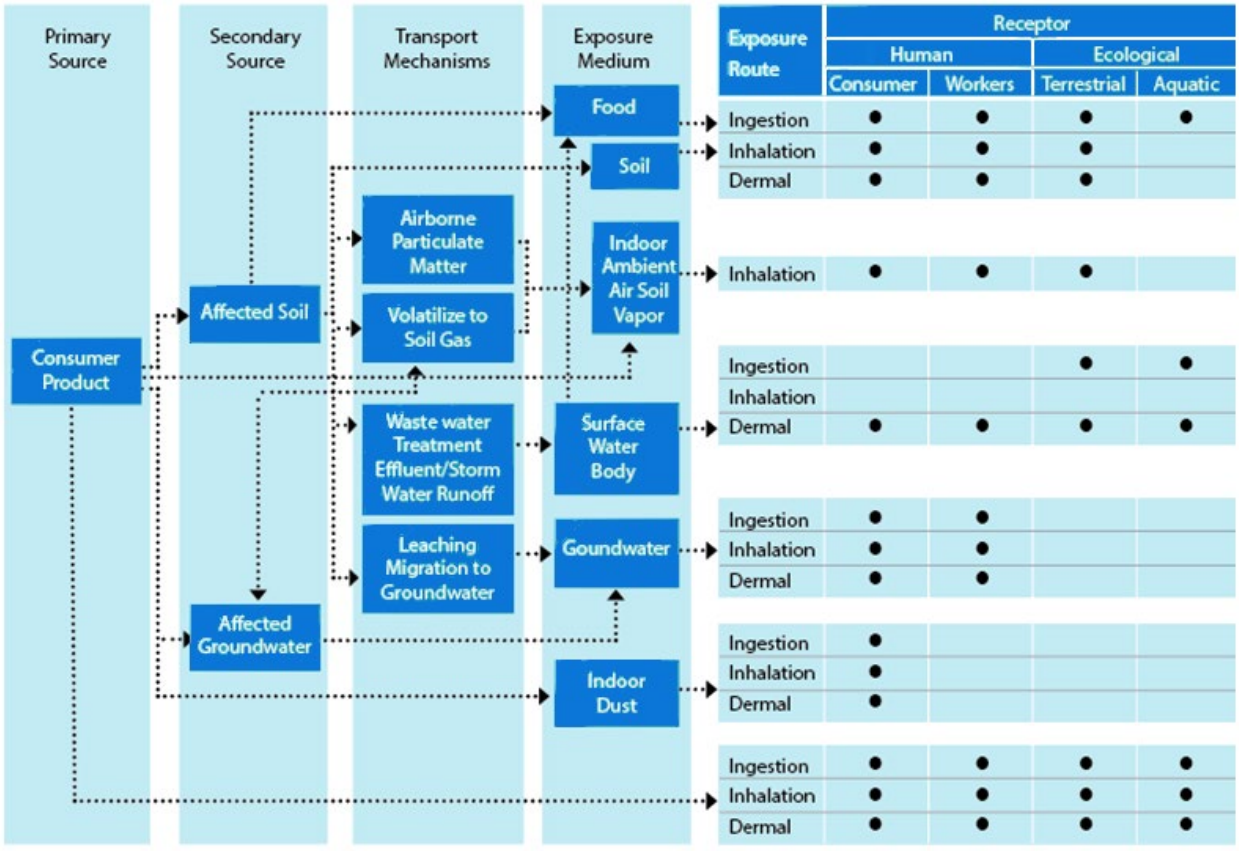


Figure 6-2 Example of a Conceptual Model Receptor Network

Constructing a conceptual model is useful in illustrating potential exposure pathways and life cycle segments. Human and ecological receptors may come into contact with a chemical or with impacted media at any point in the life cycle. Human exposure to a chemical may occur from sources within both the far-field and near-field. Fantke, Ernstoff, Huang, Csiszar, and Jolliet (2016) defined a far-field compartment as any location or environment that is distant from the use of a considered product, to and from which chemical transfers occur and within which removal processes occur. Far-field sources include environmental media (e.g., air, water bodies, or soil), biota (e.g., agricultural crops, animals, and plants), or technological system (e.g., wastewater treatment plants and landfills). A near-field compartment is defined as any indoor or near-consumer location or environment within the vicinity of the use of considered product to and from which chemical transfers occur and within which removal processes occur. Near-field sources refer to chemical exposures within a microenvironment, e.g., a residential building. Exposures to near-field consumer product sources include both direct and indirect pathways (e.g., off-gassing of consumer products or dust ingestion). Exposures from near-field sources have been shown to be the dominant source of human exposure (Csiszar, et.al., 2015) and are highly dependent on chemical properties, product characteristics, usage conditions, and user behavior.

Release of chemicals into the environment also affects ecological receptors. Identification of habitats and potential ecological receptors impacted by chemicals related to the Priority Product or replacement chemicals are important for ecological exposure assessment. Because products are almost always produced from, used in, or disposed into managed or natural landscapes, ecological receptors such as plants, fish, birds, and animals may be exposed, including sensitive ecological subpopulations such as species of special concern, threatened species, or endangered species. Ecological receptors are frequently more sensitive to adverse chemical effects than humans. In addition, many terrestrial organisms may be exposed to higher concentrations of chemicals than humans (e.g., burrowing animals would typically be exposed to higher concentrations of soil gases than humans).

Public services such as municipal wastewater treatment plants and municipal solid waste and recycling programs are downstream receptors of consumer products. Wastewater treatment plants are designed to remove conventional pollutants, such as suspended solids, biodegradable organic material, and some toxic pollutants, before water is discharged to surface water or used to irrigate landscaping and agricultural lands. However, wastewater treatment plants are not designed to treat some chemicals (e.g., contaminants of emerging concern) in consumer products which can find their way into rivers, lakes, or the oceans and potentially impacting aquatic life. Municipal solid waste programs may be the final step for consumer products, but the chemicals may leach out and impact soil and groundwater. These

services should be considered when completing a conceptual model for exposure between a consumer product and human or ecological receptor.

DATA COLLECTION

Exposure assessments may use empirical, measured, or modeled estimates. In general, when conducting exposure assessments, the responsible entity should rely on measured data over model estimates. The responsible entity may use in-house data, engineering expertise, and information about their own production process as model inputs (e.g., chemical concentrations within the product or emission rates during use). Exposure based on measured data has less uncertainty than estimates based on indirect information, such as modeling or estimation results. However, since measured exposure information (production volume, use category, chemical release, and concentrations in food, water, air, and biological samples) is not always available, responsible entities may use predictive models to estimate exposure.

SOURCES OF EXPOSURE DATA

Exposure to chemicals can be estimated by defining the exposure scenarios of interest. Exposure scenarios are typically organized around uses, use patterns, chemical or product specific information, production information, manufacturing processes, physicochemical properties, or human and environmental exposure factors. Readers should refer to Chapter 2 for a discussion of collection of data associated with the product (e.g., use and composition data). Chapter 3 contains information about human activity while Chapter 4 discusses data sources related to the workplace environment.

A responsible entity may want to start with collecting information on key physicochemical properties[35] and environmental fate. While physicochemical properties are available for, or can be estimated for many chemicals, environmental fate data are often not available or are sparse for many consumer product chemicals. These properties can be used to determine or assess specific physical or toxicological hazards, bioavailability, transport, fate, degradation, persistence, bioconcentration, and cellular uptake. Evaluating intrinsic physicochemical properties is a good initial step to predicting exposure pathways (NAS, 2014). For instance, although there are minimal field data on bioconcentration exposure for chemicals, a chemical's octanol-water partition coefficient can be used to estimate a bioaccumulation concentration factor. Other pertinent information, such as available estimates of environmental releases using databases or other tools, should also be collected for use in modeling. The environmental release estimates are critical inputs for models that calculate indirect human exposures from

[35] *For additional discussion of physicochemical properties, see section 3.4.*

the environment, such as through breathing air or drinking water. These release estimates are also needed for modeling exposures to nonhuman aquatic and terrestrial species.

Degradation products and metabolites may be of equal or greater concern than the parent compound. For example, during the wastewater treatment process, the surfactant nonylphenol ethoxylate degrades to nonylphenol, a persistent and bioaccumulative contaminant of emerging concern in aquatic environments (Ying, 2006). Nonylphenol exposure to aquatic organisms such as fish and invertebrates may cause endocrine disruption, reproductive toxicity, and developmental impairment (ECHA, 2014a; ECHA, 2012b).

US EPA summarized sources for exposure assessment data in the most recent Guidelines for Human Exposure Assessment (EPA, 2016b). This document provides information to aid data gathering for an exposure assessment. It includes data such as chemical concentrations in a medium (e.g., solvents in ground water) or at an exposure point (e.g., volatile organic compounds in the breathing zone), or physical characteristics of the medium in which the chemical is present (e.g., groundwater flow direction, depth to ground water, soil porosity, solubility). Another source from US EPA is the Exposure Factors Handbook (EPA, 2011a) which provides a summary of the available statistical data on various factors used in assessing human exposure for the general population and includes factors such as drinking water consumption, inhalation rate, and consumer product use. Many of the commonly used exposure factors can be easily found in the US EPA's downloadable tool Expofirst (v 2.0) (EPA, 2011b), which is a downloadable tool that stores more than 8,000 values extracted from more than 75 of the most commonly used tables in the Exposure Factors Handbook.

Under REACH, suppliers must provide an extended safety data sheet with exposure scenarios. This applies if a hazardous substance is registered in a quantity above 10 tons per year per registrant. An exposure scenario describes how the exposure of humans and the environment to the substance can be controlled to ensure its safe use. ECHA developed the eGuide (ECHA, 2016b), an interactive online publication, to provide information on Safety Data Sheets and exposure scenarios. ECHA also provides guidance on exposure assessment in its guidance document, Guidance on Information Requirements and Chemical Safety Assessment.

US EPA's EXPOsure toolBOX (EPA-Expo-Box) (EPA, 2016d) provides information on exposure assessment tools for estimating exposure from different media and routes (i.e., inhalation, ingestion, and dermal contact), and includes approaches for quantitating exposure concentrations. EPA-Expo-Box also provides information on how to utilize a tiered approach for exposure assessment, as recommended in US EPA's Guidelines for Exposure Assessment (EPA, 1992). The EPA-Expo-Box search function facilitates selection of tiers, media, lifestyles, and

routes of exposure. The tiered approach is a step-by-step, iterative evaluation where the assessment progresses from a relatively simple to more complex analytical processes (Figure 6-3). After completion of each tier, the responsible entity may determine whether further evaluation is warranted using more refined, higher tiered methods. A screening-level exposure assessment is often considered a Tier 1 approach since it typically uses available data and conservative assumptions to produce a high-level estimate of an exposure to a sensitive receptor. The benefit to a screening-level approach is that it is simple and inexpensive to complete and may help indicate whether a significant human health or environmental problem exists. A refined assessment often uses more scenario-specific input data and realistic assumptions which result in more realistic exposure estimates.

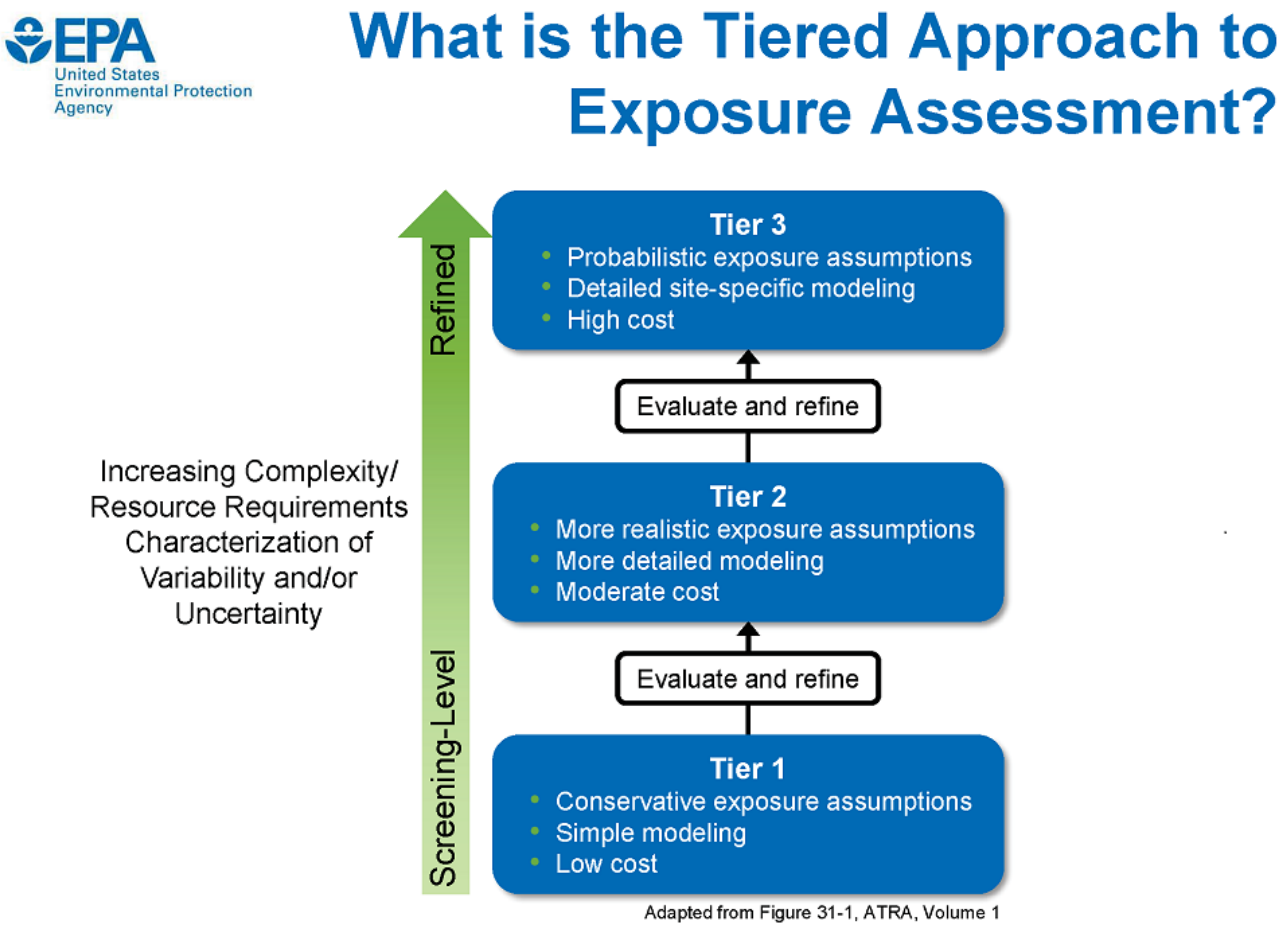


Figure 6-3 Tiered Approach to Exposure Assessment

Screening-level exposure assessments typically use a deterministic approach rather than a probabilistic approach. Deterministic assessments use point values for concentration and exposure parameters, and simple models to produce a point estimate of exposure. Probabilistic

assessments use probability or frequency distributions for media concentrations or exposure factors. Both screening-level and higher-tier assessments may use deterministic approaches, whereas probabilistic approaches are generally used for only higher-tier assessments (EPA, 2016d). Some commonly used exposure assessment tools and models available from various sources are presented in Appendix 6.

Several databases and tools allow the responsible entity to gather information about the environment into which the chemical is released. These tools range from mathematical equations that predict dilution of a volatile chemical when introduced into room air, to more complex computer models that estimate the path of a chemical through the environment over time. Some of these models can account for chemical degradation or persistence in the environment and estimate overlapping concentrations from multiple chemical releases. Ultimately, model outputs may determine either exposure endpoints (i.e., the internal concentrations or body burdens) or exposure potential by estimating intake fractions for both human and ecological receptors. Intake fraction is the ratio between the mass of substance available for contact with an organism and the mass emitted to the environment.

PUBLICALLY AVAILABLE EXPOSURE ASSESSMENT MODELS

There are numerous tools and models that are either publicly available or can be purchased to assess the Chemical(s) of Concern and alternatives being considered. The regulations provide flexibility for the responsible entity to use the most appropriate methodologies, models, tools, and decision-making processes. A responsible entity should give due consideration to the underlying assumptions when selecting models. An understanding of the equations, limitations, default values, and assumptions inherent to the model, along with the key uncertainties associated with the modeled exposure estimates, are important in model selection. The responsible entity should be aware that problems may arise when comparing results obtained from different models. Note that an exposure evaluation alone cannot be used to eliminate an alternative from consideration.

A report prepared by OECD summarizes existing models and tools that may be used for exposure assessment (OECD's 2012 survey) (OECD, 2012b). The study summarizes some of the inherent advantages of some models over others. For example, models such as US EPA's Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER), ECHA's CHEmical Safety Assessment and Reporting tool (CHESAR), and the European Union System for the Evaluation of Substances (EUSES) are integrated risk assessment models, used mostly for priority setting and screening assessment. These are usually multi-media models that combine chemical fate and distribution with environmental risk assessment and exposure of humans via

the environment. Multi-media models can address multiple target groups—children, workers, or other sensitive sub-groups, simultaneously. Other less complex models, such as CSOIL (Van den Berg, et. al., 1995), can address a single medium or exposure population specific to workers or consumers.

The software model ConsExpo (version 4.1) (Delmar, et.al., 2005) and its web-based version, ConsExpo Web, developed by the Dutch National Institute for Public Health and Environment, contains a set of generic models that enables the estimation of exposure and uptake of substances from consumer products that are used indoors. There are examples in the literature (Purdel, et.al., 2015) using ConsExpo modeling to estimate systemic exposure dose of parabens to investigate their estrogenic burden. The responsible entity could determine whether the possible exposure to alternative chemicals is substantially equivalent to Chemical of Concern, or whether the exposure differences need to be considered when considering hazard and other data.

A list of available exposure models can be found in Appendix 6 (Table 6-1) which also contains a summary of the groups (e.g., Consumer, Occupational, Children, General Population, Environment) targeted by each of the tools described (Table 6-2). Other recent developments and approaches for assessing exposure to consumer product chemicals are available in various literatures (Fantke, et.al., 2016; Isaacs, et.al., 2014; Jolliet, et.al., 2015; Csiszar, et.al., 2016a; Csiszar, et.al., 2016b; Huang, et.al., 2017).

In addition, exposure data and models are used for comparative purposes in the AA. It is very important to determine if differences in exposure estimates are truly different, or statistically indistinguishable between the Priority Product and alternatives due to uncertainty involved in exposure data or modeling. The exposure comparison can capture whether there is truly reduced exposure potential due to the inherent properties of replacement chemicals. Additionally, there may be potential trade-offs due to the change to exposure pathways with associated life cycle segment due to change of materials, process, or product. A thorough evaluation of uncertainty would allow the responsible entity to re-evaluate all the assumptions and trade-offs made during the exposure assessment and explore possible alternative assumptions and trade-offs. Chapter 9 discusses uncertainty analysis in more detail.

6.4 Summary

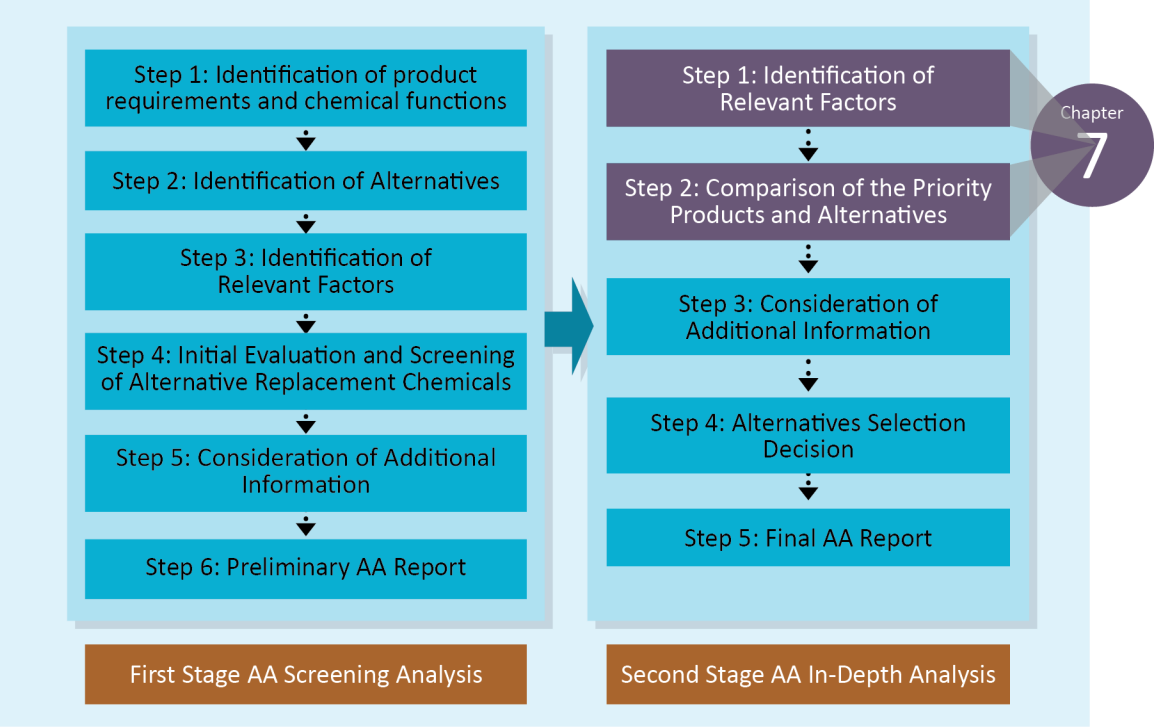
- The responsible entity must consider the relevant exposure factors identified in the first stage of the AA, such as the factors that were the basis for prioritization of the Priority Product.

- The responsible entity will need to re-evaluate associated exposure pathways and life cycle segments for the selected alternatives that move forward to the Final AA Report.
- By identifying exposure pathways for each life cycle segment, the responsible entity can eliminate unnecessary evaluations when there are no adverse impacts due to exposure.
- To aid in determining the exposure potential the responsible entity may use a variety of exposure assessment models and tools.
- Data and data sources that may aid in determining potential for exposure include:
    - Physicochemical data on the chemical;
    - Production volume and use information;
    - Data and information on production, formulation, and use processes;
    - Data on concentrations of the chemical in the product from published literature or provided by industry or consumer groups;
    - Data from the U.S. Occupational Safety and Health Administration's chemical exposure health database or provided by industry;
    - Measured and modeled data and information from exposure scenarios;
    - Human activity data; or
    - Information and recommendations found on the Exposure Factors Handbook (EPA, 2011a) that provides various factors used in assessing exposure to both adults and children.

Chapter 7 — Life Cycle Impacts

This chapter augments the life cycle discussion in Chapter 3. It addresses relevant segments, data inventory and collection, and quantification, if needed, of impacts throughout the life of a product.

Although the concept of Life Cycle Assessment (LCA) is briefly described here, it is important to note that an LCA is not required to conduct an AA. An approach that follows the LCA method is one way to quantify and assess impacts. Any approach which considers the impacts associated with the full life cycle of the product may be applied, such as those discussed in Chapter 4.



For more detailed description of the LCA process, readers can refer to several LCA guidance publications, such as the International Reference Life Cycle Data System (ILCD) Handbook,[36] American Center for Life Cycle Assessment's (ACLCA's) textbook on Environmental Life Cycle

[36] *The ILCD Handbook was developed by the Institute for Environment and Sustainability in the European Commission Joint Research Center and consists of a set of documents. (Available from http://eplca.jrc.ec.europa.eu/?page_id=86)*

Assessment (ACLCA, 2014), US EPA's Life Cycle Assessment: Principles and Practice (EPA, 2006), and others.

7.1 Life Cycle Segments

Responsible entities must consider the full life cycle of the product when assessing its impacts.[37] This will allow for thorough evaluation of the product's impacts, not only during use, but also during its other life segments. All activities during a consumer product's life span must be considered since information about impacts of one life cycle segment does not provide a sufficient basis for understanding the total environmental performance of a product. Chapter 3 discusses life cycle thinking when identifying relevant factors and the associated life cycle segments.

The life cycle activities specified in the regulations are briefly described below.

Life Cycle
Life cycle is defined as "the sum of all activities in the course of a consumer product's life span, including raw materials extraction, resource inputs and other resource consumption, intermediate materials processes, manufacture, packaging, transportation, distribution, use, operation and maintenance, waste generation and management, reuse and recycling, and end-of-life disposal."
(22 CCR § 69501.1(a)(42))

RAW MATERIALS EXTRACTION

A product's life cycle begins with raw materials and energy extraction operations. Raw materials extraction activities include the removal of metals, minerals, soil, or aggregates from the earth; oil and gas extraction; mining and dredging; and the harvesting of timber and crops.

The responsible entity evaluates impacts during the raw materials extraction life cycle segment when the alternatives under consideration use different types of raw materials or a different procedure to extract them. For example:

- Are rare materials involved in the extraction? Iridium, for instance.
- Is there a new risk introduced in the extraction process with the alternatives (e.g., use of explosives)?

[37] *See discussion of Life Cycle Thinking in Chapter 3.*

INTERMEDIATE MATERIALS PROCESSES

Intermediate materials processing includes the handling or treating of the raw materials to render them more useful than in their natural state. Intermediate processing produces a product that is used as an input to the manufacturing of a subsequent product and may include any of the following: refining, milling, spinning, weaving, molding, casting etc.

For example, raw cotton used to produce yarn is an intermediate good. When the yarn is sold to the owner of a textile mill for production of cloth, the yarn is still an intermediate good. The cumulative impacts from spinning the cotton to yarn must be included as part of an intermediate materials process.

MANUFACTURE

Manufacturing refers to producing or making the product. The responsible entity considers relevant factors, especially if a Priority Product has been listed due to worker exposures during manufacturing. Considerations include:

- Are additional materials required to manufacture the alternatives?
- Will there be significant increases in the use of energy or water?
- Will there be additional air emissions or releases to water or soil?
- Will solid waste generation be increased due to the selection of an alternative?
- Were worker exposures during manufacturing an important basis for listing the Priority Product?

PACKAGING

The act and process of packing a product to be contained, identified, and displayed for sale.

- Will there be differences in the type and quantity of materials used for packaging?
- Does the packaging need to be changed to be compatible with any of the alternatives under consideration? For example, will a formulation need to be shipped in a glass container, or a plastic bottle?

TRANSPORTATION

The act of moving, shipping, or hauling an item or product to its intended use, such as transport of an intermediate product to the manufacturing facility for the production of the final product, or transport of the final product to a distribution facility or retail centers. For example:

- Is a different mode of transport required for the alternatives?
- How far are the materials to be transported?
- Will there be an increase in greenhouse gases due to increased transportation distance?

Responsible entities may consider how future demands for an alternative may result in additional manufacturing locations, and thus, changes in transportation impacts.

DISTRIBUTION

Distribution includes the acts of storing, delivering, and supplying products to retail centers or consumers. Distribution may include transportation activities. The responsible entity decides if transportation attributed to distribution is addressed separately or together as a single life cycle segment.

During storage, special handling requirements of a given alternative may consume additional resources. Other factors that may impact this activity can be a change to the distribution chain, to the size or weight of the alternatives, or to the type of shipping containers used.

USE

The use segment refers to the consumption, application, or utilization of a product for its intended purpose.

- What are the impacts during use?
- What are the exposure pathways?
- Has the method of application changed exposure duration or intensity?
- Has the quantity of product required changed?
- Have new routes of exposure been introduced by an alternative?

OPERATION AND MAINTENANCE

Operation and Maintenance refers to the upkeep and care that are necessary to repair or keep the product in working order. A consumer product that does not wear out quickly will probably need operation and maintenance care during use. Examples of consumer products that may need such care include furniture, clothing, and footwear.

- What kinds of chemicals or products are necessary for maintenance?
- How much energy is used to operate or maintain?
- Is there a difference in the reliability or durability of the alternatives?

WASTE GENERATION AND MANAGEMENT

Waste generation and management refer to the excess of unused materials, substances and by-products and their handling.

- How much waste is generated?
- Is hazardous waste generated?
- Are there releases required to be reported under the Toxic Release Inventory program? (EPA, 1986)
- Is there any special handling required?
- Does the responsible entity mitigate waste generation impacts by participating in extended producer responsibility programs?

REUSE AND RECYCLING

Products with a recycle or reuse potential will generally use less energy than products requiring raw materials extracting and processing.

- Will there be a change in how the product can be reused or recycled?
- Is there a potential for exposure to a Chemical of Concern during reuse or recycling?

END-OF-LIFE DISPOSAL

End-of-life disposal refers to the point when a product can no longer serve the purpose for which it was designed nor serve as a feedstock for products that can use recycled content and must be discarded.

- How is the product used and where does it end after its use, i.e., landfill, POTW, air, soil?
- What is the potential for releases of Chemicals of Concern to air or water bodies from the identified disposal?
- Is the Priority Product or the alternative a hazardous waste at end-of-life?

7.2 Approaches for First Stage

Chapter 3 discusses the first stage process for identifying relevant factors. If relevant impacts are identified, then the associated relevant life cycle segments are also revealed.

During the first stage, the responsible entity applies life cycle thinking with a qualitative approach and may use a conceptual model to illustrate the exposure pathways and life cycle

segments. Responsible entities may refer to the Checklist for Identification of Relevant Factors in Appendix 3-2 to determine if any of the factors in the life cycle segments listed in Table 3-2A are relevant. The life cycle segments of interest will be those where the impacts have a material contribution, or a material difference, between the Priority Product and alternatives. The responsible entity evaluates each of the relevant factors within each life cycle segment.

For example, if a Priority Product was listed because the Chemical of Concern has the potential to cause cancer due to exposure during use, then the alternatives must, at a minimum, be evaluated for its potential impacts during the use segment. As alternatives are screened, life cycle segments previously not considered relevant may become relevant and those segments must be expanded. If for example, one of the alternatives being considered is not a carcinogen but requires significantly more energy resources during manufacturing, then the manufacturing life cycle segment becomes relevant and must be further evaluated.

Consider, for example, a polyethylene bag as the Priority Product. The alternatives being considered to replace it are paper, canvas, or nylon. Due to the change in use of raw materials, the raw materials extraction segment may be relevant. The manufacturing segment becomes relevant because the production processes differ and each have differing impacts; transportation is relevant because more trucks may be required to transport an equal amount of bags; the use segment is relevant because they each provide varying amounts of wear and use; and finally, reuse and recycling, and the end-of-life may be relevant. These findings may be presented in a narrative or in a table as in Table 7-1.

Table 7-1 Identification of Relevant Life Cycle Stages

PRODUCTS	Raw Materials Extraction	Intermediate Materials Processes	Manufacturing	Packaging	Transportation	Distribution	Use	Operation and Maintenance	Waste Generation & Management	Reuse and Recycling	End-of-Life Disposal
Priority Product & Alternatives	O	O	O		O		O		O	O	O

O Impact observed

Once the relevant life cycle segments have been identified, the same matrix can be expanded to summarize the relevant adverse impacts. See Table 7-2 for an example of a matrix with

results. Please note, that once a more in-depth analysis is underway or completed, additional relevant life cycle segments may be added or eliminated.

Table 7-2 Identification of Relevant Life Cycle Stages and Relevant Impacts

ADVERSE IMPACTS	Raw Materials Extraction	Intermediate Materials Processes	Manufacturing	Packaging	Transportation	Distribution	Use	Operation and Maintenance	Waste Generation & Management	Reuse and Recycling	End-of-Life Disposal
Environmental Impacts	O		O		O		O		O	O	O
Public Health Impacts	O		O				O		O	O	O
Waste and End-of life									O	O	
Environmental Fate	O		O				O				
Materials & Resource Consumption		O									
Physical chemical hazards											
Physiochemical properties											

O Relevant Impact Observed

The responsible entity presents a comparison of impacts across the full life cycle of the Priority Product and the alternatives. The comparison may be presented in tables or spreadsheets like Table 7-3 shown below. The information may be organized by life cycle segments, by adverse impacts, by exposure pathways, or by any other appropriate groupings. The responsible entity may use quantitative and qualitative information about the Priority Product and alternatives. A simplified qualitative screening indicating low (L), medium (M), or high (H) impact on each life cycle segment may be used during the first stage and later refined during the second stage.

These high, medium, or low impacts may be colored purple, yellow, and green, respectively, as has been done in several studies for better visual identification of differences. The responsible entity can create a matrix that best suits its needs.

Table 7-3 Matrix for Simplified Evaluation of Alternatives at Various Life Cycle Stages

Impact: Human Health

Products	Raw Materials Extraction	Intermediate Materials	Manufacturing	Packaging	Transportation	Distribution	Use	Operation and Maintenance	Waste Generation & Management	Reuse and	End-of-Life
Priority Product	L	H	H				H				H
Alternative A	H	H	M				L				L
Alternative B	L		M				M				M
Alternative C	M	H	H				H				M
Alternative D	L	L	L				M				L
Alternative E	L	L	M				M				M

Impact: Air Quality

Products	Raw Materials Extraction	Intermediate Materials	Manufacturing	Packaging	Transportation	Distribution	Use	Operation and Maintenance	Waste Generation & Management	Reuse and	End-of-Life
Priority Product	H	M	L				L				L
Alternative A	H	H	M				L				L
Alternative B	H		H				H				H
Alternative C	M	M	M				H				H
Alternative D	L	L	L				L				L
Alternative E	L	L	M				M				M

Impact: Water Quality

Products	Raw Materials Extraction	Intermediate Materials	Manufacturing	Packaging	Transportation	Distribution	Use	Operation and Maintenance	Waste Generation & Management	Reuse and	End-of-Life
Priority Product	H	M	L				L				L
Alternative A	H	H	M				L				L
Alternative B	H		H				H				H
Alternative C	M	M	M				H				H
Alternative D	L	L	L				L				L
Alternative E	L	L	M				M				M

…Continue comparison with other impacts

Products	Raw Materials Extraction	Intermediate Materials	Manufacturing	Packaging	Transportation	Distribution	Use	Operation and Maintenance	Waste Generation & Management	Reuse and	End-of-Life
Priority Product	H	M	L				L				L
Alternative A	H	M	M				L				L
Alternative B	H		H				H				H
Alternative C	M	H	H				H				H
Alternative D	L	L	L				L				L
Alternative E	L	L	M				M				M

7.3 Approaches for Second Stage

During the first stage AA, relevant factors may have been identified mostly based on qualitative information and assessment. In the subsequent second stage, the choice of relevant factors is revisited, and factors previously identified are assessed—preferably with quantitative data.[38] The principal goal of the second stage AA is to further evaluate the alternatives identified in the first stage AA and select an alternative that is justified by the analysis presented by the responsible entity. In the second stage AA, the responsible entity gathers available quantitative information on the inputs (materials and energy) and releases to the environment to reevaluate the impacts on the associated life cycle segments. In most instances, this materials and releases inventory, together with the chemical's physicochemical properties for environmental fate, may already provide the responsible entity the needed information for a relative comparison of potential impacts of the Priority Product and alternatives.

One approach that may be used to estimate and compare the environmental impacts of the product and alternatives at various life cycle stages is the use of LCA tools. Common LCA practices consider a wide range of hazard endpoints that address most of the relevant factors specified in the regulations. The responsible entity may use the LCA process to estimate the

[38] *22 CCR section 69505.6(a)*

impacts for each life cycle segment included in the analysis. Understanding the impacts at different stages of the product's lifespan can help identify burden shifting when comparing alternatives. Again, LCA is not needed in AA if the responsible entity can resolve trade-offs without resorting to LCA.

Whether the responsible entity uses LCA tools and databases or conducts its own data inventory and process analysis, the following activities are involved in determining impacts at each life cycle stage: identifying the scope of analysis, collecting data, and determining impacts.

IDENTIFYING THE SCOPE OF ANALYSIS

In the first stage of the AA, all life cycle segments specified in the regulations, as discussed above, must be considered to determine their relevance for further evaluation during the AA. After initial evaluation, some life cycle segments may be eliminated from further analysis if there are no material differences between the Priority Product and the alternatives in these stages. The remaining relevant life cycle stages must then be included in the scope for more in-depth evaluation in the second stage AA. The responsible entity may create a life cycle flow diagram with the remaining relevant life cycle stages and then gather as much process data as possible to determine the amount of materials, water, and energy used, as well as wastes and emissions, at each life cycle stage. Figure 7-1 shows a simplified flow diagram.

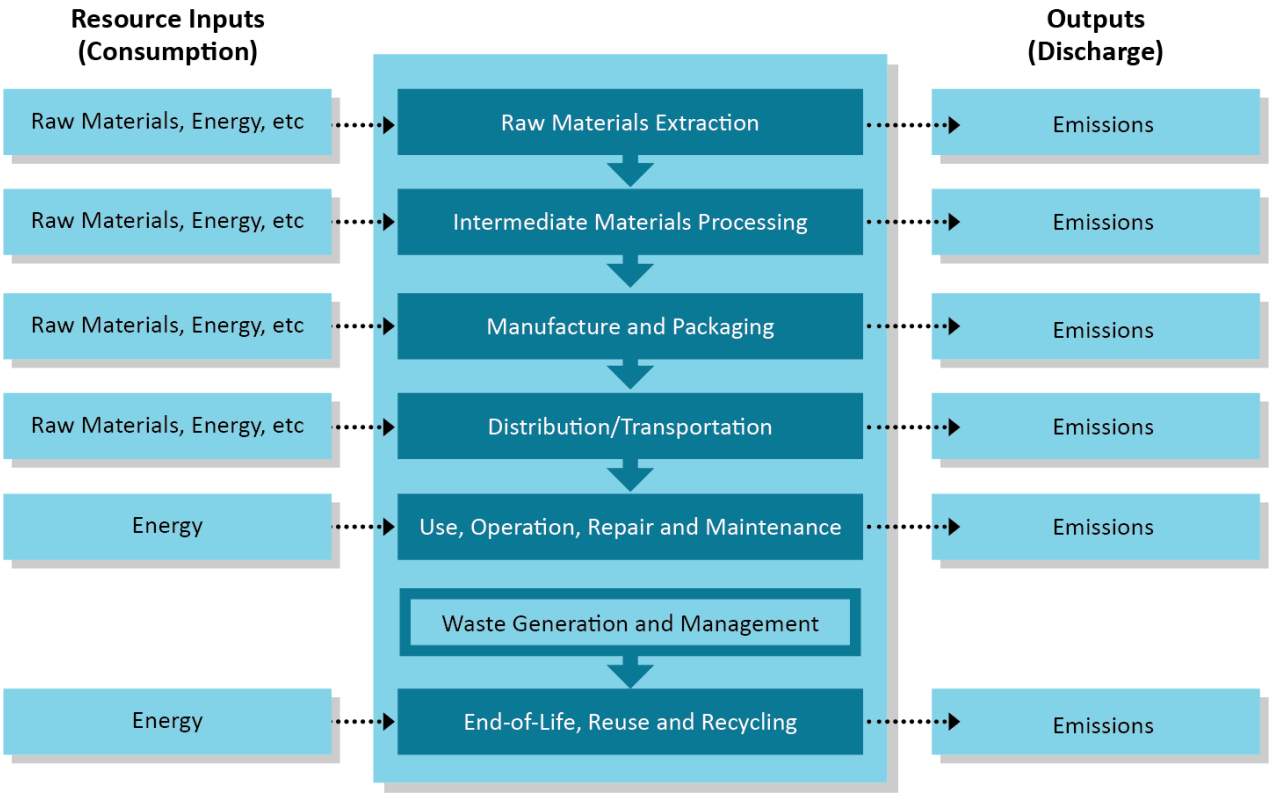


Figure 7-1 Simplified Flow Diagram

DATA COLLECTION

Once the scope is defined, the materials and energy input and the releases for each relevant life cycle segment must be determined:

- How much raw materials or energy is used?
- How much waste is generated?
- What are the releases or emissions?

Using these data, the responsible entity establishes the similarities or differences between the Priority Product and the alternatives being considered. The type of available data and information, whether quantitative or qualitative, will dictate to what extent the responsible entity may be able to quantify the materials and energy inputs during the second stage.

When collecting and comparing data, it is important to use the same functional basis to have a fair comparison between the Priority Product and alternatives. The product function and performance are attributes of the product which must be met by the alternatives being considered. The responsible entity may choose to define a function or specify a performance

standard for a Priority Product, so that those properties can then be objectively compared. For example, the responsible entity specifies the number of wipes needed to clean an area measuring one cubic meter. If the Priority Product requires one wipe and the alternative being considered requires two, then the amount of materials and resources needed to manufacture the Priority Product should be compared to twice that for the alternative. Another example is a canvas bag as an alternative to single use plastic bag. Both bags are designed for a different number of uses. The canvas bag needs more resources when manufactured and is likely to produce greater environmental impacts when compared to plastic on a bag to bag basis. To make the comparison fair, the responsible entity defines the performance standard for duration. How many bags are required to carry one month's or one year's shopping?

Although it would be ideal to have data that are specific to the product, in the absence of process-specific data, responsible entities may use commercially available databases to estimate the emissions or releases from their product (see Appendix 7-2). Process information is available through various sources, and values can also be obtained from many government and research institutions, many of which are freely accessible. Inventory databases are also available from commercial sources, such as Ecoinvent, and publicly available sources, such as the U.S. Life Cycle Inventory Database. Furthermore, Chapter 9 provides example approaches when there is an absence of manufacturing process information.

Having the needed input data for each life cycle stage, one can then estimate the emissions and the corresponding health and environmental impacts coming from the products being evaluated.

MULTIMEDIA LIFE CYCLE IMPACTS

After gathering the materials and energy input and quantifying emissions, the responsible entity evaluates impacts at each life cycle segment and makes an informed comparison of the Priority Product and alternatives. This can be done either by making a qualitative determination or have a more in-depth quantification of impact potential determined through life cycle impact assessment.

In a life cycle impact assessment, the life cycle inventory (inputs and outputs) are converted to a common equivalent unit for the specific impact that would result from the releases or consumption of materials or energy. For example, greenhouse gases contribute to the Global Warming Potential (GWP). The GWP indicates the amount of warming a greenhouse gas causes over a given period—typically 100 years. GWP is a midpoint indicator expressed as carbon dioxide (CO_2) equivalent. Gases contributing to global warming are converted to CO_2 equivalent using the characterization factor to allow for comparison. The example below in

Table 7-4 explains this characterization factor. Methane and carbon dioxide emissions both contribute to the GWP. However, methane is 25 times more potent than carbon dioxide in terms of GWP.

Table 7-4 Example of How Characterization Factor is Used to Obtain Global Warming Potential

Greenhouse Gas	Inventory Data	Characterization Factor	Global Warming Potential – GWP (CO_2 equivalent)
Carbon Dioxide (CO_2)	5 kg	1	5 kg
Methane (CH_4)	2 kg	25	50 kg

There are LCA software packages that calculate the impacts based on process data inputs. Widely used among these programs are Gabi (Thinkstep, 2016) and SimaPro (SimaPro, 2016). Though these programs can assist with the process, they are not required for estimating impact if material use and emissions are properly identified and quantified.

Table 7-5 lists the typical midpoint impact categories examined with LCA along with the corresponding relevant factors required by the regulations.

Table 7-5 Typical Midpoint Impact Categories

Midpoint Impact Categories	SCP Regulations: Factors to Consider for Relevance
Global Warming Potential	Adverse air quality impacts/Greenhouse Gases
Ozone Depletion Potential	Adverse air quality impacts/Stratospheric ozone depletion substances
Photochemical Smog	Adverse air quality impacts/Tropospheric ozone forming compounds
Particulate Matter Emissions	Adverse air quality impacts/Particulate matter
Eutrophication	Adverse ecological impacts; Adverse water quality impacts
Acidification	Adverse ecological impacts
Ecotoxicity	Adverse ecological impacts
Human Health Effects	Adverse human health impacts
Resource Depletion	Materials and resource consumption impacts
Water Use	Materials and resource consumption impacts

Figure 7-2 shows an example of classification of life cycle inventory inputs and outputs and characterization onto appropriate impact categories of global warming potential (GWP), human health toxicity potential (HHTP), and abiotic depletion potentials (ADP).[39]

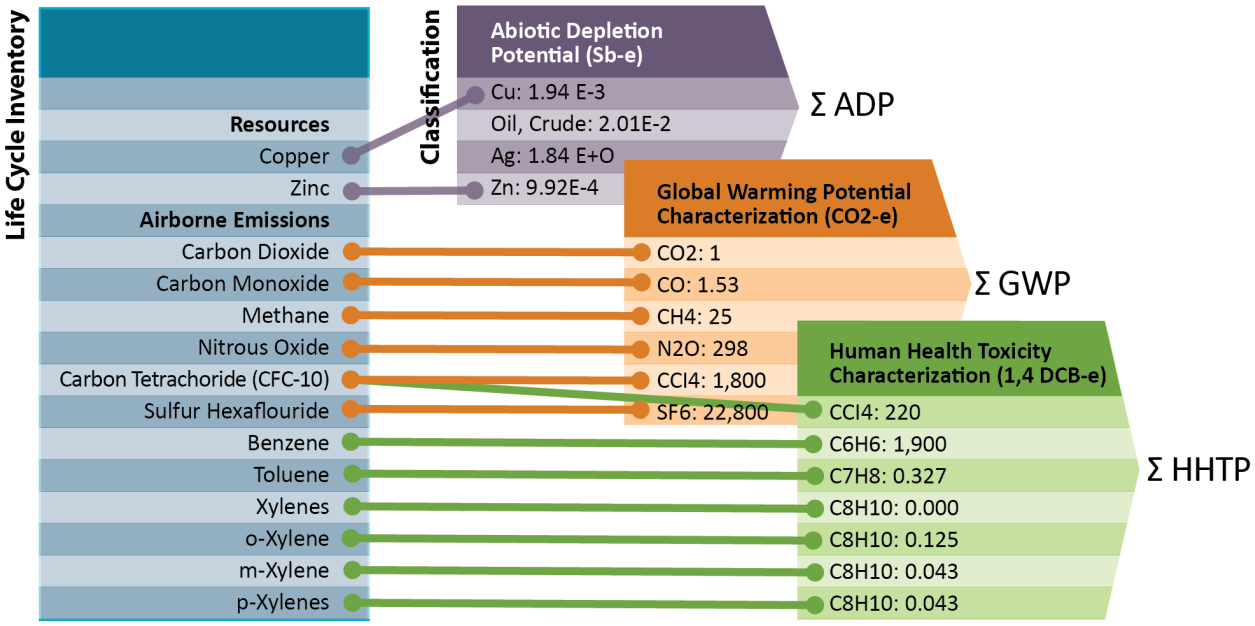


Figure 7-2 Classification and Characterization of LCI Data
(Adapted from: Environmental Life Cycle Assessment – Measuring the Environmental Performance of Products. American Center for Life Cycle Assessment. 2014)

Appendix 7-1 lists the SCP factors and corresponding life cycle impact categories.

The adverse impacts that must be evaluated are unlikely to be addressed by one model, software application, or analytical tool. The responsible entity may need to use multiple analytical tools to address the identified relevant impacts or rely on other information sources. For example, LCA methodologies typically address two categories of ecological impacts: aquatic and terrestrial toxicity. The SCP regulations include specific water quality impacts (e.g., increase in chemicals with Maximum Contaminant Levels). If water quality is a relevant factor, the responsible entity needs to address the Maximum Contaminant Levels, using other data, tools, or approaches to evaluate water quality impacts not addressed by the LCA analytical tool used. Some factors can be determined directly just by looking at the inventory amounts and

[39] *Abiotic resource depletion includes depletion of nonrenewable resources, i.e., fossil fuels, metals, and minerals.*

determining whether the process discharges will exceed the relevant Maximum Contaminant Levels).

7.4 Uncertainty

Results and conclusions drawn from an AA are only as good as the data used. Many times, assumptions and best professional judgment are used to fill data gaps when conducting an AA. Assessing whether a change in the value of a parameter would result in a different conclusion is an important part of the analysis. Chapter 9 further details approaches to addressing uncertainty.

7.5 Tools and Data Sources

Appendix 7-2 lists databases, life cycle impact assessment models, and software programs that may be used to conduct the AA.

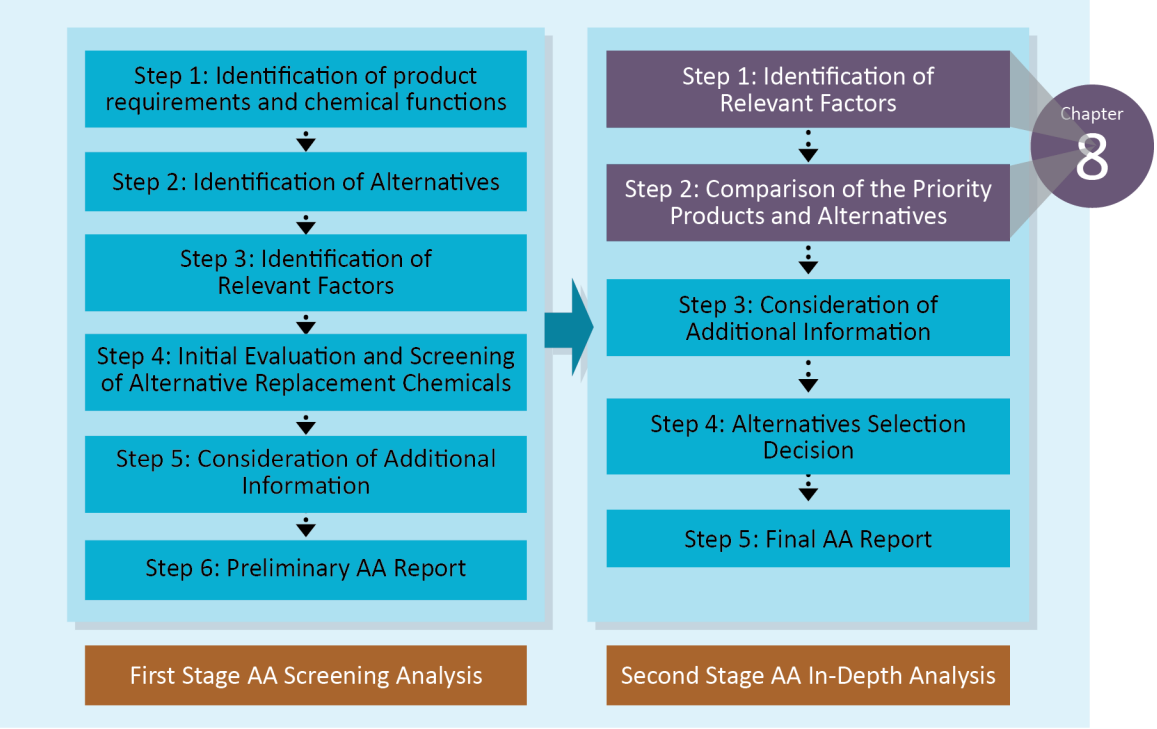
7.6 Summary

- The SCP regulations require consideration of the life cycle of the product for the AA.
- Relevant factors and their associated life cycle segments define the scope of the AA.
- The responsible entity needs to clearly define product function and performance to have an objective comparison based on equivalent function and performance.
- The responsible entity may use LCA methods to quantify impacts by creating an inventory of materials, water, energy, and emissions. This inventory is then associated with the impacts caused by these factors.
- Typical life cycle assessment impact categories do not fully cover the SCP regulation's entire list of potentially relevant factors. The responsible entity may use other tools, such as chemical hazard assessment, to address some of these factors. Some factors can be determined directly from the inventory amounts related to the impacts, such as using water consumption to address material and resource consumption.
- The responsible entity needs to describe methodologies or tools used to identify, quantify, or evaluate factors it determined to be relevant.

Chapter 8 — Economic Impacts

This chapter presents methods that can be used to conduct an economic analysis as required by the SCP regulations. The regulations do not specify an approach but require responsible entities to show that the economic impacts across the relevant life cycle stages of the product and alternatives are considered when selecting an alternative.

An economic impact assessment is required to address costs to public health, the environment, government agencies, and non-profit organizations for all AAs. However, if the responsible entity chooses to keep the Chemical of Concern in the Priority Product, a quantified comparison of the internal costs of the Priority Product and the alternatives must be included in the AA Report.



The focus of an economic analysis in the manufacture of a product may be internal costs, such as those relating to raw materials, direct labor, variable or fixed overhead expenses, and marketing. Historically, when substances were released into the air, water, or soil, the resulting cost of pollution was shared by society. The broader SCP second stage AA process requires the responsible entity to evaluate costs such as public health costs, environmental costs, and cost associated with government agencies and non-profit organizations to manage waste, or to oversee environmental cleanup that may result from releases of the Priority Product or

alternatives. Costs must be evaluated, monetized, and compared for any relevant life cycle segments.

In AA, the principal goal of the economic impact assessment is to determine relative costs across the life cycle of the Priority Product and its alternatives. Economic impact assessment in alternatives analysis is not about determining the absolute value of the costs, but rather, it is being done to have an economic comparison between the Priority Product and the alternatives. The costs estimated through this process should not be used for other purposes.

The Department is aware that some economic information may be confidential. Responsible entities may indicate that information is confidential and substantiate that claim according to the process in Article 9 of the regulations at the time of submittal. Responsible entities will submit a redacted and unredacted version of the document for which confidentiality is claimed and only the redacted version will be shared publicly. The Department will protect responsible entity's confidential and trade secret information from disclosure to the public.

The nature and complexity of the tasks in this section may require unique and advanced capabilities not routinely used by responsible entities. The likely existence of data gaps and the need for a variety of tools and methodologies may require a narrative clearly describing assumptions, limitations, and methods used in the economic analysis.

8.1 Existing economic Guidance Documents

There are several existing documents that describe approaches to conducting economic analyses, but most of these either focus on impacts of regulations (such as US EPA's Guidelines for Preparing Economic Analyses) (EPA, 2010), or impacts of chemicals in general, rather than a direct analysis of impacts at the product level. In addition, there is a wide range of variability in the approaches and methodologies used in economic impact analysis. To ensure that the Priority Products and alternatives being considered are adequately compared, the responsible entity should use an approach or methodology that is consistent across the Priority Product and alternatives, when possible.

The European Chemical Agency's (ECHA's), "Guidance on the Preparation of Socio-Economic Analysis (SEA) as Part of an Application for Authorisation" (ECHA, 2011d), provides approaches and detailed steps to estimate public health and environmental costs. ECHA's guidance provides a process to scope, assess, interpret, and quantify the human health and environmental impacts. The SEA provides guidance on analyzing and documenting whether the

socio-economic benefits of the continued use of a substance outweigh the risks of continued use for human health and the environment.

A report prepared for the Department, "Cost Benefit Analysis Support for California EPA's Green Chemistry Initiative" (Horvath, et.al., 2012), summarizes existing guidelines and data sources, benefit cost analysis, and life cycle costing tools. It provides a benefit cost analysis case study using a fictitious example of selecting materials for baby bottles. Although the case study is not meant to be comprehensive, it provides the basic principles that may be considered. This document incorporates a life cycle perspective, assessing the effects of manufacturing, production, and downstream effects, including end-of-life, but does not provide detailed steps for completing a cost benefit analysis.

8.2 Internal Costs

If the responsible entity decides to retain the Priority Product based on internal cost impacts, the AA report needs to include a comparison of the internal costs between the Priority Product and the alternatives. Internal cost should not be the only factor to consider when making decisions. External costs should also be considered as discussed below.

As required by the SCP regulations, the Final AA Report must include a quantified comparison of the internal costs including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs.[40] Include other factors that have been used in the analysis if they contribute to the economic impacts. The Priority Product, as well as each alternative considered, will have its own set of impacts and associated costs. Costs related to facility or product redesign to reduce energy consumption or wastes should be included as an internal cost.

[40] *22 CCR section 69505.6(a)(3)(B)*

An alternative may be considered economically infeasible if adopting it would significantly reduce the responsible entity's operating margin. The responsible entity may determine that the alternatives are not economically feasible because they would have a significant impact on its operating margin.

Economically Infeasible
If the Responsible Entity's alternative selection decision is to retain the Priority Product based in whole or in part on internal cost impacts, this decision must be explained in the AA Report. The AA Report must include a quantified comparison of the internal cost impacts of the Priority Product and the alternatives, including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs.

The responsible entity will present the cost calculations, with an emphasis on the areas where there is a significant difference between the Priority Product and the alternatives. Establishing the appropriate operating margin is a business decision, but responsible entities should still provide their reasoning for claiming significant reduction in operating margin. If they feel it is confidential business information, responsible entities should designate it as such and provide complete documentation and a redacted copy of the documentation being submitted.

8.3 External Costs

Regardless of the responsible entity's internal costs findings, the regulations require the responsible entity evaluate, monetize, and compare the impacts of the Priority Product and the alternatives on:

- Public health and environmental costs, and
- Costs to governmental agencies and non-profit organizations that manage wastes, oversee environmental cleanup and restoration efforts, and charged with protecting natural resources, water quality, and wildlife.

This Guide suggests approaches to estimate the external costs and does not restrict the use of other approaches that the responsible entity believes are appropriate for their situation. It is possible that the monetization approaches may require data that may not be available. The responsible entity should examine the approaches and determine the appropriate method where data may be available. Again, because of the wide range of variability in the approaches, the responsible entity should use a method that is consistent across the Priority Product and the alternatives. If there are no available data to proceed with the monetization of impacts, the responsible entity documents the work conducted to show the good-faith effort done. The responsible entity then uses professional judgment to make a qualitative cost comparison of

the Priority Product and alternatives, focusing only on the relevant impacts identified in previous steps. Refer to Chapter 9 on addressing informational needs and uncertainty.

8.4 Willingness to Pay

Willingness to pay is a key economic concept for assessing economic benefits in benefit-cost analysis. It is an approach that assigns values to life, health, or ecosystem services. It measures the value that individuals are willing and able to give up for a reduction in risks to their health and safety or for environmental improvements. Willingness to pay estimates provide a monetary value for changes in health and safety risks or ecosystem services based on the preferences of those who are affected by them.

Willingness to pay is estimated in two principle ways: revealed preference and stated preference. Revealed preference method examines market choices people make between income versus goods related to health or the environment.[41] For example, the value of preventing a fatality is estimated from the amount that people are willing to pay for products that reduce the risks. Their choice to pay for these products reveals their preference. Stated preference methods rely upon surveys that essentially simulate markets to ask people about tradeoffs they would make between income and health or the environment.[42]

The willingness to pay approach has been used when assessing the life-saving benefits of regulations by providing a dollar value on reduced fatality risks, often expressed as statistical lives "saved" by the regulations. When applied for the purpose of economic evaluation in alternatives analysis, it captures how much people are willing to pay to reduce the risk of dying from conditions that may be caused by environmental pollution.

This approach has also been applied to valuing environmental impacts.

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[41] Revealed preference techniques use information from related markets to impute a value for non-market goods. A related market is one that indirectly reveals values for non-market goods. An example of a revealed preference approach would be the measurement of the economic value of noise nuisance as reflected in house prices: houses in noisy areas are likely to be cheaper than comparable houses in quieter but otherwise similar areas.

[42] These markets are often constructed or hypothetical markets.

8.5 Public Health Costs

Public health costs are costs associated with the adverse public health impact[43] defined in the SCP regulations. Table 8-1 includes a list of human health toxicological hazard traits that must be considered throughout the life cycle of the Priority Product and alternatives. It is not likely that all the hazard traits will be applicable for a single chemical or alternative. However, any hazard trait found to be relevant needs to be monetized to the extent possible. The impact on public health may occur during any of the life cycle segments of the Priority Product or alternatives being considered.

For example, if the Department lists a Priority Product for its respiratory toxicity potential, the responsible entity evaluates and monetizes the health costs associated to individuals who use the product and may develop, among other effects, asthma. The cost of asthma includes both direct costs, like medicines, doctor visits, and hospital stays, and indirect costs, such as missed workdays.

The subsequent sections in this chapter present approaches that may be used to evaluate and quantify public health costs due to the product's potential to cause illness, death, or disability.

Table 8-1 Cost of Adverse Public Health Impacts by Life Cycle Segments[1]

Toxicological Hazard Trait	Raw Materials Extraction	Intermediate Materials Processes	Manufacturing	Packaging	Transportation	Distribution	Use	Operation and Maintenance	Waste Generation & Management	Reuse and Recycling	End-of-Life Disposal	Total Costs[2]
Carcinogenicity												

[43] *22 CCR section 69501.1(a)(6) "Adverse public health impacts" means any of the toxicological effects on public health specified in Article 2 of Chapter 54, or exceedance of an enforceable California or federal regulatory standard relating to the protection of public health. Public health includes occupational health.*

Toxicological Hazard Trait	Raw Materials Extraction	Intermediate Materials Processes	Manufacturing	Packaging	Transportation	Distribution	Use	Operation and Maintenance	Waste Generation & Management	Reuse and Recycling	End-of-Life Disposal	Total Costs[2]
Cardiovascular Toxicity												
Dermatotoxicity												
Developmental Toxicity												
Endocrine Toxicity												
Epigenetic Toxicity												
Genotoxicity												
Hematotoxicity												
Hepatotoxicity & Digestive System Toxicity												
Immunotoxicity												
Musculoskeletal Toxicity												
Nephrotoxicity & Other Urinary System Toxicity												
Neurodevelopmental Toxicity												
Others….												
TOTAL												

[1]Consider only relevant life cycle segments

[2]Cost will include mortality and morbidity costs

QUANTIFYING HEALTH IMPACTS

Health impacts may be quantified using the following suggested approaches:

- Morbidity and Mortality
  - Number of incidents of disease (e.g., heart attacks, lung cancer),
  - Number of premature mortalities
  - Number of lost years
- Disability Adjusted Life Year (DALY) or Quality Adjusted Life Year (QALY)

The responsible entity will determine the exposed population (workers, consumers, or sensitive subpopulations).

Morbidity

Morbidity costs may be estimated by:

- Determining the number of cases resulting from exposure to the Priority Product, and
- Determining the cost per case

The annual cost can be determined by multiplying the treatment cost per case by the number of cases per year:

Annualized Cost = Number of cases per year × Present value of cost per case

The responsible entity may use exposure-response studies to estimate the probability of adverse cases that can be attributed to a chemical or product. The regulations do not require a traditional risk assessment, but the responsible entity can use that approach if preferred. Various models can help identify exposure pathways and potentially exposed populations (see chapter 6). The responsible entity should account for both populations directly exposed (e.g., a personal care or hygiene product that is applied to the body) or indirectly exposed (e.g., contaminants that have settled in dust on carpets, floors, clothing, counter tops, or other surfaces). Nonusers such as children could be passively exposed to the chemicals released from these products.

US EPA's "Cost of Illness Handbook" may be used when estimating direct medical costs of illnesses associated with environmental pollutants (EPA, 2007). There are also estimates of willingness to pay for some illnesses. Where data is available, the willingness to pay approach can also be used to monetize morbidity costs.

In general, existing monetization analyses of human health impacts are more commonly available for certain priority endpoints (e.g., cancer and reproductive toxicity), but not for many other hazard traits or endpoints. This may present challenges in cases where the Priority Product or its alternatives are associated with endpoints for which monetization information has not been developed. It is anticipated that data will become more widely available as the need for information on other hazard traits or endpoints arises.

Mortality

If data are available, another approach to estimate cost to public health is to determine the number of lives lost due to illness and use the Value Statistical Life (VSL) to monetize the lives lost.

Example 8-1: Value of Statistical Life

If a sample of 100,000 people are willing to pay an average of $100 to reduce their individual risk of dying by 1 in 100,000 over the next year, the total amount that the group is willing to pay to save one statistical life in a year would be $100 × 100,000 = $10 million. This is the value of statistical life (VSL). Another example suppose that airbags reduce chances of dying in a car accident over the life of the car from 1⁄5,000 to 1⁄10,000 (0.0002 − 0.0001 = 0.0001). Air bags save the life of 1 driver per 10,000 cars. If 10,000 car buyers are willing to pay an extra $300 for an air bag, then these car buyers put value on a statistical life as $3 million ($300 × 10,000 = $3 million for each life saved). Various studies provided different estimates of VSL. The US EPA uses $7.4M as the value of VSL (2006 dollars).

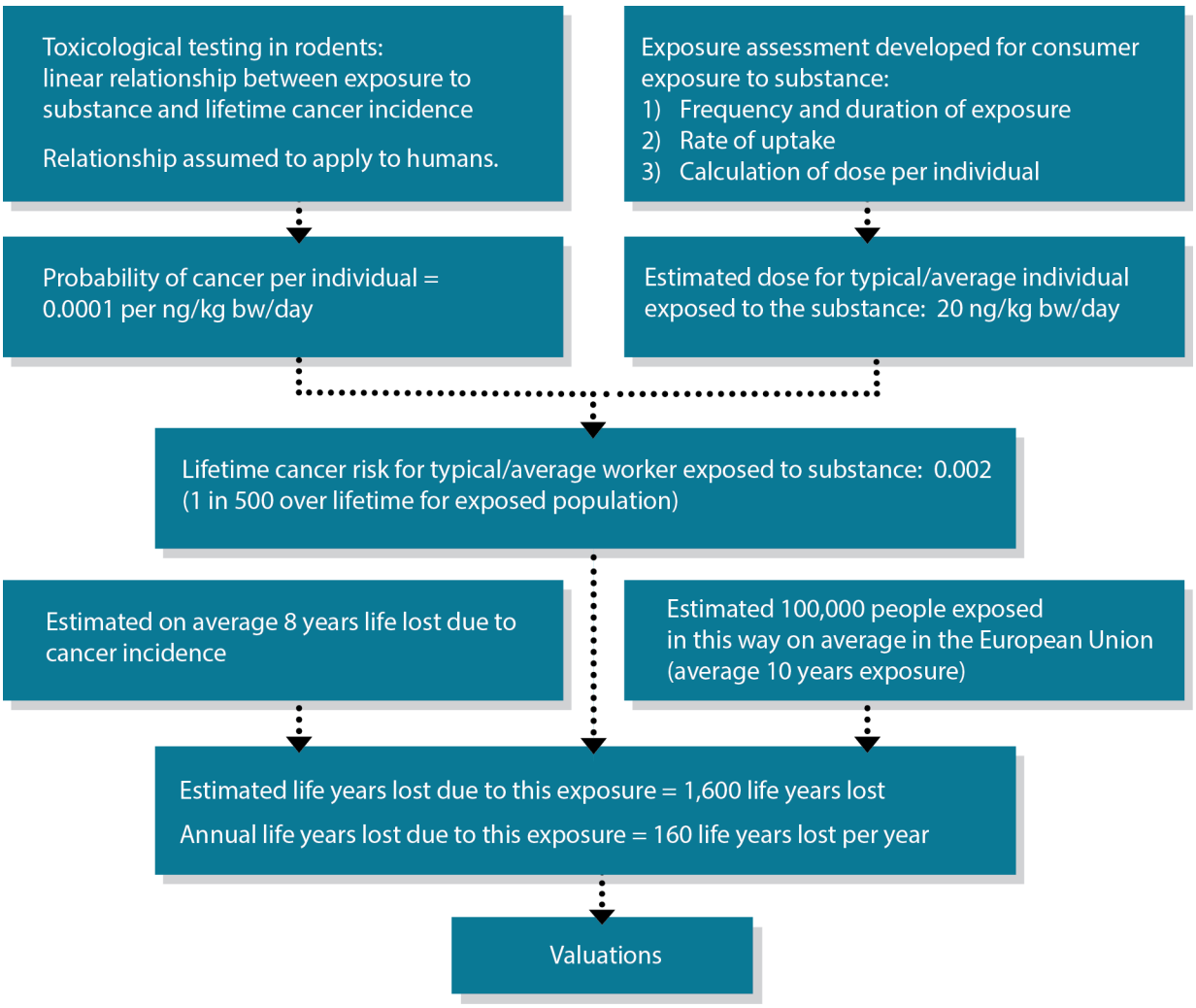
The VSL represents people's willingness to pay for small changes in fatal risk reduction. It is the value that individuals place on a marginal change to the probability of death. See Example 8-1 for details.

In 2006, US EPA recommended that the central estimate of $7.4 million be used for VSL in all benefits analyses that seek to quantify mortality risk reduction benefits regardless of the age, income, or other population characteristic (EPA, 2016c).

In its SEA Guidance document, ECHA discussed the types of data that are likely needed to quantify the impacts on public health:

- Quantitative estimates of the relationship between individual exposure and the incidence of a defined health effect (e.g., skin irritation, respiratory illnesses, cancer) and derivation of a probability of that effect being manifested (i.e., dose-response relationship)
- Assessment of exposure including the frequency and duration of exposure, the rate of uptake of the substance by the relevant route (e.g., inhalation. oral, dermal) to be able to estimate an average dose or range of doses
- A measure of actual impact of the health effect (e.g., numbers of life years lost due to contracting cancer)
- An estimate of the total population exposed and, if possible, the distribution of exposure within the population

A flowchart example is presented in ECHA's SEA Guidance document. Figure 8-1 illustrates the quantification of health impacts for consumer exposure to a carcinogen. ECHA's SEA Guidance, Appendix B, presents unit costs for mortality where a monetary value is assigned to a statistical life and life year lost. The mean value of life year lost, at 2003 prices, was approximately €55,800. For the example illustrated in Figure 8-1, if 160 life years will be lost due to exposure to a carcinogen, and the given value of statistical life year is €55,800, the annual health impact cost due to this carcinogen is €8.9 million per year (160 × €55,800 = €8.9 million).



Adapted from: European Chemicals Agency. The Guidance on the Preparation of Socio-Economic Analysis as Part of an Application for Authorization. January 2011.

Figure 8-1 Illustration of Quantification of Health Impacts for Consumer Exposure to a Carcinogen

Disability Adjusted Life Year (DALY) and Quality Adjusted Life Year (QALY)

Another approach to quantify human health impacts is the use of Disability Adjusted Life Years (DALY). DALY is a measure of years lost due to premature mortality, and years of life spent suffering disease.

$$DALY = YLL + YLD$$

where, YLL = years of life lost
YLD = years of life lived with disability

Once the number of DALY is determined, one can use the monetary value of the DALY to monetize the impact caused by the exposure to the chemical.

The World Health Organization's *The Global Burden of Disease 2004 Update* (WHO, 2008b) study presents DALY estimates for world regions and lists DALY by cause (illness), sex and age group, and countries grouped by income per capita. Since DALYs are aggregate numbers resulting from the illness caused by several factors, one of the challenges on the use of DALY from these studies is determining the amount of DALY attributable to a specific product or chemical.

DALYs may also be obtained from life cycle impact assessment models, such as ReCiPe and Eco Indicator 99. These models use a damage-oriented approach where they transform the life cycle inventory results into endpoint impacts and have three damage categories that include damage to human health (expressed in DALY), damage to ecosystem, and damage to resources.

QALY, just like DALY, is a measure that combines mortality with morbidity in single numerical units. It is the arithmetic product of life expectancy combined with a measure of the quality of remaining life-years. One QALY equates to one year of perfect health, while 0 (zero) QALY associates with death. A year of less than perfect health life expectancy is worth less than 1 QALY.

Monetize by using willingness to pay per QALY. Several studies provide estimates of the value of willingness to pay per QALY.

8.6 Environmental Costs

The responsible entity must also evaluate and monetize the potential adverse impacts that may be caused by the Priority Product or alternatives on the environment. Environmental costs include any of the costs to the following:

- Air quality impacts[44]
- Ecological impact[45]
- Soil quality impacts[46]

[44] *22 CCR section 69501.1(a)(2)*
[45] *22 CCR section 69501.1(a)(3)*
[46] *22 CCR section 69501.1(a)(7)*

- Water quality impacts[47]

In addition, it may include costs from an exceedance of an enforceable state or federal standard relating to the protection of the environment.

Table 8-2 summarizes the environmental impacts that may occur during any life cycle segment of the Priority Product or the alternatives. Impacts to air, soil, water, and ecological receptors may occur during one segment or may occur across multiple segments during the life cycle of the Priority Product and its alternatives.

Table 8-2 Environmental Impacts for Various Life Cycle Segments

Environmental Impact	Raw Materials Extraction	Intermediate Materials Processes	Manufacturing	Packaging	Transportation	Distribution	Use	Operation and Maintenance	Waste Generation & Management	Reuse and Recycling	End-of-Life Disposal	Total Costs[2]
Air quality impacts												
Ecological impacts												
Soil quality impacts												
Water quality impacts												

[47] *22 CCR section 69501.1(a)(9)*

QUANTIFYING ENVIRONMENTAL IMPACTS

The impact and associated costs for soil, air, water, or ecological receptors, such as wildlife, may not always be quantifiable. However, the focus should be on the change in benefit or service that the environment can provide for either economic welfare or public health. The cost of environmental impacts can be estimated using the volume or mass of emissions, wastes generated, or materials and resources used.

A simple approach to quantify environmental impacts may be as follows:

1. Identify the emissions, wastes, or resources used which cause adverse impacts to be relevant factors
2. Estimate volume or mass of emissions, wastes, or resources used
3. Apply a cost per ton of emissions, wastes, or resources used (AlChE-CWRT, 2000)

ECHA's SEA Guidance document presents external costs for selected pollutants where the damages caused by the emissions were monetized in euros. For example, the average damage per ton of emissions was estimated to be approximately: €6,600 for nitrogen oxides; €1,400 for volatile emissions and €16,000 for ammonia.

Life Cycle Impacts Assessment: Ecosystem Damage

A responsible entity may likewise conduct a life cycle impact assessment of the product and use endpoint models such as ReCiPe or Eco Indicator 99.

The endpoint impacts on damage to ecosystem may be expressed as "biodiversity adjusted hectare years (BAHY)." Cost per endpoint damage can then be obtained from various studies, such as Weidema (2009), which estimates the cost on environmental damage to be approximately €1400/BAHY. The U. S. Department of Defense's draft report (DoD, 2014) on sustainable acquisitions uses endpoint impact characterization as an approach to estimate environmental costs to meet its goals. The report discusses the use of endpoints and monetized these impacts by multiplying the quantity of the endpoint impact by the cost factor.

Ecosystem Services

Valuation of ecosystem services is another approach in valuing the impacts of products on the environment. Ecosystem services are the benefits that humankind enjoys from the ecosystem. Economic valuation of ecosystems is based on the premise that ecosystem and biodiversity services are scarce, and their depreciation or degradation has associated costs to society. Ecosystem services have been grouped into four broad categories: provisioning, such as the

production of food and water; regulating, such as the control of climate and disease; supporting, such as nutrient cycles and crop pollination; and cultural, such as spiritual and recreational benefits. Ecosystem valuation may be a challenging task as one puts a price tag on nature.

The commonly used tool for assessing the overall economic value of an ecosystem service is the Total Economic Value framework (DEFRA, 2007). It is a framework for organizing different types of value that people might associate with an ecosystem service. The framework comprises use and non-use values. Use values are further broken into direct use, indirect use, and option values. Non-use values typically refer to existence and bequest value. The main types of economic valuation methods of ecosystem services are based on willingness to pay approaches. The revealed preference and stated preference methods are most used to value ecosystem services.[48]

Although the ecosystem services approach is presented here, its use in estimating the cost of a specific product's impact on ecosystem may be challenging. As mentioned earlier, responsible entity can use any approach it feels appropriate for their situation and does not have to follow all the approaches presented here.

Some companies still use the ecosystem valuation approach though to demonstrate sustainability leadership. One example is discussed in PUMA's Environmental Profit and Loss Account report.[49] In this report, PUMA estimated the value of land use impact which was attributed with the farming of cotton, rubber, and cattle ranching for leather. They estimated the per hectare value to the ecosystem from academic literatures which ranged from €63 (arid

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[48] Using stated preference methods to value ecosystem services has both advantages and limitations. The primary advantage of stated preference methods is that they can measure values for some benefits that revealed preference methods cannot, such as non-use values. The disadvantage of stated preference methods arises from the speculative nature of measuring intended behavior rather than actual behavior. Some experts recommend relying on stated preference methods primarily for values where revealed preference methods are not available. Others recommend relying on a combination of stated preference methods and revealed preference methods when possible. For a comprehensive overview of various stated preference and revealed preference methods than can be used to value ecosystem services, see National Research council. Valuing Ecosystem Services: Toward Better Environmental Decision-making. National Academies Press. 2005. See also USEPA. Guidelines for Preparing Economic Analyses. Washington, D.C.: U.S. Environmental Protection Agency. 2014."

[49] PUMA's Environmental Profit and loss Account for the year ended 31 December 2010.

grasslands in Pakistan) to €18,653 (coastal wetlands in US). The "per hectare" value was then multiplied by the land area for each ecosystem type where conversion took place.

8.7 Costs to Government Agencies and Non-Profit Organizations

The responsible entity must evaluate the cost to government agencies and non-profit organizations (NPOs) that manage waste, mitigate waste releases, and protect natural resources impacted by the Priority Product or alternatives. The costs to these public agencies need to be evaluated. For instance, if the relevant impacts indicate that an environmental medium (e.g., soil, air, water, or ecological receptor) may be affected, then the responsible entity identifies which government agencies and NPOs may be impacted.

California Environmental Agencies

- Air Resources Board and local air districts
- Coastal Commission
- Department of Fish and Wildlife
- Department of Resources Recycling and Recovery
- Office of Environmental Health Hazard Assessment
- Sanitation districts
- State Lands Commission
- State Water Resources Control Board and regional boards
- Wildlife Conservation Board
- Cities and Counties

Not an exhaustive list

GOVERNMENT AGENCIES

The costs to government include waste management—solid and hazardous waste costs, wastewater management costs and the costs that the state would be required to ensure that adequate facilities are in place or existing facilities upgraded to mitigate impacts that would be created by the product.

The responsible entity scopes and identifies the state or local government agencies that handle and oversee waste management or abatement programs, or are charged with protecting natural resources, water quality, or wildlife, to properly quantify the impacts to those agencies, and may report it as in Table 8-3. The responsible entity will determine if the alternatives would result in additional costs on government agencies to comply with the environmental laws, such as upgrading facilities to comply with the Clean Water Act. The responsible entity also considers the range of Regulatory Responses it anticipates or plans to employ and estimates the costs that a government agency may incur.

Table 8-3 Government Agencies and Non-profit Organizations

Release to Media	Governmental Agencies	Non-Profit Organizations
Air Impact		
Ecological Impact		
Soil Impact		
Water Impact		

NON-PROFIT ORGANZIATIONS

The responsible entity must evaluate and document costs of impacts to NPOs that manage waste, oversee environmental cleanup and restoration efforts, and charged with protecting natural resources, water quality, and wildlife. NPOs that are merely advocacy organizations are not covered under this SCP regulatory requirement. Consider only those NPOs that are charged to conduct the mentioned activities to comply with various environmental regulatory requirements, such as:

- **California Stormwater Quality Association.** The California Stormwater Quality Association's mission is to assist the State Water Resources Control Board and municipalities throughout the state of California in implementing the National Pollutant Discharge Elimination System (NPDES) stormwater mandates of the Federal Clean Water Act.
- **PaintCare, Inc.** PaintCare Inc. was formed to serve as the representative stewardship organization of architectural paint manufacturers to fulfill their obligations under the California Paint Stewardship Law which aims to reduce the costs and environmental impacts of the disposal of post-consumer paints. PaintCare was created by the American Coatings Association, the primary trade association of the paint and coatings industry.

- **Mattress Recycling Council.** The Mattress Recycling Council was formed by the industry to operate recycling programs in states which have enacted mattress recycling laws. Each state's program is funded by a recycling fee that is collected when a mattress or box spring is sold. The fees pay for the transportation and recycling of the mattresses.
- **San Francisco Estuary Institute.** The San Francisco Estuary Institute's (SFEI) Regional Monitoring Program for Water Quality in San Francisco Bay (RMP) is a collaboration between SFEI, the Regional Water Quality Control Board, and the regulated discharger community tasked with monitoring contaminants in San Francisco Bay (the Bay).

Non-Profit Organization: San Francisco Estuary Institute

The San Francisco Estuary Institute's (SFEI) Regional Monitoring Program for Water Quality in San Francisco Bay (RMP) is a collaboration between SFEI, the Regional Water Quality Control Board, and the regulated discharger community tasked with monitoring contaminants in San Francisco Bay (the Bay). This monitoring takes the place of required environmental monitoring by each individual discharger and instead provides a more comprehensive assessment of chemicals that may be impacting the Bay and an enhanced ability to inform management decisions. This assessment is accomplished through routine monitoring of water, sediment, bivalves, bird eggs and sport fish as well as special studies to understand chemicals that may be of concern in the future.

When SFEI's RMP discovers a chemical of concern in the Bay, they must first devote resources to learning more about the presence of the chemical through monitoring and to understand potential adverse impacts due to this chemical. The group has developed a tiered approach to chemicals management, and in most circumstances, chemicals that reach the top tiers of this framework are then subject to routine monitoring, special studies to better understand the sources and fate of the chemical to the Bay, and planning control and/or treatment actions.

If a selected alternative were to become a chemical of moderate to high concern for San Francisco Bay, the costs to SFEI to routinely monitor the chemical, assess potential impacts, and develop control strategies can be estimated by reviewing the annual budget of SFEI. Costs would include sample collection, sample analysis, data analysis, and staff time for literature toxicity reviews and analysis, report generation, and control plan development. Information about chemical-specific costs for analysis can also be obtained by inquiring with recognized laboratories.

Based on the potential impacts that would result from the Priority Product and alternatives, the responsible entity identifies non-profit organizations that are charged in protecting the receptors impacted. If NPOs are identified, the responsible entity gathers available data needed to estimate the cost to these NPOs. One source of data is the NPO's financial report. Determine if NPOs are expected to conduct inspection, monitoring, sampling, testing, or other additional activities to protect the environment. Responsible entities may use qualitative cost comparison if they could not obtain the required data to monetize the NPO cost.

8.8 Benefit Cost Analysis

Benefit Cost Analysis (BCA) is a decision-making tool that considers the cost to implement an alternative balanced against the benefits that are realized through the alternative. The BCA method includes a "no action" scenario—for an AA this means retaining the Priority Product and the costs associated with it.

The results of BCA are then reported by comparing the benefits against the costs. The Benefit-Cost Ratio, Return on Investment, and Net Present Value methods may be used to compare and report potential costs versus the benefits. Table 8-4 summarizes methods commonly used to report findings.

Table 8-4 Benefit Cost Analysis Reporting Methods

Method	Formula	Decision
Benefit Cost Ratio (BCR)	$BCR = \frac{\text{Discounted Benefits}}{\text{Discounted Costs}}$	A BCR greater than 1 means the benefits outweigh the costs and the investment should be considered. If the ratio is less than 1, the costs outweigh the benefits. If the BCR is equal to 1, the benefits equal the costs.

Method	Formula	Decision
Net Present Value (NPV)	NPV = Discounted benefits − Discounted costs	A positive NPV means that benefits outweigh costs and the investment should be considered. A negative NPV means that the costs outweigh the benefits. An NPV of 0 means the benefits are equal to the costs.
Return on Investment (ROI)	$ROI = \frac{(\text{Discounted Benefits} - \text{Discounted Costs})}{\text{Discounted Costs}}$	If the ROI is positive, the benefits exceed the costs and the investment should be considered. A negative ROI means that the costs outweigh the benefits. An ROI of 0 means the benefits equal the costs. The higher the ROI, the better is the investment. The ROI indicates how effective the investment is in generating profit.

8.9 Summary

- The responsible entity must estimate and monetize public health impacts. One method of doing so would be using toxicological and exposure data to determine the number of life years lost and monetizing it with the value of statistical life year. Another approach is to use DALY and the value of statistical life year or using morbidity data and cost of illness.

- The responsible entity may estimate environmental costs by determining the cost of damages per ton of emissions or using life cycle end-point impact assessment models to determine ecosystem damage, and then using estimated costs per ecosystem damage.

- The responsible entity identifies government agencies and non-profit organizations that are charged with protecting the environmental medium that may be potentially impacted by the Priority Product and alternatives. The responsible entity will work with these organizations to determine their costs.

- The responsible entity may choose any method, including those presented in this chapter, to estimate costs to public health, the environment, and government. There is no prescribed specific methodology or preferences.

- The responsible entity will describe in their AA Report the approach taken, tools, models, or software used to conduct the analysis.

- If there are no available data to proceed with monetization of impacts, the responsible entity documents the work conducted and uses professional judgment to make a qualitative cost comparison.

Chapter 9 — Information Needs in AA

The quality of AA decisions is dependent on the quality of the information used. The availability and quality of the information sources is critical to supporting the decision-making in AA. A credible AA is largely dependent on documenting and communicating these information sources and uncertainties in an AA report. This chapter discusses a process for collecting information and approaches to evaluating and addressing uncertainties (including data gaps) before making an alternatives selection decision about a preferred alternative.

CHAPTER 9 AT A GLANCE

The responsible entity needs to collect different types of information for the purpose of a comprehensive AA, including, but not limited to, hazard and exposure information, physicochemical data, product function and technical information, product life cycle multimedia impacts information, and costs.

The responsible entity may employ the following steps to use information in the AA process: locate information, evaluate information, assemble information, make informed decisions, and document rationale(s).

The responsible entity should use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to conduct an AA. For missing data, the responsible entity may use proxy data, read-across, Quantitative Structure-Activity Relationship, or other methods to estimate data that are necessary to inform decisions.

The responsible entity documents and reports uncertainties during its information collection and decision-making process. Depending on resource availability and the significance of the uncertainty, the responsible entities may conduct different types of uncertainty analysis, especially if it affects the decision.

9.1 Overview of Information Use in AA

Figure 9-1 provides a schematic representation of the flow and use of information in an AA process. In practice, it is usually an iterative process to collect information and analyze relevant human health, environmental, technical, and economic impacts of alternatives. Generally, the

flow of information in the AA process starts with research to locate appropriate information from a variety of sources.

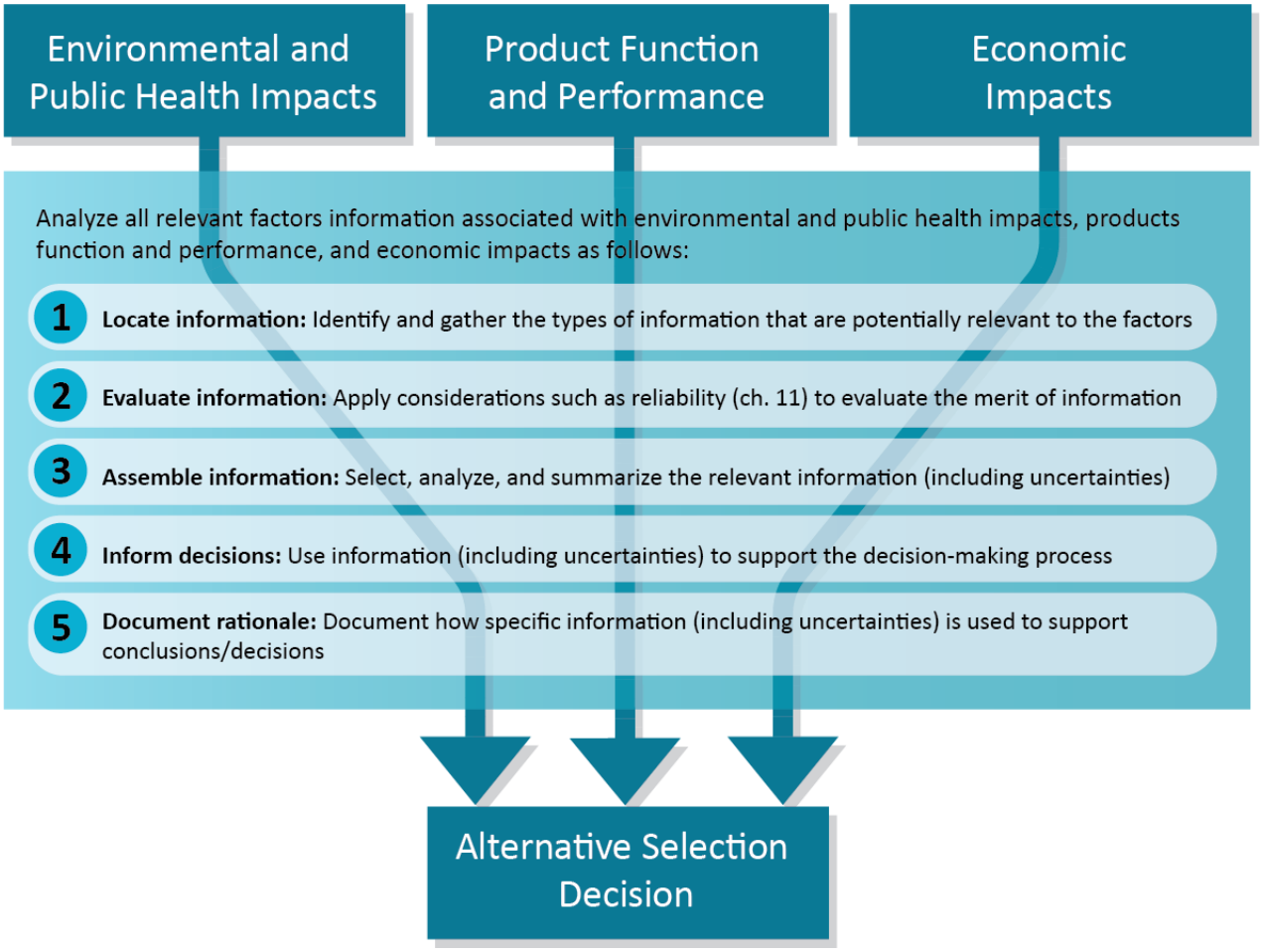

Figure 9-1 Schematic Representation of Information Use in AA Process

9.2 Information Sources

An AA process may involve many different information types and sources, such as:

- Government agency reports, databases, and documents (such as the Department's website);
- Publicly available information, reports, and databases;
- Published documents (journals, articles, books, references, handbooks, encyclopedia, patents);
- Internal company files and data;
- Operating logs and journals;

- Industry, supplier, and manufacturer reports and databases;
- Lab test results;
- Related historical case studies reports;
- Process and equipment specifications, standards, and requirements;
- Expert judgment; or
- Surveys and audits.

In general, the responsible entity collects and documents information sources in their AA Reports using the following hierarchy:

- Reliable information,[50] when applicable[51] – reliable information may not be available for certain chemical substances or formulations; then
- Other information sources, such as measured data on a chemical or process, internal cost information, measured data from a suitable analog chemical, and estimated data from appropriate models.

When selecting an alternative, it is crucial to document and communicate the study design and information sources used.

There are many published guides by international, federal, or state agencies for different steps of the analysis, such as hazard assessment and life cycle impact assessment. Each guide provides detailed information on data sources. For example, the US EPA's High Production Volume (HPV) Chemical Challenge Program (EPA, 1999), ECHA's Guidance on REACH (ECHA, 2011b), and OECD's Manual for the Assessment of Chemicals (OECD, 2012a) provide assistance on searching chemical-specific information. For process-specific information and multimedia life cycle impacts, the US EPA's report, "Life Cycle Assessment: Principles and Practice," provides detailed guidance on the collection of process data and other information for relevant life cycle impact assessment (EPA, 2006).

The information review and selection process for an AA is usually case-dependent and requires expert judgment. In some cases, there may be an extensive amount of available information with varying degrees of usefulness. In such cases, systematic information review approaches are available to guide the data evaluation in a consistent way. ECHA's Practical Guide 2 document for REACH (ECHA, 2010) may serve as a good resource for information review. It

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[50] 22 CCR section 69501.1(a)(57)(A)(4)

[51] A review criterion of reliable information is specified in 22 CCR section 69505.9(a)(3); detailed discussion is in Chapter 11 of the Guide.

provides methods and detailed steps that the responsible entity may use to assemble all the available information and address conflicting information.

9.3 Addressing Data Gaps

When there is an absence of information on the chemical or process, the responsible entity may use any of a variety of approaches to address data gaps. While the SCP regulations do not require the responsible entity to generate new information, there are some best practices available for filling data gaps. These approaches may help the responsible entity to identify relevant factors, support decision-making, and select future research efforts. In this section, we present some of these best practices to address different types of data gaps.

This guide does not address data gaps associated with inherent limitations within a specific method. For example, a given LCA method may have methodological limitations in which certain environmental impacts are not covered by that method. The following sections provide methods for addressing critical knowledge gaps in either process details (e.g., emissions or raw material inputs) or chemical properties (e.g., hazard traits or physicochemical properties).

MANUFACTURING PROCESS-SPECIFIC DATA GAPS

Process-specific gaps will exist when there is no available specific or generic information that is sufficiently representative of the given process in the product's life cycle. In other words, process-specific data gaps may exist when:

- Data do not exist for a specific process for a chemical and product combination (e.g., lack of data on resource and materials consumption and emissions/discharge from the process); or
- Data exist for a similar process, but the data are not adequate because they have been generated:
    - In a different region,
    - In a different period, or
    - Using a different technology (Manfredi, et.al., 2012).

To address the process-specific data gap for a product's life cycle impacts, the responsible entity may use proxy data sets or extrapolated data to provide a reasonable estimate. Proxy estimates use existing environmental data from one process to represent a similar process. Extrapolated estimates derive new process data for a product with a data gap by modifying the process data for a known product with equivalent functions but different manufacturing characteristics. See Example 9-1 on using proxy and extrapolated data.

Example 9-1: Using Extrapolated Data and Proxy Data to Address Process-Specific Life Cycle Data Gaps

Assume product A's process emissions are known and product B's process emissions in the manufacturing life cycle segments are unknown

Method 1: Direct proxy

If product A and product B are assumed to have equivalent function and similar characteristics,
process emissions of product B = process emissions of product A.

Method 2: Averaged proxy

If product A is manufactured in region A and product B is manufactured in country B, and assuming, process emissions of product B = Weighted average process emissions of product A from four countries in Region A according to production volume (C_1 represents country 1, C_2 is country 2, etc.),

process emissions (PE) of product B = [(% of volume C_1)(PEC_1 of product A) + (% of volume C_2) (PEC_2 of product A) + (% of volume C_3)(PEC_3 of product A) + (% of volume C_4)(PEC_4 of product A)]

Method 3: Scaled proxy

For a multi-component product B, if process emissions data are available for 85% weight of the components represented by product A then the data gap is bridged by linearly scaling up the data for 85% of component to 100%,

process emissions (PE) of product B = (PE of product A)/(85%)

Method 4: Extrapolated data

If product A and product B are assumed to have equivalent function but have a different manufacturing characteristic (represented by production parameter X_a and X_b, respectively),

process emissions of product B = process emissions of product A × Function (X_a, X_b).

Adapted from: Milà i Canals, L., Azapagic, A., Doka, G., Jefferies, D., King, H., Mutel, C., Nemecek, T., Roches, A., Sim, S., Stichnothe, H., Thoma, G., and Williams, A. Approaches for Addressing LCA Data Gaps for Bio-based Products. Journal of Industrial Ecology, October 2011, 15 (5), 707–725.

In some cases, the responsible entity may conduct additional research or surveys to address process-specific data gaps. A survey might be used to collect information on product turnover

rates, maintenance frequency and needs, changes in manufacturing processes, and types of uses other than the product's intended use.

In general, the United States, Canada, Western Europe, and Japan have the most current and available and current statistical information for processes involved in different life cycle segments in product systems. In regions and countries where data are unavailable, it may be acceptable to use proxy data between similar countries or regions or to use extrapolated data after a comparison of characteristics of similar processes. When using extrapolated data or existing generic data to address data gaps, it is important to consider the data source, accuracy, age, etc. (DEFRA, 2007).

CHEMICAL SPECIFIC DATA GAPS

Chemical-specific data are mostly used for evaluation of hazard traits or potential exposures of chemicals. For chemical-specific data gaps, read-across and trend analysis (such as Quantitative Structure-Activity Relationship (QSAR) model), have been extensively used to estimate or predict missing endpoints.

Read-across is a technique used to predict hazard traits information for one chemical by using hazard traits information of another chemical based upon their structural or functional similarity. This technique can be used to estimate physicochemical properties, environmental fate and transport, ecotoxicity, and human health hazards. Read-across is an appropriate data-gap filling method for endpoints with qualitative characterization, such as binary (e.g., toxic or non-toxic) or ordinary (e.g., positive, negative, or indeterminate). The limitation of using read-across technique is that it requires trained experts to correctly group chemicals based on either structural similarity, mechanistic or analogue approach. The hazard trait information for the known chemical must be of high enough quality to establish confidence in the prediction.

Trend analysis is a technique of predicting toxicology by analyzing correlations (e.g., increasing, decreasing or constant) between a hazard trait to an effect such as molecular mass, carbon chain length, or other physicochemical property (ECHA, 2008). An observed trend in the experimental data for a given hazard trait can be used as the basis for interpolation or extrapolation. For example, a hypothetical example shows that when carbon chain length increases, acute aquatic toxicity increases (Raise, et.al., 2016). Using trend analysis for data gaps is best suited for quantitative endpoints if a high number of chemicals with molecular similarity are identified with experimental results. Trend analysis requires a large enough data set to ensure statistical confidence. It also relies on trained expertise to ensure that the correct conclusions are drawn from the analysis.

QSAR is also a type of trend analysis method and is used to predict an unknown chemical property or biological activity (e.g., a toxicological endpoint) of a chemical. Figure 9-2 illustrates a QSAR mathematical relationship: a biological activity or property is a function of chemical structural properties. A QSAR model relates one or more quantitative parameters derived from chemical structure to a quantitative measure of a property or activity (e.g., a toxicological endpoint) based on measured or testing data. For example, the responsible entity may use a QSAR model to characterize the trend in bioconcentration factor (BCF)[52] values across a wide range of chemicals of increasing molecular weight. QSAR models are most useful for filling data gaps when not enough chemicals with molecular similarity are found for a target chemical so that a read-across approach is inadequate. However, users need to understand the model's designed calculating mechanism and applicability to make sure the chemical of interest are within the prediction domain to increase the confidence of the predicted results.

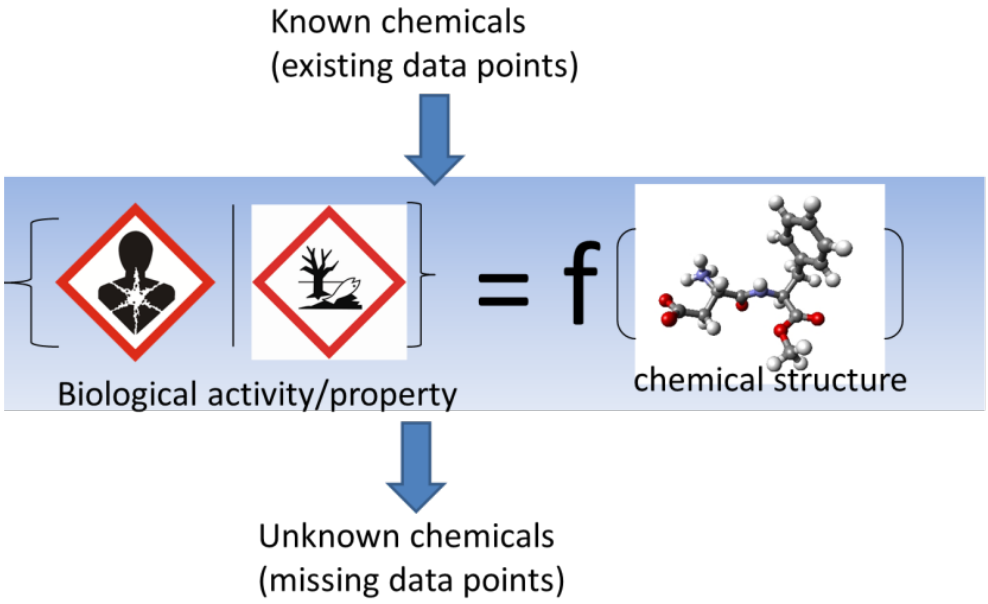


Figure 9-2 Graphical Representation of QSAR Approach to Address Chemical-Specific Data Gaps

Table 9-1 provides some examples of publicly accessible read-across/SAR models to assist users in applying these techniques to address data gaps. ECHA's *Guidance on Information*

[52] *Bioconcentration factor (BCF) is to a term created in the field of aquatic toxicology related to the measurement of bioaccumulation. It can be calculated as the ratio of the chemical concentration of a substance in an organism's tissue, to its equilibrium concentration in surrounding water expressed in equivalent units.*

Requirements and Chemical Safety Assessment[53] and *Read Across Assessment Framework (RAAF)* (ECHA, 2017), OECD's *Guidance on Grouping of Chemicals* (OECD, 2014), and the European Center for Ecotoxicology and Toxicology of Chemicals (ECETOC)'s Technical Report on *Category Approaches, Read-Across (Q)SAR* (ECETOC, 2012), provide more details and best practices about these techniques.

Table 9-1 Examples of Read-Across/Structure-Activity Relationship (SAR) Models to Address Chemical-Specific Data Gaps

Tool/model	Developer	Applicability	Main features/ methodology
Analog Identification Methodology (AIM)	US EPA	Conducts a comprehensive structural analog analysis and data identification in support of chemical assessment and read-across approaches.	Provides hyperlinks to experimental data sources for 700 individual atoms, groups, and super fragments indexed in a predefined database.
CAESAR	EU based consortium	Provides prediction on: bioconcentration factor, skin sensitization, carcinogenicity, mutagenicity, developmental toxicity.	QSAR models
ChemACE	US EPA	Facilitates read-across to fill data gaps for untested substances.	Identifies structural diversity in a chemical inventory and highlights analogous clusters for potential read across.

[53] *22 CCR section 69505.5(a)*

Tool/model	Developer	Applicability	Main features/ methodology
CRAFT	Molecular Networks	Evaluates the chemical reactivity, persistence, biodegradation, and fate of chemical compounds in the environment.	Knowledge base of chemical reactivity and biodegradation derived from the University of Minnesota Biocatalysis and Biodegradation Database; provides generation and evaluation of biodegradation products of chemicals in the environment.
Danish QSAR Database	Danish Ministry of the Environment EPA	A repository of estimates from over 70 QSAR models for 166,072 chemicals. The QSAR models encompass endpoints for physico-chemical properties, fate, ecotoxicity, absorption, metabolism, and toxicity.	Enables searches on CAS, chemical name, and any of the parameter fields (endpoint, inventory); displays QSAR predictions and 2D structure image in html format for individual records.
DSSTox	US EPA	Provides a public forum for searchable, standardized chemical structure files associated with chemical inventories or toxicity data sets of environmental relevance.	Provide full, open access to toxicity data files for chemical structure-analog searching.

Tool/model	Developer	Applicability	Main features/ methodology
ECOSAR	US EPA	Predicts aquatic toxicity.	ECOSAR uses structure-activity relationships (SARs) to predict the aquatic toxicity of chemicals.
EPI Suite	US EPA	Provides screening-level estimates of physicochemical and environmental fate properties.	Based on a representation of the chemical structure in Simplified Molecular Information and Line Entry System (SMILES) notation.
OCHEM	EU based	Provides a Web platform for data storage, model development and chemical information.	Creates QSAR models, runs predictions, screen compounds, and optimizes molecules. Various physicochemical and toxicological properties available.
OECD QSAR Toolbox	OECD	Helps to fill gaps in (eco) toxicity data needed for assessing the hazards of chemicals	Groups chemicals based on mechanism of action, structural similarity, or common metabolites. Searches for available experimental result and possible similar chemicals by using a read-across approach.

Tool/model	Developer	Applicability	Main features/ methodology
Oncologic	US EPA	Predicts cancer-causing potential of fibers, metals, polymers, and classes of organic chemicals.	Applies the rules of structure activity relationship (SAR) analysis to correlate the biological activity to a chemical's structure.
Toxicity Estimation Software Tool (TEST)	US EPA	Estimates toxicity from molecular structure.	Uses multiple QSAR methodologies to estimate toxicity and physical properties.
Toxmatch	EU Joint Research Center	Facilitates the grouping of chemicals into categories and read-across.	Compares datasets based on various structural and descriptor-based similarity indices; calculates pair wise similarity between compounds.
toxRead	IRCCS: The Laboratory of Environmental Toxicology and Chemistry	Shows similar chemicals, structural alerts, and relevant features in common between chemicals.	Provides a graphical representation and colored toxicity alerts of the results when the user provides the chemical of interest, the endpoint, and enters several similar chemicals (up to six).
ToxTree	EU Joint Research Center	Estimates various toxic hazards	A decision-tree approach

Tool/model	Developer	Applicability	Main features/ methodology
VEGA	EU based consortium (includes IRCCS, US EPA, UK FERA, and others)	Provides a new generation platform (includes CAESAR platform) of QSAR models to support toxicity prediction for regulatory and research purposes.	Varies depending on the QSAR model used.

In addition, new research is underway to help address data gaps in chemical properties. For example, there is an increasing knowledge of relationships among chemical structures, physicochemical properties, in-vitro data, and in-vivo toxicology data on many existing chemicals. This new research helps rapidly predict and screen potential toxicological and other adverse impacts of new and existing chemicals that have not been fully characterized (Judson, et.al., 2009). The incorporation of such new approaches and tools may help the responsible entity to address chemical-specific data gaps for the AA. For example, US EPA's Toxicity Forecaster (ToxCast) uses high-throughput screening methods and computational toxicology approaches to predict toxicological responses (EPA, 2016a). Additionally, the 2014 NAS Report describes the use of physicochemical properties to predict ecological and human health hazards. Table 9-2 lists some examples of new computational tools designed to estimate the chemical's toxicological and exposure information. However, these emerging predictive models and tools currently have certain limitations to support regulatory decisions. Different models and tools are associated with different levels of confidence in the predicted hazard trait results. In general, the prediction models for physicochemical properties are mature with high level of confidence. For human health hazard traits, predicting carcinogenicity and mutagenicity is more reliable than predicting developmental toxicity. The predictive models for ecological hazard traits have relatively large error range due to larger uncertainty in experimental values and difficulty in building a general model for many chemical groups. The models predicting environmental fates are generally less reliable, particularly biodegradation rates, given the complicated microorganisms involved and the wide range of conditions in which biodegradation occurs (Tao, et.al., 2015). Another challenge for these computation models is that the prediction of chemical mixtures usually lacks rigorous scientific method and large enough empirical data sets.

Table 9-2 Examples of New Computation/Prediction Tools to Address Chemical-Specific Data Gaps

Tool	Developer	Applicability	Results
iCSS ToxCAst Dashboard	US EPA	An interactive tool to explore rapid, automated (or in vitro high throughput) chemical toxicological screening data	Results from assay endpoints (high-throughput screening data) generated by the US EPA Toxicity Forecaster (ToxCast) Project and the federal Toxicity Testing in the 21st century (Tox21) collaboration.
ChemSTEER	US EPA	Program to estimate exposures and environmental releases for chemicals manufactured and used in industrial/commercial settings.	Provides release rates for different environmental media.
E-FAST	US EPA	Estimates amount of chemical released to air, surface water, landfills, and from consumer products.	Calculates appropriate human potential dose rates for a wide variety of chemical exposure routes and estimates the number of days per year that an aquatic ecotoxicological concern concentration will be exceeded for organisms in a water column.

Finally, when there are no reliable tested, experimental, or measured data available that are sufficiently indicative of the given property for the chemical(s) or the resulting impact, the responsible entity may use

- Measured data from a suitable analog,
- Approximations based on surrogate data, or
- Estimated data from computational models.

When the responsible entity has determined that there are no measured data, suitable analogs, suitable surrogates, or appropriate estimation models, it may be appropriate to indicate that

there are “No data.” The responsible entity may indicate “No data” for the relevant factor in the AA Reports. It is important to document diligent data collection efforts and communicate any research needs for the relevant factor with “no data.” Although responsible entities are not required by the SCP regulations to fill in data gaps, the approaches discussed in this section may help to identify information collection and research priorities, continue the AA process, and inform decisions.

When there are too many data gaps to allow an alternative to be used as a viable alternative, the responsible entity should document their data collection efforts and explain why a chemical is eliminated from consideration due to data gaps. For example, in GreenScreen® (Clean Production Action, 2016b), if there are too many important data gaps, the chemical is given a Benchmark U for “unknown”. This Benchmark indicates there was insufficient data to enable the chemical to be benchmarked and most users would eliminate this chemical as a potential alternative. The QCAT method (WA ECY, 2015) assigns a grade with a ‘dg’ subscript for those chemicals containing a data gaps and the more the number or importance of the data gaps, the lower the grade is assigned. In this way, the responsible entity conducting the AA explains why an alternative is not viable due to data gaps.

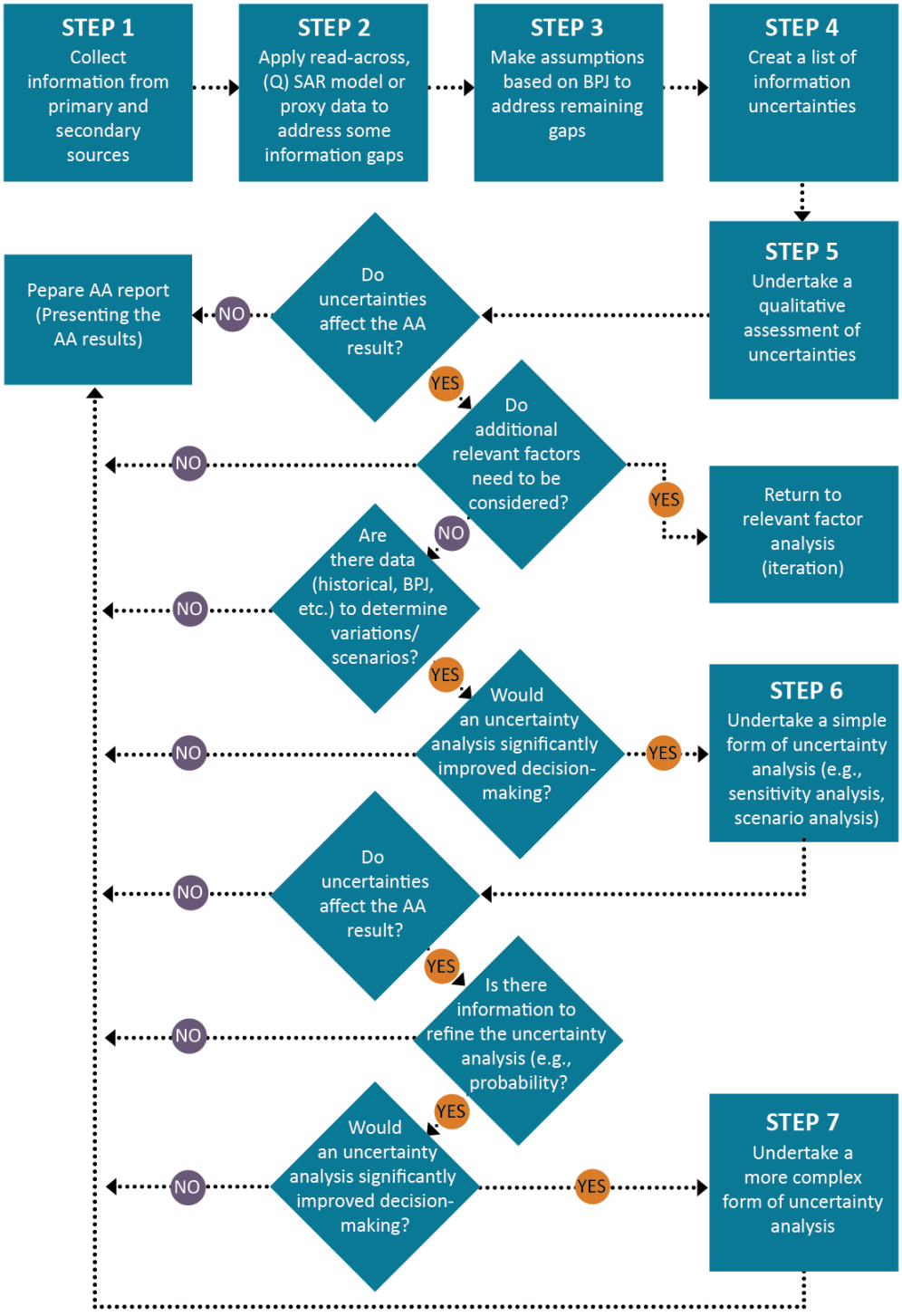
“No data” (ND) – Consider using ND in AA Reports to indicate that the responsible entity has reviewed measured data and literature, made estimations using models, and used expert judgement, yet there is still insufficient information to evaluate AA factors.

9.4 Addressing Uncertainty

The AA outcome is likely to be partly based on assumptions, projections, estimations, predictions, and best professional judgments that are applied to fill information gaps in the AA process. During the AA, the responsible entity will be able to distinguish the key uncertainties and scale of these uncertainties. The responsible entity may treat uncertainty in several ways.

Documenting and reporting uncertainties is important to ensure adequate consideration, especially those critical to decision-making. When the uncertainty is large enough to overwhelm any relative differences between alternatives, it becomes impossible to determine whether one alternative is truly superior to another. A good practice for dealing with uncertainty is to conduct a qualitative or quantitative uncertainty analysis. One example is a sensitivity analysis of key assumptions. An uncertainty analysis "aims to test whether different (reasonable) estimates or assumptions could affect the conclusions, and if this is likely, how significant any such difference is."11 The level of resources required and the level of detail for an uncertainty analysis is usually proportional to the significance and scale of the uncertainties. In other words, the responsible entity may focus on addressing uncertainties that are likely to have greater relevance (i.e., those that prevent them from reaching a reliable AA conclusion).

Uncertainty can be addressed using a stepwise approach. Figure 9-3 outlines multiple steps that can address different types of information gaps and uncertainties encountered in an AA. The following briefly describes this approach:



BPJ: Best Professional Judgment; QSAR: (Quantitative) Structure-Activity Relationship

Figure 9-3 An Example of Stepwise Approach to Address Information Gaps or Uncertainties in AA

Step 1: Collect data from primary and secondary sources

The responsible entity does a comprehensive search of the literature and existing databases for available data. Primary sources include scientific literature or measured data from site-specific or process-specific sources. This information is supplemented with searches of secondary sources, which cover recent high-quality review papers, peer-reviewed advisory reports, published handbooks, or peer-reviewed databases. The data collected from primary sources are more specific for the purpose of the study and contain the firsthand data for the topic. Compared to primary sources, secondary data tend to be available and inexpensive to obtain. Secondary data is one step away from original data and include an analysis, summary, generalization, or interpretation of original data based on expert experience. Secondary data from an authoritative body or peer-reviewed sources are especially valued starting points to collect and analyze information.

Step 2: Apply read-across, QSAR model, or proxy data to address some data gaps

For missing chemical-specific information, the responsible entity uses a read-across technique, a trend analysis, or QSAR models. These tools and models have been used extensively to predict hazard trait information. To address the process-specific data gap for a product's life cycle impacts, the responsible entity may be able to obtain sufficient information using proxy data or extrapolated data to provide a reasonable estimate. Both concepts are discussed in more depth in section 9.3.

Step 3: Make assumptions based on best professional judgments to continue AA

If the responsible entity encounters data gaps that may prevent completion of the AA process, these data gaps may be addressed by expert estimates, historical case reports, or assumptions made based on best professional judgments. For example, expert knowledge may be used to estimate the likelihood of possible scenarios, relative significance of uncertainties, or range of values for missing information.

Step 4: Create a list of uncertainties

Early in the AA process, it is important to identify, consider, and document uncertainties in each step of the AA process. These uncertainties may be related to approaches to addressing data gaps and assumptions. Are there missing data, model uncertainties, database uncertainties, or limited data sets? There may also be differences between known Priority Product manufacturing processes and process changes needed to manufacture an alternative.

Step 5: Undertake a qualitative assessment of uncertainties

The responsible entity may use many of the available approaches and methods to show the effect and extent of potential uncertainties on their AA outcome. For example, ECHA suggests a ranking system, such as +++, ++, +, -, −− or −−− to communicate both the direction (underestimate or overestimate) and magnitude (minor, medium or major effect) of the uncertainties (e.g., +++ is a major overestimate; − is a minor underestimate) (ECHA, 2012a). Other examples include the World Health Organization methods to characterize uncertainty. The simplest ranking method suggested in their 2008 guidance document (WHO, 2008a) is to use a scale ranging from "low" to "high" to express the degree of severity of the uncertainty. For example, a "low" level would imply that a large change in the source would have only a small effect on the results, a "medium" level would imply that a change would have a proportional effect and a "high" level would imply that a small change would have a large effect.

The responsible entity then needs to judge whether the qualitative characterization of uncertainties is sufficient to help make decisions, or if a quantitative uncertainty analysis is needed. This judgment depends on many factors, such as available resources, importance to the final decision, and whether there is information and knowledge available to conduct a quantitative uncertainty analysis.

As shown in Figure 9-3, there are a series of questions that the responsible entity may answer to identify or categorize the uncertainties. The following questions are intended to help guide the data collection and focus the uncertainty analysis on the true sources of the uncertainty:

- Do the uncertainties affect the AA results?
- Do additional relevant factors need to be considered? If yes, return to relevant factor analysis.
- Are there adequate data to determine variations or set up scenarios?
- Would uncertainty analysis significantly improve decision making? If yes, undertake sensitivity or scenario analysis (step 6).

Step 6: Undertake a simple form of quantitative uncertainty analysis

Uncertainties that have a major influence on AA outcomes can be assessed using either sensitivity analysis or scenario analysis. These analyses use the best available information to determine the low and high estimates for each major parameter or build worst- and best-case scenarios. If the AA result is not affected significantly, then no further uncertainty analysis is necessary. However, if the outcome of the AA changes significantly (e.g., the choice of

alternatives changed), then a more complex uncertainty analysis may be conducted or more consideration may be given to the range of values for the key parameters.

Uncertainty analysis has limited value if: (1) it is not possible to determine realistic low and high estimates, (2) it is not possible to determine the worst- and best-case scenarios, or (3) no data are available. The following questions should help guide whether a more complex form of uncertainty analysis is needed (per step 7):

- Is there information to refine the uncertainty analysis?
- Would an uncertainty analysis significantly improve decision making?

Sensitivity analysis: A "what-if" type of analysis to determine the sensitivity of the outcomes of an analysis to changes in input parameter values (e.g., using the maximum and the minimum fuel efficiency to assess how the outcomes are affected). If a small change in a parameter results in relatively large changes in the outcomes, the outcomes are sensitive to that parameter (Refer to Example 9-2).

Scenario analysis: A "what-if" type of analysis to determine the sensitivity of the outcomes of an analysis to changes in the conditions used for an analysis (i.e., combinations of parameters). Scenario analysis is a means of performing multiple sensitivity analyses at the same time (Refer to Example 9-3).

Step 7: Undertake a complex form of uncertainty analysis

Other statistical methodologies based on probability distributions such as Monte Carlo simulations, bootstrapping, or less conventional methods such as fuzzy set theory (Tan, et.al., 2008) and Bayesian analysis (Lo, et.al., 2005) can also be applied to uncertainty analysis at a more complex level. These techniques may be used to help the responsible entity understand how uncertainties could alter an AA outcome and incorporate that consideration into decision-making process. For example, probabilities are assigned to the ranges of estimated parameters or scenarios in Monte-Carlo simulations, which generates numerous possible outcomes and the likelihood of their occurrence. Results are typically reported as a frequency distribution graph like the familiar bell-shaped curve. The responsible entity can determine the probability that the results will fall within a certain range, or the most likely value of the result. Expert knowledge is generally required to undertake a complex form of uncertainty analysis. More detailed descriptions of these statistical techniques are outside of the scope of this guide.

Final Step: Presenting the uncertainty in the AA Reports

The responsible entity needs to fully describe the uncertainties in the submitted AA report.

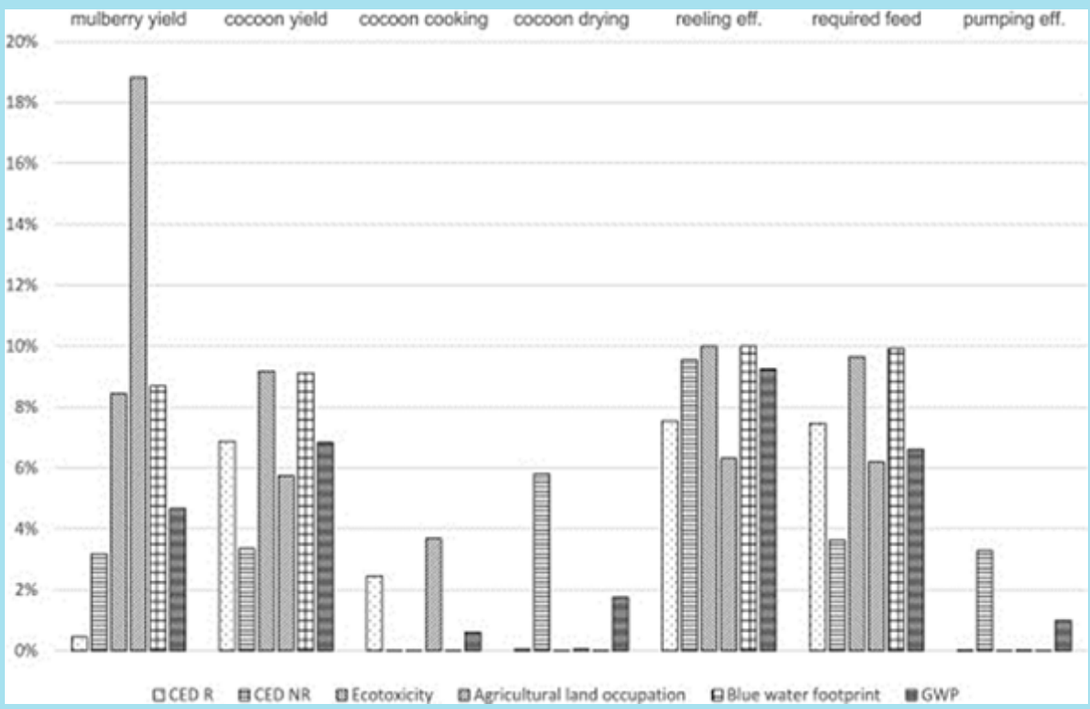
Furthermore, documenting the uncertainties will demonstrate that the responsible entity fully understands the following:

- Key sources of uncertainty and their impacts on the AA results;
- Overall degree of uncertainty and of the confidence that can be placed in the AA results;
- Critical assumptions and their importance to the AA results. This may include the details of any assumptions related to subjective expert judgments;
- Unimportant assumptions and why they are considered as unimportant; and
- Key conflicting information or key scientific debates involved and how they might impact the AA results.

During its evaluation of the report, the department will consider whether the analysis is clear and compelling. Data transparency, strength of analysis and arguments, and defensibility of conclusions are all indicators of the strength of the analysis.

Example 9-2: Applying Sensitivity Analysis in Life Cycle Multimedia Impacts Evaluation

This case study applied life cycle assessment to quantify environmental impacts for raw silk production. The values were calculated for the following environmental impacts: cumulative energy demand, ecotoxicity, land occupation, water footprint, and global warming potential. A sensitivity analysis was performed to evaluate the impact of uncertainty in the life cycle related input data (i.e., those assumptions and proxy data sets used to address data gaps). The process-specific parameters related to silkworm production and cocoon characteristics included: mulberry yields, cocoon yields, boiler efficiency, drier efficiency, reeling efficiency (the efficiency of converting cocoons into raw silk), pump efficiency and required feed. The sensitivity analysis helps assess which of these characteristics has the greatest effect on the overall environmental impact. Each parameter is changed once by 10%, keeping the others constant, and the resultant percentage change in the environmental impact shown as a percentage in the figure below. For example, the result shows that changes in the efficiency of converting cocoons into raw silk (i.e., reeling efficiency) have a very large observed effect on all the environment impact categories.

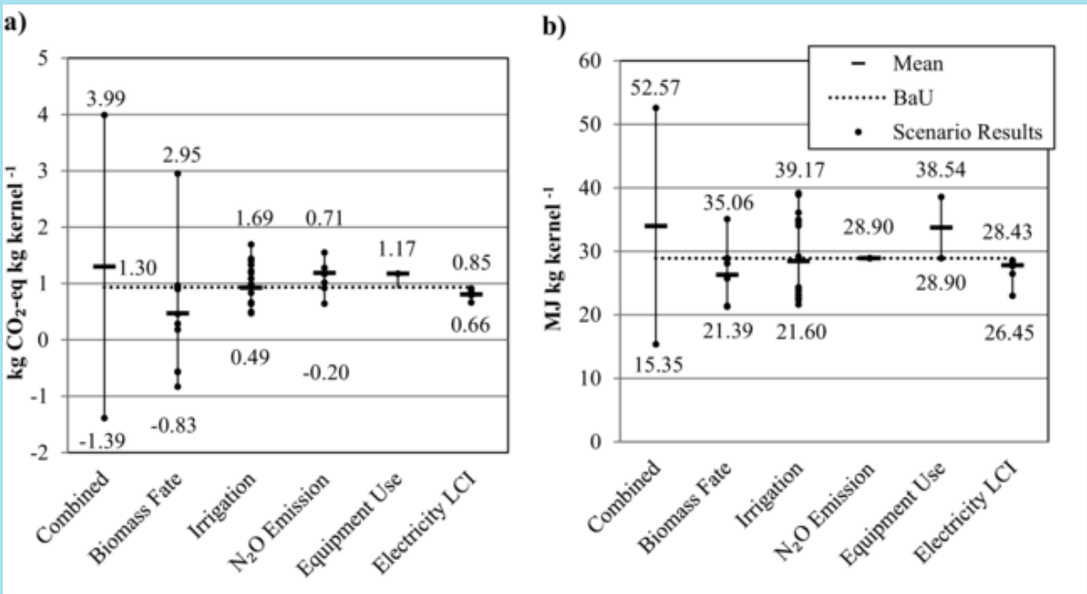


CED R: Cumulative energy demand for renewable energy resources
CED NR: Cumulative energy demand for non-renewable energy resources
GWP: Global warming potential

Sensitivity analysis results of variation of input parameters.
Source: Astudillo, M. F., Thalwitz, G., and Vollrath, F. Life Cycle Assessment of Indian Silk. Journal of Cleaner Production, October 2014, 81, 158-167.

Example 9-3: Applying Scenario Analysis in Life Cycle Multimedia Impacts Evaluation

The case study presents the calculation of the energy use and greenhouse gas (GHG) emissions for California almonds. In this case, scenario analysis was used to explore different plausible management assumptions and the boundary extremes of possible almond production practices in California. Scenarios for biomass fate, irrigation energy use, nitrous oxides emissions from orchard soils, and fuel combustion in field equipment were designed to test how these assumptions would influence the potential net GHG emissions and energy use for almond production. For example, the best-case scenario for waste biomass utilization sends 100% of the woody biomass to gasification power plants. The typical practice sends only a portion of the woody biomass for power generation. In addition, gasification plants comprise a small portion of the biomass power plants in California. Evaluation of impact to the results under these extreme scenarios provided some insights of the boundary conditions for the highest and lowest potential net GHG emission and energy use for almond production in California. Scenario analysis showed utilization of orchard biomass for electricity production had the greatest potential effect on GHG emissions and relatively high impact on energy use. A more detailed discussion is available from the source reference.



Scenario analysis results of combination of life cycle analysis model parameters/assumptions on annual (a) GHG emissions and (b) energy use per kilogram almond kernel.

Source: Kendall, A., Marvinner, E., Brodt, S., and Zhu, W. Life Cycle Based Assessment of Energy Use and Greenhouse Gas Emissions in Almond Production, Part II - Uncertainty Analysis through Sensitivity Analysis and Scenario Testing. Journal of Industrial Ecology, 2015, 19(6), 1019-1029.

Example 9-4: How Uncertainties in AA Could Be Presented

Uncertainty may be presented in a summary matrix, which lists different sources of uncertainty grouped by types of assessments (i.e., hazard, exposure, and risk characterization) along with the magnitude of uncertainty for each of the sources by using plus/minus signs. An example of an uncertainty summary matrix is shown in the table below.

Example Uncertainty Summary Matrix for Chemical Safety Assessment

Parameter	Source Name	Source Type	Direction & Magnitude of Uncertainty
Hazard traits[1]	Source 1	Model	−
Hazard traits[1]	Source 2	Input parameters	+++
Hazard traits[1]	Source 3	Input parameters	+
Hazard traits[1]	Source …	…	…
Hazard traits[1]	Source n	Input parameters	++/− −
Exposure factors[2]	Source 1	Scenario	++
Exposure factors[2]	Source 2	Model	+
Exposure factors[2]	Source 3	Model	+/−
Exposure factors[2]	Source 4	Input parameters	−
Exposure factors[2]	Source …	Input parameters	…
Exposure factors[2]	Source m	Input parameters	−

[1] Overall effect on hazard estimate (e.g., Mainly affected by overestimation from Source 2, which is uncertainty that may be reduced by…)

[2] Overall effect on exposure estimate (e.g., Mainly affected by overestimation from Source 1 and Source 2. Source 1 can be reduced by…)

Legend: +, ++, +++: low, moderate, and high overestimates
−, − −, − − −: low, moderate, and high underestimates

Source: Adapted from European Chemicals Agency (ECHA) Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.19: Uncertainty Analysis. November 2012.

9.5 Summary

- The responsible entity may use various types of information to compare functional and performance impacts, adverse impacts, multimedia life cycle impacts, and economic impacts of the product and alternatives.

- Information collection is a time-consuming activity and can be more efficient if the responsible entity follows a structured approach to gather information. Reliable information, as defined in regulations, are preferred to conduct an AA (when available and applicable).

- When information is not available, the best practice is to apply a range of approaches to address two primary categories of data gaps – namely, process-specific and chemical-specific data gaps – to carry out an AA.

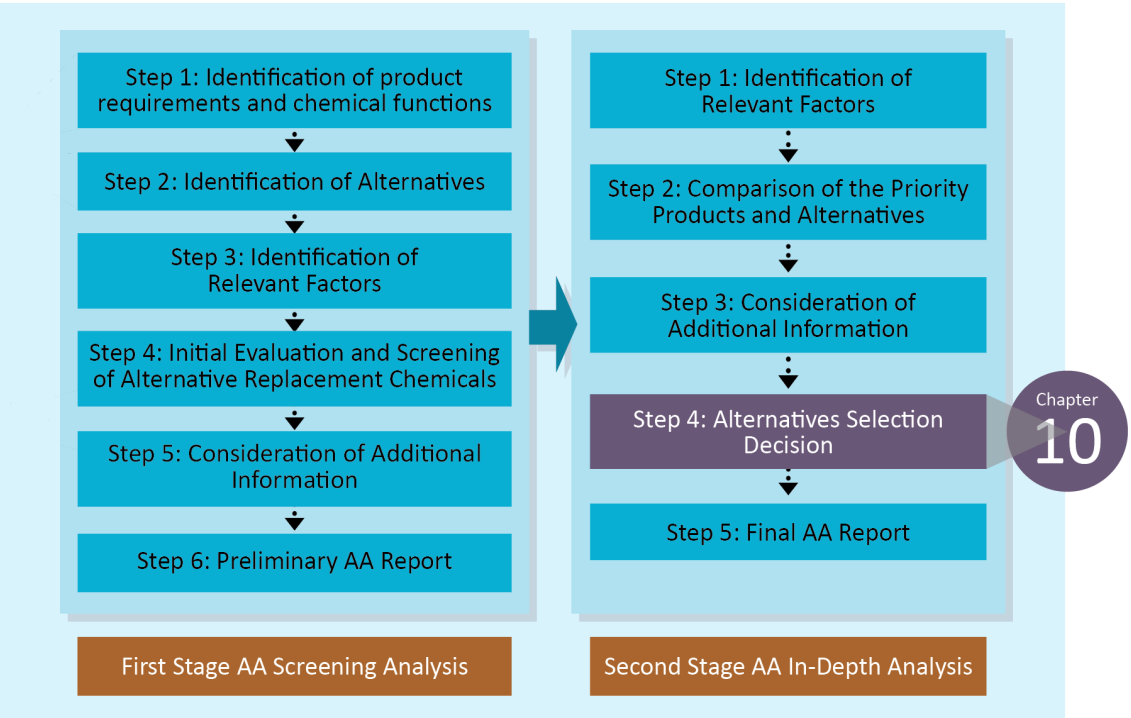
- As a good practice, the responsible entity needs to fully consider uncertainties (including data gaps) before making a decision. The stepwise approach presented in this chapter is a useful method for the responsible entity to evaluate and address uncertainties in AA.

- The tenets outlined in the introduction of this guide apply to selection, use, and application of appropriate data. The responsible entity should document the data in information used – either measured, referenced, or modeled – with transparency.[54] This is critical to ensure that the department properly interprets the information in the report.

[54] *Transparency refers to open, comprehensive, and understandable presentation of information.*

Chapter 10 — Selection of Alternatives

This chapter describes approaches and methods the responsible entity may use to present data, compare the product with its alternatives, and make a final decision. Although this chapter focuses on the final selection of alternatives, the comparison techniques presented here may also be applicable in the first stage AA during the screening of alternatives. It is likely that some alternatives will immediately display superior qualities according to some factors and inferior qualities according to others. It may be beneficial for the responsible entity to perform more data collection or analysis in the first stage to facilitate the screening process. This may, in turn, reduce the level of effort required for these tasks in the second stage.



10.1 Analyses, Comparisons, and Methodologies

The AA process requires a comparison of a Priority Product with alternatives by analyzing several predefined factors. Public health impacts, environmental impacts, life cycle processes, product function and requirements, and economics are all evaluated to make a decision. The consideration of a variety of factors will result in various trade-offs requiring value judgments. The challenge is in handling a large amount of complex information in a consistent way.

Alternatives are likely to exhibit varying degrees of adverse impacts. For example, an alternative may demonstrate similar performance as the Priority Product and may exhibit marginally fewer hazards traits or impacts. However, upon closer evaluation, the responsible entity may find other adverse impacts that could result from this alternative but are not observed in the Priority Product. The subsequent sections address methods for comparing the impacts of each alternative and the potential trade-offs that the responsible entity may have to evaluate.

The decisions regarding alternatives selection will require evaluation and comparison of multiple variables. The following decision-making techniques provide a rational framework for representing and relating the relevant factors, and for evaluating alternative solutions using quantitative and qualitative data. For additional tools, standards, methods, and models for assessing and comparing alternatives, please refer to the following report, Chemical Alternatives Analysis: Methods, Models, and Tools (Kuczenski, et.al., 2010).

SEQUENTIAL FRAMEWORK (STPP 2014)

A sequential framework may be used in instances where the responsible entity is comparing alternatives by beginning with the relevant impacts of most significance. It allows for removal of criteria that do not differ among the alternatives.

The responsible entity determines which impacts are most significant based on its values and the objectives identified in the rulemaking for the Priority Product. Then, the responsible entity establishes the relative importance of the adverse impacts it has identified.

The inherent advantage of this approach is that it establishes a hierarchy of the impacts and may allow the responsible entity to eliminate alternatives that do not address the prioritized impacts while meeting the product's baseline requirements. This approach is effective when the responsible entity can identify a clear hierarchy of impacts or preferences.

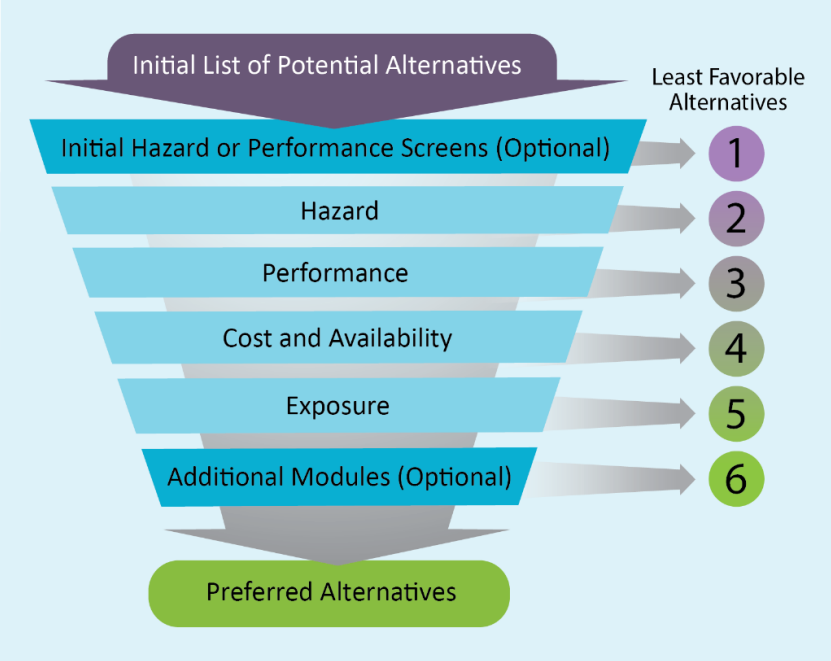


Figure 10-1 Sequential Framework (IC2, 2013)

Figure 10-1, from The Interstate Chemicals Clearinghouse (IC2) Alternatives Assessment Guide (IC2, 2013), illustrates the sequential framework based on the IC2 AA Guide's suggested hierarchy.

SIMULTANEOUS FRAMEWORK

The simultaneous framework considers all attributes at once, allowing good performance on one attribute to offset less favorable performance on another.

The IC2 AA Guide illustrates the simultaneous framework concept as shown in Figure 10-2.

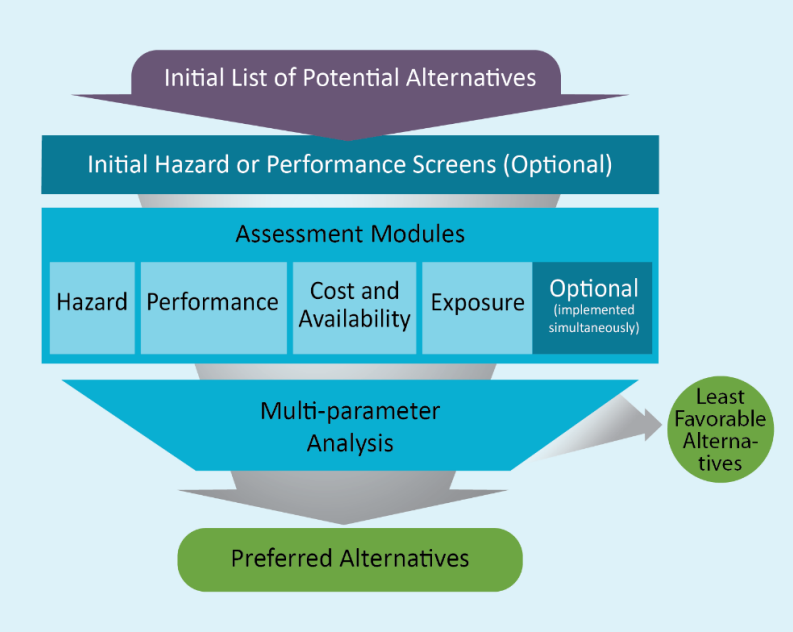


Figure 10-2 Simultaneous Framework (IC2, 2013)

HYBRID FRAMEWORK

The hybrid framework is a combination of the sequential and simultaneous frameworks. First, alternatives are screened out based on attributes that are considered very important (sequential). After screening is applied, the simultaneous framework is used for the remaining alternatives. Figure 10-3 illustrates the hybrid framework concept.

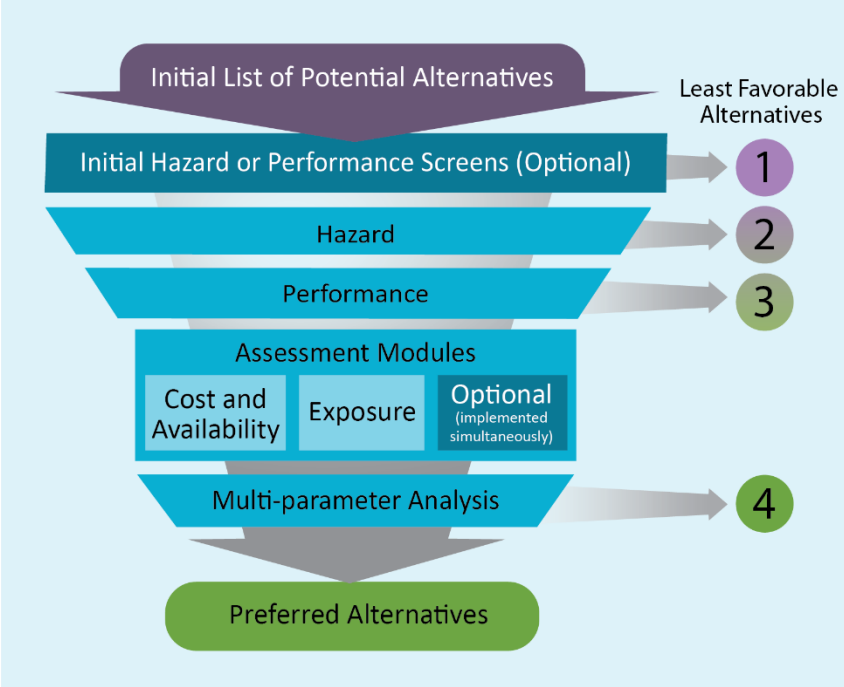


Figure 10-3 Hybrid Framework (IC2, 2013)

Table 10-1 provides a general discussion on the advantages and disadvantages of the three decision frameworks discussed above.

Table 10-1 Comparison of Decision Frameworks

Decision Framework	Pros	Cons
Sequential Framework	• Establishes an evaluation hierarchy for the impacts which includes ranking the impacts by level of importance. • Compares alternatives using the evaluation hierarchy in a series of steps. • Filters out less desirable alternatives. • Does not require the use of a decision method.	• Does not establish weighting criteria for impacts. • Does not establish ranking criteria for alternatives. • Does not allow consideration of trade-offs between impacts. • Requires assigning an order of importance to the impacts. • The evaluation hierarchy will vary since it is based on the responsible entity's values.

Decision Framework	Pros	Cons

Simultaneous Framework	• Considers all or a set of impacts at once allowing for trade-offs (e.g., good performance on one attribute to offset less favorable performance on another attribute)
	• Establishes an evaluation hierarchy for impacts which includes:
	  ○ Weighting criteria,
	  ○ Trade-off criteria,
	  ○ Ranking impacts by level of importance, and
	  ○ Ranking criteria for alternatives.
		• The evaluation hierarchy will vary since it is based on the responsible entity's values.
		• Requires establishing weighting criteria which can be resource- and time-consuming.
		• Requires the use of computerized calculations.
		• Requires the use of decision methods to evaluate trade-offs between impacts.

Hybrid Framework	• Combines parts of both Sequential and Simultaneous Frameworks.
	• Establishes an evaluation hierarchy for the impacts which includes:
	  ○ Weighting criteria,
	  ○ Trade-off criteria,
	  ○ Ranking impacts by level of importance, and
	  ○ Ranking criteria for alternatives.
	• Uses the Sequential Framework to screen alternatives based on impacts deemed of high importance.
		• The evaluation hierarchy will vary since it is based on the responsible entity's values.
		• Requires establishing weighting criteria which can be resource- and time-consuming,
		• Requires the use of computerized calculations.
		• Requires the use of decision methods to evaluate trade-offs between impacts.

DECISION ANALYSIS

An approach known as multi-criteria decision analysis (MCDA) (Malloy, et.al., 2011; Kuczenski, et.al., 2010; Malloy, et.al., 2015; Cinelli, et.al., 2014) allows the responsible entity to compare multiple and often conflicting criteria or impacts simultaneously.

In MCDA, the responsible entity weights the relative importance of the impacts and applies a mathematical model to compare the alternatives simultaneously. The weight of each impact may be allocated according to the priority assigned by the responsible entity. Weights may also be assigned by considering surveys and modeling and may rely on technical expertise.

The weighting (or hierarchy) established by the responsible entity must be included in the submitted AA Report. Each responsible entity, based on its priorities, may arrive at a different decision. Factors are of equal importance when no weighting is applied. However, even if the responsible entity does not deliberately apply weighting factors, a value judgment is still being made on their relative importance.

The regulations and this guide do not require that all responsible entities, for any given Priority Product, establish the same weighting or hierarchy. Establishing standard weighting criteria would create a prescriptive process for decision-making which would be counter to the goals of the regulations. By allowing flexible weighting factors (or hierarchies), decisions will be based on current science or best practices at the time the AA is conducted.

Two commonly used MCDA methods are the multi-attribute utility theory (MAUT) and outranking (Malloy, et.al., 2013). The MAUT is an optimization tool where the decision maker has a well-defined set of preferences that can be represented on a dimensionless utility scale. The performance of an alternative for a given decision criterion is assigned a score between 0 and 1 and is multiplied by the weight assigned to the criterion. It then aggregates the weighted scores to arrive at a total score for the alternative. In this method, the preferences are transitive: if Alternative A is preferred to Alternative B, and Alternative B is preferred to Alternative C, then the decision maker will prefer Alternative A to Alternative C.

Outranking models do not create utility functions as described above. Rather, this approach directly compares the performance of two alternatives one at a time in terms of each criterion established by the decision maker. It is as if all alternatives are engaged in a tournament over each criterion, with the alternative having the best overall record as the preferred alternative.

The MAUT and outranking models are examples of two MCDA methods that a responsible entity may use in their decision-making process. MAUT and outranking models are examples of

the simultaneous comparison method. An overview of three decision methods discussed in the IC2 Alternative Assessment Guide is included for (1) the simple comparison method, (2) the iterative comparison method, and (3) the simultaneous comparison method.

The simple comparison describes a simple, heuristic approach for summarizing the impacts associated with the original chemical or product and its alternatives. This type of summary can reveal when an alternative is clearly superior or inferior to the original. For this simplified assessment, the guiding principles of "safe and effective" are used to define preferences among alternatives (IC2, 2013).

The iterative comparison method describes the comparison of alternatives using a hierarchy of criteria based on assessor values. The assessor identifies the threshold conditions for the criteria and eliminates alternatives that do not achieve the desired threshold values. This type of approach is typically used for screening by eliminating those options that do not achieve minimum thresholds (IC2, 2013).

The simultaneous comparison method takes all relevant criteria into account simultaneously using weighted criteria to define preferences and offset conflicts among criteria. This type of analysis can both identify a preferred alternative and provide a relative ranking of the alternatives. This type of assessment is complicated. Determining criteria weighting can be resource- and time-consuming, and the simultaneous comparison usually requires computerized calculations (IC2, 2013).

Basically, all these methods require the responsible entity to: (1) compare the human health and environmental hazards and exposure routes associated with the product and the proposed alternatives; (2) quantify the relevant criteria for each alternative; (3) identify the relevant assessment factors; (4) compare the relevant assessment factors for the product and potential alternatives using the relevant criteria; and (5) conduct uncertainty analysis.

10.2 Information Presentation

When completing the AA Report, the responsible will ensure the following:

- All assumptions have been documented;
- The information the responsible entity collected or considered for the analysis is arranged in a logical order;
- There is sufficient information upon which to base the analysis;
- The relevant factors and impacts are clearly presented to stakeholders reviewing the AA report; and

- The findings, critical interim decisions, and conclusions of its analysis are documented for each step of the decision process.

The information presented must be clear and concise to be understandable, yet comprehensive enough to provide a meaningful explanation of the analysis. The responsible entity must present the rationale which justifies each of its assertions. While the values used to weight factors need not be justified, the AA report must make it clear how those values are determined and affect the decision-making process.

A responsible entity may present a matrix or summary of the comparative results for the Priority Product and each alternative. An advantage of a matrix is that it makes it easier to show how a single category of information varies when the Priority Product is compared to alternatives.

While numeric data can be easily presented in a matrix, the analysis of qualitative data cannot always be presented as readily in formats, such as graphs, charts, or figures. A responsible entity must convey its key findings in a narrative and support claims with convincing evidence. The AA report should include a narrative of any conclusions drawn from any secondary reports. Simply referencing secondary reports is not sufficient. A matrix may be suitable for the presentation of qualitative data provided the information contained in the report is properly footnoted and presented in a concise manner.

During the AA, the responsible entity will make many interim decisions, such as determining which factors are relevant, screening alternatives, determining the boundaries of the life cycle evaluations, and selecting the final alternative. The information collected in the AA Report needs to provide a sound basis for each of the interim decisions presented in the analysis and for the ultimate selection. Providing the information and conclusions in the AA Report is not enough. The responsible entity is expected to provide insight into how to interpret the results and into its final decision making. This transparency will improve the credibility of the AA process with both stakeholders and the department.

When the responsible entity considers a variety of alternatives, a potentially large number of relevant factors may arise, making the matrix large and more difficult to interpret. In these instances, a series of matrices or tables may be necessary to adequately present the information in a streamlined manner. For example, a table to illustrate the relevant life cycle segments may be appropriate, with a separate table identifying the relevant factors within each of the life cycle segments. Graphics can also be used to map the life cycle segments examined for the Priority Product and the alternatives along with a narrative explaining the rationale used to keep or eliminate life cycle segments for consideration.

PRIORITY PRODUCT INFORMATION

The responsible entity must describe the relevant functional, performance, and legal requirements of the Priority Product that must be met for an alternative to be considered viable. A matrix that identifies the attribute or feature of the Priority Product and the role the Chemical of Concern plays may be useful to readily identify those attributes that may require a trade-off. Table 10-2 summarizes potential functional, performance and legal requirements that may be applicable to a broad range of products. The functional requirement, for example, of a grocery bag may include the strength and capacity. Performance of the grocery bag may also include reusability or strength of the bag. Any product attributes deemed necessary should be included in the analysis.

Table 10-2 Priority Product & Alternatives Information

Description & Functionality: What does the product do? Do other attributes affect how this is carried out?

Attribute/Feature	Priority Product	Role of the Chemical of Concern	Alt 1	Alt 2	Alt 3
Strength					
Capacity					

Performance: How long is it expected to last? One-time use?

Attribute/Feature	Priority Product	Role of the Chemical of Concern	Alt 1	Alt 2	Alt 3
Durability					
Lifetime					
Reusable					
Reliability					

Quality: Customer expectations

Attribute/Feature	Priority Product	Role of the Chemical of Concern	Alt 1	Alt 2	Alt 3
Aesthetics (color, size)					

Legal Requirements:

Attribute/Feature	Priority Product	Role of the Chemical of Concern	Alt 1	Alt 2	Alt 3
Safety					
Maintenance					

SCOPE OF RELEVANT FACTORS

Depending on the relevant life cycle segments, impacts, or factors being evaluated or compared, the responsible entity may need to use a combination of formats or tables to present this information clearly and concisely. For example, let us assume that the responsible entity completes two iterations of screening alternatives. In the first round, the responsible entity evaluates twelve alternatives and narrows the number down to eight because certain alternatives demonstrate greater human health impacts across multiple life cycle segments and therefore must be eliminated. The responsible entity prepares a corresponding table to show the first round of comparisons, and then prepares a second table comparing the remaining eight alternatives. Table 10-3 illustrates a high-level qualitative comparison between the Priority Product and the remaining eight alternatives.

Table 10-3 Relevant Life Cycle Segments & Factors

Life Cycle Segment	Factor or Impact	Priority Product	ALT 1	ALT 2	ALT 3 thru 8
Raw Material Extraction	Environmental Impacts	H	O	O	O
	Public Health Impacts	H	O	O	O
	Waste and End-of-Life	H	H	H	
	Environmental Fate				
Raw Material Extraction	Materials & Resources Consumption Impacts				
	Physical Chemical Hazards				
	Physicochemical Properties				
Intermediate Processes	Environmental Impacts				
	Public Health Impacts				
	Waste and End-of-Life				
	Environmental Fate				
	Materials & Resources Consumption Impacts	H	H	H	H
	Physical Chemical Hazards				
	Physicochemical Properties				

Life Cycle Segment	Factor or Impact	Priority Product	ALT 1	ALT 2	ALT 3 thru 8
Manufacture	Environmental Impacts	H			
	Public Health Impacts	H			
	Waste and End-of-Life				
	Environmental Fate	H			
	Materials & Resources Consumption Impacts				
	Physical Chemical Hazards				
	Physicochemical Properties				
Packaging & Transportation		NA	NA	NA	NA
Distribution		NA	NA	NA	NA
Use	Environmental Impacts	H	H	H	H
	Public Health Impacts	H	H	H	H
	Waste and End-of-Life				
	Environmental Fate	H	H	H	H
	Materials & Resources Consumption Impacts				
Use	Physical Chemical Hazards				
	Physicochemical Properties				

Life Cycle Segment	Factor or Impact	Priority Product	ALT 1	ALT 2	ALT 3 thru 8
Operation & Maintenance		**NA**	**NA**	**NA**	**NA**
Reuse & Recycling	Environmental Impacts	**H**		**H**	
	Public Health Impacts	**H**		**H**	
	Waste and End-of-Life	**H**		**H**	
	Environmental Fate	**H**		**H**	
	Materials & Resources Consumption Impacts				
	Physical Chemical Hazards				
	Physicochemical Properties				
End-of-Life		**NA**	**NA**	**NA**	**NA**

H Impact observed (high)
M Impact observed (medium)
L Impact observed (low)

NQ Data not available (impact not quantifiable)
O Data not available
NA Not Applicable

The qualitative analysis used to identify the relevant life cycle segments and impacts may be subsequently revised to focus on those impacts which are most germane to the remaining alternatives. For instance, the responsible entity identifies the relevant adverse public health and environmental impacts. The responsible entity then employs an impact-specific evaluation which can take various forms. In the following tables, the Priority Product is compared to the three alternatives:

- Table 10-4a illustrates adverse health impacts associated with the relevant life cycle segments for the Priority Product and the three alternatives under evaluation;
- Table 10-4b illustrates an example of the specific hazard traits that need to be considered under adverse public health impacts posed by the Priority Products and the alternatives being considered;
- Table 10-5a illustrates the relevant life cycle segments for the Priority Product and the three alternatives under evaluation; and
- Table 10-5b illustrates only the "use" life cycle segment for the Priority Product and the three alternatives under evaluation for specific adverse air quality impacts. Note that air quality is a subset of the larger range of adverse environmental impacts.

A responsible entity will evaluate the Toxicological Hazard Traits of the Priority Product and the alternatives under consideration and retains replacement chemicals that reduce or eliminate overall adverse impacts.

Table 10-4a Adverse Public Health Impacts

Product Name	Raw Materials Extraction	Intermediate Processes	Manufacturing	Packaging & Transportation	Distribution	Use	Operation & Maintenance	Waste generation & Management	Reuse & recycling	End-of-Life
Priority Product	**NA**					**H**				
Alternative 1	**NA**		**L**			**H**				
Alternative 2	**NA**		**L**			**H**				
Alternative 3	**NA**		**O**			**H**				

H Impact observed (high)
M Impact observed (medium)
L Impact observed (low)
NQ Data not available (impact not quantifiable)
O Data not available
NA Not Applicable

Table 10-5b Toxicological Hazards Traits

Product	Carcinogenicity	Cardiovascular Toxicity	Dermatotoxicity	Developmental Toxicity	Endocrine Toxicity	Epigenetic Toxicity	Genotoxicity	Hematotoxicity	Hepatotoxicity & Digestive System Toxicity	Immunotoxicity	Musculoskeletal Toxicity	Nephrotoxicity & Other Toxicity to the Urinary System	Neurodevelopmental Toxicity	Neurotoxicity	Ocular Toxicity	Ototoxicity	Reproductive Toxicity	Respiratory Toxicity
Priority Product																		
ALT 1																		
ALT 2																		
ALT 3																		

Table 10-6a Relevant Life Cycle Segments

Product	Raw Material Extraction	Intermediate Processes	Manufacturing	Package & Transportation	Distribution	Use	Operation & Maintenance	Waste Generation & Management	Reuse & Recycling	End-of-Life
Priority Product										
Alternative 1										
Alternative 2										
Alternative 3										

The responsible entity will evaluate the Priority Product and the alternatives for their potential to cause environmental impacts, including releases to air, soil, water, or ecological receptors. A responsible entity may create a matrix that identifies the life cycle segments that are impacted by each of the alternatives and readily identify those that should or should not be carried forward for further evaluation.

Table 10-7b Air Quality Use Segment

Product	CA Toxic Air Contaminants	Emissions of Greenhouse Gases	Emission of Nitrogen Oxides	Emission of Particulate Matter	Emission of Stratospheric Ozone Depleting Compounds	Emissions of Sulfur Oxides	Emissions of Tropospheric Ozone-Forming Compounds
Priority Product							
Alternative 1							
Alternative 2							
Alternative 3							

ECONOMIC IMPACTS

The responsible entity will consider the economic impacts of the Priority Product and potential alternatives across the product's life cycle.

The economic impacts may not be fully understood during the first stage. However, if the responsible entity has sufficient information to narrow the scope of alternatives being considered, it may do so in the Preliminary AA Report. A responsible entity may use existing tools and approaches to scope and preliminarily evaluate alternative ingredients for their products, their social benefits, and consumer acceptance—provided those tools are also described in the Preliminary AA Report.

As detailed in Chapter 8, costs associated with public health, environmental impacts, and costs to government agencies and non-profit organizations must be included in the Final AA or Abridged AA Report. A Benefit Cost Analysis, or a similar method, may be used to compare the Priority Product and the alternatives. The benefits of avoiding or reducing public health and environmental impacts should be fully characterized. Alternatives that offer inherent protection are preferred for their capacity to mitigate an exposure.

The responsible entity tabulates costs and compares impacts for each life cycle segment, relevant hazard trait, and the alternatives to the Priority Product (illustrated in Table 8-2). By collecting information for each segment and across the life cycle of the product and its alternative, the public health impacts that are avoided or reduced can be legitimately compared. A similar comparison should be done for environmental costs, and costs to governmental agencies and non-profit organizations.

A responsible entity may consider the internal economics but is not required to do so unless it elects to retain the Priority Product in lieu of implementing an alternative. Tables 10-6a and 10-6b illustrate summary tables for the economic impacts and internal costs associated with the Priority Product and each alternative considered.

Table 10-8a Economic Impacts

Parameters	Priority Product	ALT 1	ALT 2	ALT 3
Public Health Impacts				
Environmental Impacts				
Costs to Government & Public Agencies				
Cost to Non-Profit Organizations				

Table 10-9b Internal Costs (Only if retaining Priority Product)

Parameters	Priority Product	ALT 1	ALT 2	ALT 3
Manufacturing				
Marketing				
Materials				
Equipment Acquisition				
Resource Consumption				
Others…				

The regulations detail the required content for all AA reports. The responsible entity may present the information[55] it collects in a matrix, or other summary format, that provides a clear, visual comparison of the collected information. See Appendix 1- Required information for AA Reports. The responsible entity must ensure that the information conveyed is understandable and provides stakeholders with the rationale for any argument made.

10.3 Summary

- The responsible entity reviews the type of and quality of information for its analysis.
- There are three decision frameworks that the responsible entity can choose to follow: sequential, simultaneous, or mixed frameworks.
- Multi-criteria decision analysis may be used as a decision method in AA.
- The responsible entity determines the most suitable presentation for the type of information (qualitative or quantitative) being used.
- The responsible entity needs to identify the product function, performance, and the legal requirements of the Priority Product and alternatives to ensure the selected choice is feasible.

[55] *22 CCR section 69501.1(a)(40)*

- The responsible entity establishes the hierarchy of adverse impacts and multimedia life cycle impacts observed. This hierarchy depends on both the goals of the regulation and their company's core values. The selected alternative should provide protection to public health and the environment and be functionally acceptable, technically feasible, and economically feasible.

- The responsible entity provides a comparison of economic impacts. If the Priority Product will be retained, include internal cost impacts to help explain the selection.

- The responsible entity must ensure the transparency of the analysis to improve credibility of the report and provide insight into the decision making.

Chapter 11 — Self-Evaluation of AA

This chapter provides a structured approach that the responsible entity may use to evaluate its AA Reports before submitting it to the Department. It is a starting point to build best practices to improve the overall quality of the AA Reports.

CHAPTER 11 AT A GLANCE

This chapter provides guidance on how to self-evaluate AA Reports and Alternate Process AA Work Plans. Best practice approaches presented in this chapter will improve efficiency and help responsible entities meet the substantive and administrative requirement of the AA under the SCP regulations. Recommended steps:

- Submit the AA Reports or Alternate Process AA Work Plan on a timely basis.
- Check for comprehensiveness of the AA Reports: checklist for AA Reports content, scope of relevant comparison factors, scope and comparison of alternatives, and selected alternative and implementation.
- Check for reasonableness of the AA Reports. Evaluate whether the AA conclusions are based on reliable information, the merits of the supporting information quality, and the adequacy of the analysis. Three quality metrics – *reliability, validity, and plausibility* – are introduced and discussed from this perspective.

The self-evaluation approach and quality metrics introduced in this chapter are not required by SCP regulations. They serve only as recommendations for the responsible entity to ensure that the AA contains all the applicable information needed to determine conformance with the SCP regulations.

11.1 Department Review Criteria and General AA Evaluation Approach

The SCP regulations specify the criteria that the Department will use to review AA Reports and determine if the AA Report or Alternate Process AA Work Plan conforms to the administrative and substantive requirements of the regulations.[56]

Department AA Review Criteria (22 CCR section 69505.9(a))

In reviewing AA Reports and Alternate Process Work Plans for conformance with the substantive and administrative requirements, the Department will consider:

(1) Whether the AA Report or Alternate Process AA Work Plan was submitted on a timely basis;
(2) Whether, and to what extent, the responsible entity considered and addressed all applicable provisions pertaining to the preparation and submittal of an AA Report or Alternate Process AA Work Plan, whichever is applicable;
(3) Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA were based on reliable information, when applicable.

The Department will solicit public comments on the Final AA Reports or Abridged AA Reports by posting them on its website. This provides an opportunity for interested persons to provide feedback on any posted report. The Department will review the public comments and determine if it is necessary for the responsible entity to respond to concerns raised by the public. Public participation provides an additional mechanism to improve the quality of the AA.

Because the AA process involves complex information gathering, analyses, decision-making and reporting activities, self-evaluation of AA Reports using the recommendations in this chapter before submission of reports to the Department may save time and effort for all parties involved. The responsible entity may follow the approach shown in Figure 11-1 to evaluate its AA Report.

[56] *22 CCR section 69505.9(a)*

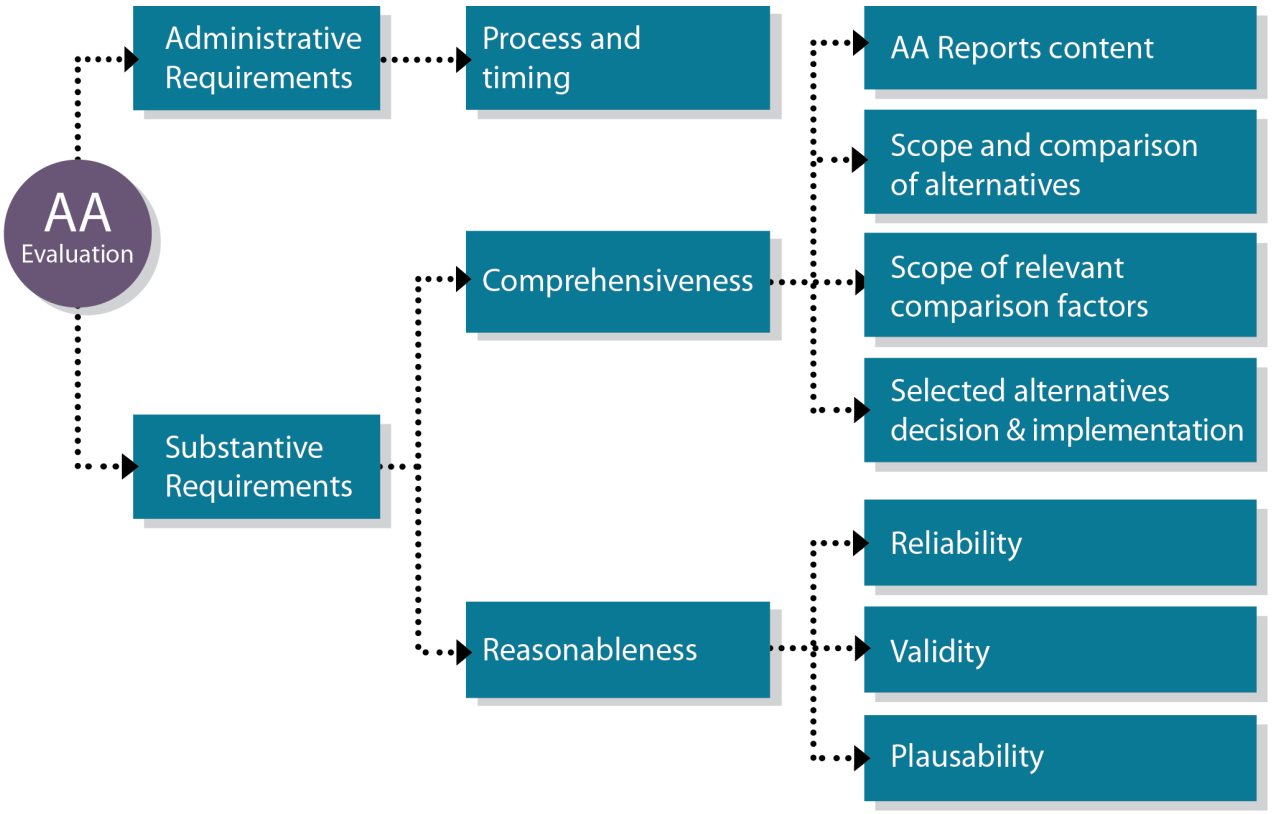


Figure 11-1 A General Approach for AA Self-Evaluation

To conform to the administrative requirements, the responsible entity must submit the AA Report by the due date:

- Preliminary Report, Abridged AA Report, or Previously Completed AA: 180 days after the date the product is listed on the final Priority Products list, unless the Department specifies a different due date in the Priority Products list.[57]
- Final AA Report: 12 months after the date the Department issues a notice of compliance for the Preliminary Report.[58] If the responsible entity uses an alternate process AA, the Department will specify an appropriate due date for submittal of the Final AA Report based on its evaluation of the responsible entity's Alternate Process AA Work Plan.[59]

[57] *22 CCR section69505.1(b)(2)(A)*

[58] *22 CCR section 69505.1(b)(2)(B)*

[59] *22 CCR section 69505.4(c)(1)(C)*

The SCP regulations and the Department's website provide more details on AA Report options, and the timing of submittals.

One way the responsible entity may assess whether the report conforms to the substantive requirements of the SCP regulations is to evaluate the comprehensiveness and reasonableness of the AA. The following sections discuss details of these two aspects.

11.2 Evaluation of Comprehensiveness

The comprehensiveness of an AA may be evaluated using a checklist for the content of the AA report. The completeness of the AA Report is demonstrated if it contains all the required content elements specified in the regulations and summarized in Appendix 1.

Comprehensiveness of the AA Report: Recommendations for self-evaluation focus on addressing the following information:
Checklist for AA Report
Scope of relevant comparison factors
Scope and comparison of alternatives
Selected Alternative and Implementation

The following are four of the primary areas for this evaluation:

1. CHECKLIST FOR AA REPORT

Appendix 1 contains a checklist to assist the responsible entity fulfill the AA Report requirements. The checklist includes both a list of the required elements and a narrative providing additional detail.

2. SCOPE OF RELEVANT COMPARISON FACTORS

For the AA Report, the responsible entity describes the relevant factors, associated exposure pathways, and life cycle segments that were evaluated and compared to the Priority Product and its alternatives. For each factor where the exposure pathway and life cycle segment are determined not to be relevant, the AA Report must explain the rationale and pertinent findings that support this determination.[60] A responsible entity may follow the examples provided in Appendix 3-2 to organize and present the rationale and supporting information for identifying these relevant factors.

[60] *22 CCR section 69505.7(f)*

3. 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 all factors associated with the impacts, and the rationale for any trade-offs made among the factors.

The Preliminary AA Report must identify and describe the alternatives selected for further evaluation in the second stage of the AA, and include an explanation of the rationale for the selection decision. The responsible entity includes a work plan for the second stage AA effort.

4. SELECTED ALTERNATIVES AND IMPLEMENTATION

In the Final AA Report, the responsible entity identifies and describes the alternative(s), if any, to the Priority Product. The description of the alternatives selection decision must include:

- An analysis that evaluates and compares the selected alternative(s) 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.
- To implement the selected alternatives, the Final AA Report must include a detailed implementation plan, which includes:
- Key milestones and dates for implementing the selected alternative; and
- Regulatory Response(s) that the responsible entity wishes to propose and a work plan to implement them.

To implement the selected alternatives, the Final AA Report must include a detailed implementation plan,[61] which includes:

- Key milestones and dates for implementing the selected alternative; and
- Regulatory Response(s) that the responsible entity wishes to propose and a work plan to implement them.

[61] *22 CCR section 69505.7(k)(2)*

11.3 Evaluation of Reasonableness

A reasonableness evaluation can help the responsible entity demonstrate that: (1) the conclusions of the AA are based on reliable information; (2) the merits and quality of the supporting information are well-established; and the adequacy of the analysis is acceptable. A reasonableness evaluation helps the responsible entity demonstrate to what extent the analysis addressed all applicable AA requirements. It may also help the responsible entity to decide whether the information with a claim of trade secret protection is true, accurate, and complete.

For this Guide, a reasonableness evaluation may focus on three primary areas: reliability, validity, and plausibility.[62] Reliability and validity assessments address the technical aspects of how the information is evaluated. Plausibility considers the non-technical aspects that supplement the AA evaluation and are not covered by reliability and validity.

RELIABILITY

The SCP regulations provide review criteria and the definition of reliable information. One review criterion is "whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA were based on reliable information."[63] The definition of reliable information,[64] relates to the source of supporting information. Thus, reliability, as used in this Guide is related to how well the supporting information provides evidence of the findings.

Some key standards to help the responsible entity consider reliability are listed below:

- Whether the study or other scientific information was published in a scientifically peer reviewed report or other literature
- Whether the study or other scientific information was published in a report by the United States National Academies
- Whether the study or other scientific information was published in a report by an international, federal, state, or local agency that implements laws governing chemicals

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[62] Different terms are being used synonymously to communicate the quality of the information used for chemical hazard/risk assessment, Life Cycle Assessment, and other individual steps of AA. More detailed background information on harmonization of these terms and different information quality evaluation approaches are provided in Appendix 11.

[63] 22 CCR section 69505.9(a)(3)

[64] 22 CCR section 69501.1(a)(57)

- Whether the study or other scientific information was conducted, developed, submitted, prepared for, or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes
- Whether the study design was appropriate to the hypothesis being tested, and sufficient to supporting the proposition(s) for which the study is presented to the Department

Note in some cases, the above considerations for reliable information may not be applicable to certain types of information, such as internal cost information including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs. Reliable information may also not be available for certain chemicals or processes.

VALIDITY

For the purposes of this Guide, validity is the extent to which chosen information is applicable and appropriate for the AA. The responsible entity may consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects. For different steps of the AA such as hazard and exposure evaluation and life cycle impacts assessment, validity may relate to whether the information is relevant, representative, and adequate (see details in Appendix 11). Relevance means data and tests are appropriate for a specific evaluation. Representativeness refers to the degree to which the data set reflects the true population that the analyst is trying to describe. Adequacy is the completeness of data used in the analysis.

Some key questions to help responsible entity consider the validity of the information are listed below:

- To what degree is the information relevant and representative to the purpose and scope (alternatives under consideration and relevant comparison factors) of the AA?
- What is the level of rigor used to generate the information, including the use of quality controls, when relevant?
- To what degree is the information independently confirmed, corroborated, or replicated?
- Are the critical parameters or uncertainties influencing the analysis of relevant factors considered adequately?
- Are the models, methods, approaches appropriate for analysis of the relevant factors?

- Are the exposure scenarios for all the use patterns and life cycle segments adequately considered?

PLAUSIBILITY

For the purposes of this Guide, plausibility relates to the good communication of the AA based on its organization, presentation, and documentation of the analysis. A clear and logical organization supports the conclusions of the analysis and contributes to the persuasiveness of the rationale (i.e., the presentation of information is sufficient to allow a reader of the AA Report to understand the trade-offs between alternatives and the Priority Product). A responsible entity needs to evaluate the plausibility of any results, approaches, methods, supporting information, assumptions, boundary conditions, limitations, rational, and uncertainties in the AA. Some key questions to help the responsible entity consider plausibility are as follows:

- Have the analytical tools, models, and software (including uncertainties) used to conduct the AA been documented and described?
- Would someone who has a general knowledge of an AA but is not familiar with the methods be able to understand the methods, tools, or approaches being described?
- Is the description of the approach, assumptions, limitations, and interpretation of the results sufficient to lead to the conclusion(s)?
- Is the logic behind the AA decisions and arguments sound? Have the arguments been made in a transparent manner?
- Can the AA goal (i.e., to identify impacts and inform decision-makers about potential trade-offs of alternatives) be met adequately with the available information?
- Have any published methodologies or guidelines used, and any deviations from those methodologies or guidelines been identified?
- Has all the supporting information been cited?
- If currently unavailable information became available, could it be used to validate and address any uncertainties that have been identified?

A frequently asked question related to the reasonableness evaluation is “How detailed should an AA be?” The answer must be decided on a case-by-case basis. In general, it is recommended that the responsible entity build its analysis using supporting information that is as reliable, valid, and plausible to the extent possible. Since time and resources available to conduct AAs are limited, the level of detail may be proportionate to: (1) the trade-offs among different relevant factors between the Priority Product and alternatives, and (2) whether uncertainties in

these areas would have a significant influence on the decision. For example, the closer the balance between trade-offs, the more details are helpful in the decision-making.

11.4 Summary

- The responsible entity needs to submit its AA Reports by the specified submittal dates.
- The responsible entity is encouraged to use the report checklist (Appendix 1) and review the following contents of its report for comprehensiveness: (1) scope of relevant comparison factors, (2) scope and comparison of alternatives, and (3) selected alternatives and implementation. The review should confirm that the applicable regulatory AA requirements for preparing and submitting an AA Report have been considered and addressed.
- The responsible entity evaluates reasonableness of its AA Reports by considering reliability, validity, and plausibility to demonstrate the extent to which the analysis considered and addressed all applicable regulatory AA requirements.
- The key purpose of self-evaluation is to help the responsible entities review the quality of their AA work. The review will help to answer some key questions:
    - whether the AA reports communicate well a complete, transparent, and thorough analysis
    - whether there is sufficient information to support and justify the rationale
    - whether there is reasonable basis to indicate a course of action (e.g., to choose a specific safer alternative, or to claim there is no viable alternative)

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**. 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.

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.

Cradle to Cradle Products Innovation Institute. **The Cradle to Cradle Certified™ Products Standard** is a multi-attribute, continuous improvement methodology that evaluates products across five categories of human and environmental health.

European Chemicals Agency (ECHA). ECHA has published various guidance documents such as:

- Guidance on the Preparation of an Application for Authorisation – European REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) regulation requires that firms using Substances of Very High Concern (SVHC) must assess suitable alternatives and, if suitable alternatives are available, may prepare a substitution plan. REACH regulation (Annex XV) calls for comparison of risks, in addition to other attributes including economic feasibility and technical feasibility. ECHA publishes various guidance documents to help stakeholders to fulfill their obligations under the REACH regulation.

- Guidance on the Preparation of Socio-Economic Analysis as Part of an Application for Authorisation - This document describes the socio-economic analysis under the REACH procedure on applications for authorization.

European Commission. 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.

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 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 a step-by-step method to assess the risks and evaluation criteria for selection of sustainable substances.

German Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, 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.

German Society for International Cooperation (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.

International Organization for Standardization (ISO) 14044: 2006. Environmental Management – Life Cycle Assessment - Requirements and Guidelines. This standard specifies requirements and provides guidelines for Life Cycle Assessment.

Interstate Chemicals Clearinghouse (IC2). Alternatives Assessment Guide (Version 1.0). This document provides a modular and tiered approach on how to conduct an Alternatives Assessment. It covers several topics including hazard, exposure, cost and availability, performance life cycle concerns, decision etc. Each module also contains several levels of complexity ranging from a basic assessment to a more complete and technically robust review.

Lowell Center for Sustainable Production. Lowell Center 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 Academy of Sciences. A Framework to Guide Selection of Chemical Alternatives. This report demonstrates a decision framework for evaluating potentially safer substitute chemicals as primarily determined by human health and ecological risks.

National Institute for Occupational Safety and Health (NIOSH). 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.

Organisation for Economic Co-operation and Development (OECD). Assessment of Chemicals. OECD assists countries in developing and harmonizing methods for assessing risk to human health and the environment, including methodologies for hazard and exposure assessment.

Stockholm Convention Persistent Organic Pollutants Review Committee. General Guidance on Considerations Related to Alternatives and Substitutes for Listed Persistent Organic Pollutants and Candidate Chemicals. 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.

US Environmental Protection Agency (EPA) Safer Choice Program. **Design for the Environment Alternatives Assessments**. This website describes the Chemicals Alternatives Assessment methodology and key hazard evaluation criteria to identify safer replacement chemicals to toxic chemicals.

US Occupational Safety and Health Administration (OSHA). **Toolkit for Safer Chemicals**. This website presents an overview of the steps involved in alternatives assessment for workplaces and salient resources.

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APPENDICES

Important Note

The Appendices are numbered to match the chapters that correspond to the content. Note that there are appendices that have been reserved for future content.

Appendix 1 — Required Information for AA Reports

A summary of AA Report contents required by the regulations.[65]

AA Report Contents
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 • Function, performance, legal requirements, and role of Chemical of Concern in the product

[65] *22 CCR section 69505.7*

AA Report Contents

Scope of Relevant Comparison Factors

- Identification of which factors and associated exposure pathways and life cycle segments were determined to be relevant
- Discussion of how relevant factors and associated exposure pathways and life cycle segments were identified
- Rationale for determination of factors to be not relevant

Scope and Comparison of Alternatives

- Description of alternatives
- Information collected and evaluated to assess potential alternatives
- Rationale and methods used for elimination of alternatives from further consideration
- 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
        - Cost 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.

AA Report Contents

Supporting Information

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

Additionally, for Final AA Report:

- Identification of the information that is not currently available, but if it were available, could be used to validate information used for the AA and address any uncertainties in the AA.

Selected Alternatives

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.

AA Report Contents

Work Plan and Implementation

Preliminary AA 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 case that the Department 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, 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 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 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 and include supporting information for this determination.

SCOPE AND COMPARISON OF ALTERNATIVES

The AA Reports must include the scope and comparison of alternatives.[66] Specifically, the responsible entity identifies and describes the alternatives chosen to be evaluated and compared, and explains the rationale for selecting and screening out specific alternatives at each stage of the alternatives comparison.

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:

- **PRELIMINARY AA REPORT AND ABRIDGED AA REPORT**
  - A matrix or other summary format;
  - A clear visual comparison summarizing relevant adverse impacts;
  - The relevant exposure pathways and life cycle segments;
  - The Chemical(s) of Concern and each alternative replacement chemical being considered; and
  - The comparative results of evaluating the above information.

- **FINAL AA REPORT**
  - A matrix or other summary format;
  - A clear visual comparison summarizing the relevant comparison factors;
  - The relevant exposure pathways and life cycle segments;
  - The Priority Product and each alternative considered;
  - The comparative results of evaluating the above information;
  - A description of any relevant safeguards provided by other federal and California State regulatory programs that were considered; and
  - Selected alternative(s) and recommended next steps.

[66] *22 CCR section 69505.7(g)*

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 or guidelines used, and any deviations from those methodologies 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 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 analysis.

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: (1) an analysis that evaluates and compares the selected alternatives against the Priority Product; and (2) 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 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 stage 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, 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

This Appendix compiles potential information sources for the responsible entity to identify alternatives. 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. The responsible entity should review the additional information on a database to decide if it is suitable for specific product or application. 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).

- **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.
- **Chemical Hazard Data Commons** (http://healthybuilding.net/content/data-commons). This free web-based service, provided by Healthy Building Network (available to the public soon), is a tool to help find information about chemical substances and groups. It includes authoritative hazard listings, the GreenScreen® List Translator, comprehensive access to GreenScreen® assessments both public domain and licensable, and linked searches of other databases including, PubChem, ChemIDplus, eChemPortal, HSDB, Pharos, and the ECHA Registration Dossiers.
- **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 US 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.
- **International Uniform Chemical Information Database (IUCLID)** (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.
- **Interstate Chemicals Clearinghouse (IC2)** (http://theic2.org/). This website has database on:
  - **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
  - **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
- **Massachusetts Toxics Use Reduction Institute (TURI)** (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://guides.turi.org/beyondmsds). 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.
- **US EPA Safer Choice Program:**
  - **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.
  - **Safer Chemical Ingredients List** (http://www2.epa.gov/saferchoice/safer-ingredients). A list of chemical ingredients that US EPA's Safer Choice Program determined to be safer than traditional chemical ingredients.

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

Table 3-1 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. For example, Chapter 54 Green Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant Data, Title 22, California Code of Regulations (22 CCR) provides definitions of hazard traits, a framework for relating scientific information to hazard traits, and general guidance on whether a given chemical exhibits a hazard trait based on the scientific evidence. In the tables included in this Appendix, 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

As listed in California Code of Regulations, title 22, section 69501.1(a)(42)

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

TABLE 3-1B – ADVERSE IMPACTS

Adverse impacts as listed in California Code of Regulations, title 22, section 69505.5(c)(2)(A) through (G)

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

Adverse environmental impacts as listed in California Code of Regulations, title 22, section 69501.1(a)(4)

Factor	Subfactor	Subfactor parameter
Adverse air quality impact[1]	California Toxic Air Contaminants[2]	--
	Greenhouse gases[3]	Carbon dioxide
	Greenhouse gases[3]	Hydrofluorocarbons
	Greenhouse gases[3]	Methane
	Greenhouse gases[3]	Nitrogen trifluoride
	Greenhouse gases[3]	Nitrous oxide
	Greenhouse gases[3]	Perfluorocarbons
	Greenhouse gases[3]	Sulfur hexafluoride
	Greenhouse gases[3]	Other global warming potential gases[4]

Factor	Subfactor	Subfactor parameter
Adverse air quality impact[1]	Nitrogen oxides	--
	Particulate matter[5]	--
	Stratospheric ozone depletion substances[6]	--
	Sulfur oxides	--
	Tropospheric ozone forming compounds[7]	--
Adverse ecological impacts[8]	On aquatic, avian or terrestrial animal, plant organisms, or microbes	--
	On aquatic and terrestrial ecosystems	--
Adverse soil quality impacts[9]	Compaction or other structure changes	--
	Erosion	--
	Loss of organic matter	--
	Soil sealing	--
Adverse water quality impacts[10]	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[11]	--
	Introduction/ Increase in California CWA pollutants[12]	--
	Introduction/ Increase in chemicals with MCLs[13]	--

Factor	Subfactor	Subfactor parameter
Adverse water quality impacts[10]	Introduction/Increase in chemicals with Notification Levels[14]	--
	Introduction/Increase in chemicals with public health goals for drinking water under California Safe Drinking Water Act[15]	--
Exceedance of an enforceable California or federal regulatory standard relating to the protection of the environment[16]	--	--

[1] 22 CCR section 69501.1(a)(2)
[2] 22 CCR section 69501.1(a)(2)(A)
[3] 22 CCR section 69501.1(a)(2)(B)
[4] 22 CCR section 69405.4
[5] 22 CCR section 69405.7
[6] 22 CCR section 69405.8
[7] 22 CCR section 69405.1
[8] 22 CCR section 69501.1(a)(3)
[9] 22 CCR section 69501.1(a)(7)
[10] 22 CCR section 69501.1(a)(9)
[11] Section 303 (c) of the federal Clean Water Act (CWA)
[12] Section 303(d) of the federal Clean Water Act
[13] The primary Maximum Contaminant Levels (MCL) adopted under section 64431 or section 64444 of chapter 15 of CCR
[14] Health and Safety Code section 116455
[15] Health and Safety Code section 116270 et seq.
[16] 22CCR section 69501.1(a)(4)(E)

Adverse public health impacts as listed in California Code of Regulations, title 22, section 69501.1(a)(6)

Factor	Factor
Carcinogenicity	Immunotoxicity
Developmental toxicity	Musculoskeletal toxicity
Reproductive toxicity	Nephrotoxicity and other urinary system toxicity

Factor	Factor
Cardiovascular toxicity	Neurodevelopmental toxicity
Dermatotoxicity	Neurotoxicity
Endocrine toxicity	Ocular toxicity
Epigenetic toxicity	Ototoxicity
Genotoxicity	Reactivity in biological systems
Hematotoxicity	Respiratory toxicity
Hepatotoxicity and digestive system toxicity	Exceedance of an enforceable California or federal regulatory standard relating to the public health

Adverse waste and end-of-life effects as listed in California Code of Regulations, title 22, section 69501.1(a)(8)

Factor
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 as listed in California Code of Regulations, title 22, section 69501.1(a)(32)

Factor
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 as listed in California Code of Regulations, title 22, section 69501.1(a)(45)

Factor
Renewable resources consumption[1]
Nonrenewable resources consumption[2]

[1] 22 CCR section 69501.1(a)(45)(B)

[2] 22CCR section 69501.1(a)(45)(C)

Physical chemical hazards as listed in California Code of Regulations, title 22, section 69501.1(a)(48), as specified in article 6 of chapter 54

Factor
Combustion facilitation
Explosivity
Flammability

Physicochemical properties as listed in California Code of Regulations, title 22, section 69501.1(a)(49), as specified in section 69407.2

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

TABLE 3-1C – EXPOSURE PATHWAYS

Chemical quantity information as listed in California Code of Regulations, title 22, section 69505.5(c)(3)(A)

Factor
Quantities necessary to manufacture the Priority Product
Volume/mass placed into stream of commerce in California

Exposure factors as listed in California Code of Regulations, title 22, section 69505.5(c)(3)(B) and section 69503.3(b)

Subcategory	Factor	Subfactor
Market presence of product	Statewide sales by volume	--
Market presence of product	Statewide sales by number of units	--
Market presence of product	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

Subcategory	Factor	Subfactor
Potential exposure to Candidate Chemical(s) in the product during life cycle	Types of uses	Sensitive subpopulation potential use or exposure
		Workers, customers, clients, and members of the general public in homes, schools, workplaces, or other locations
Potential exposure to Candidate Chemical(s) in the product during life cycle	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	--

TABLE 3-1D – ADDITIONAL FACTORS REQUIRED FOR SECOND STAGE AA

Factor Subcategory	Factor
Product function and performance[1]	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

Factor Subcategory	Factor
Product function and performance[1]	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[2]	Public health and environmental costs
	Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, 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] 22 CCR section 69505.6(a)(2)

[2] 22 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 relevant for comparison, but do not necessarily encompass all the factors that the SCP Regulation require the responsible entity to consider. 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.

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.
Could the alternative change raw materials extraction and processing (e.g., process involved, energy used, resources consumed, and discharge to air/water/soil)?		
Could the alternative change intermediate materials production processes (e.g., process involved, raw materials used, energy used, resources consumed, and discharge to air/water/soil)?		
Could the alternative change product manufacture (e.g., process involved, energy used, resources consumed, and discharge to air/water/soil)?		
Could the alternative change distribution and transportation for all segments (e.g., mode of transportation, energy used, and discharge to air/water/soil)?		

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.
Could the alternative change 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	Could it result in any changes to emissions of California Toxic Air Contaminants (e.g., Benzene, Cr (VI))?		
	Could it result in any changes to the emissions of greenhouse gases (e.g., CO2, methane) into the atmosphere?		
	Could it result in any changes to emissions of compounds that might lead to tropospheric ozone formation (e.g., NOx, CO)?		
	Could the product or any of the alternatives 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)?		
	Could it result in any changes to any acute or chronic toxicity to aquatic, avian, or terrestrial animal or plant organisms or microbes?		
	Could it result in any changes in population size, reduction in biodiversity, or changes in ecological communities?		

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 ecological impacts	Could it result in any changes to abilities of an endangered or threatened species to survive or reproduce?		
	Could it result in any changes to deterioration or loss of environmentally sensitive habitats?		
	Could it result in any changes to vegetation contamination or damage?		
Adverse soil quality impacts	Could it result in any changes to soil compaction or other soil structure changes?		
	Could it result in any changes to soil erosion?		
	Could it result in any changes to the loss of organic matter in soil?		
	Could it result in any changes to soil sealing? *		
Water quality impacts	Could the product be expected to enter a Publicly Owned Treatment Works (POTW) through municipal sewage (e.g., personal care products down the drain)?		

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.
Water quality impacts	Could the product be expected to directly enter the municipal storm sewer systems (e.g., car wash detergents)?		
	Could it result in any increase in biological oxygen demand within the water system?		
	Could it result in any increase in chemical oxygen demand within the water system?		
	Could it result in any increase in temperature of water systems?		
	Could it result in any increase in total dissolved solids in water systems?		
Public health impacts	Could it bring about the change of carcinogenicity?		
	Could it bring about the change of developmental toxicity?		
	Could it bring about the change of reproductive toxicity?		
	Could it bring about the change of endocrine toxicity?		

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.
Public health impacts	Could it bring about any change on discharge/release exceed an enforceable California or federal regulatory standard relating to the protection of public health?		
Waste and end-of-life effects	Could it result in any change to the volume or mass of the waste materials and byproducts generated during the life cycle?		
	Could it result in any change to special handling to mitigate adverse impacts resulted from the waste materials?		
	Could it result in any change to the ability to reuse or recycle materials resulting from the treatment of solid waste or wastewater?		
	Could it result in any change to discharge(s) or disposal(s) to storm drains or sewers that adversely affects operation of wastewater or storm water treatment facilities?		
	Could it result in any change to aerobic and anaerobic half-lives of the product, its constituents, or its likely breakdown products?		
	Could it result in any change to aqueous hydrolysis half-life of the product, its constituents, 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.
Environmental fate	Could it result in any change to bioaccumulation of the product, its constituents, or its likely breakdown products?		
	Could it result in any change to biodegradation of the product, its constituents, or its likely breakdown products?		
	Could it result in any change to consumption of renewable resources, including solar and wind energy, timber, agriculture, and water, throughout the life cycle?		
	Could it result in any change to persistence of the product, its constituents, or its likely breakdown products?		
Materials and resource consumption	Could it result in any change to consumption of renewable resources, including solar and wind energy, timber, agriculture, and water, throughout the life cycle?		
	Could it result in any change to consumption of nonrenewable resources, including petroleum, coal, metals, minerals, or other finite resources throughout the 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.
Physical chemical hazards	Could it result in any change to consumption of renewable resources, including solar and wind energy, timber, agriculture, and water, throughout the life cycle?		
	Could it result in any change to consumption of nonrenewable resources, including petroleum, coal, metals, minerals, or other finite resources throughout the life cycle?		
	Could any discharge/release during life cycle or any of its likely breakdown products exhibit flammability?		
Physico-chemical properties	Could it result in any change to vapor pressure or saturated vapor pressure of the product, its constituents, or its likely breakdown products?		
	Could it result in any change to water solubility or lipid solubility of the product, its constituents, or its likely breakdown products?		
	Could it result in any change to octanol-water partition coefficient or octanol-air partition coefficient of the product, its constituents, 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.
Physico-chemical properties	Could it result in any change to sorption coefficient for soil or sediment of the product, its constituents, and/or its likely breakdown products?		

* Soil sealing – meaning covering surface soil with a layer of impervious material or changing the nature of the soil so that it behaves as an impermeable medium. (22 CCR section 69501.1(a)(7)(D))

TABLE 3-2C - EXAMPLE CHECKLIST FOR IDENTIFICATION OF RELEVANT EXPOSURE 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	Could it change the quantities of the Chemical(s) of Concern or alternative replacement chemicals necessary to manufacture the product?		
	Could 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	Could it change statewide sales of the product by volume?		
	Could it change statewide sales of the product by number of units?		
	Could 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?		

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.
Occurrence or potential occurrence of exposure	Has the Chemical(s) of Concern or alternative replacement chemical(s) been identified on the Toxics Release Inventory (TRI) as a chemical with substantial releases (1 million pounds or 10% of production/importation)?		
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	Could there be potential change in dermal, ingestion, or inhalation contact during the product's life cycle?		
	Could people be potentially exposed to the Chemical(s) of Concern or alternative replacement chemical(s) during the life cycle of the product?		
	Is the product sold for household and recreational use?		

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.
Potential exposure	Could the product be potentially used by or exposed to sensitive subpopulations, including infants, children, pregnant women, elderly individuals, or other group that may comprise sensitive receptors due to history of illness or nature of occupation?		
	Could workers, customers, clients, or the public come in contact with the product or releases from the product in homes, schools, workplaces, or other locations?		
	Could it result in any change to frequency, extent, level, or duration of potential exposure for each use scenario and end-of-life scenario?		
	Could it result in any change to engineering and administrative controls that reduce exposure concerns associated with the product?		
	Could it result in 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 assessment? Yes/No/Unknown	If "no," reason why factors not relevant.
Product function and performance	Could it change the useful life of the product?		
	Could it change the function and performance the product?		
	Could it change the functional acceptability of the product?		
	Could it change the technical feasibility of the product?		
Economic impacts	Could it change the public health and environmental costs for any relevant exposure pathway or life cycle segment?		
	Could it change the costs to manage waste or oversee environmental cleanup and restoration efforts to governmental agencies and non-profit organizations?		
	Could it change the costs to governmental agencies and non-profit organizations charged with protecting natural resources, water quality, or wildlife?		

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.
Economic impacts	Could it change manufacturing costs?		
	Could it change marketing costs?		
	Could it change materials and equipment acquisition costs?		
	Could 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 the responsible entity 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. The responsible entity should review the additional information on a database or tool to decide if a database or tool fits its 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-A - EXAMPLE CHECKLIST FOR IDENTIFICATION OF RELEVANT LIFE CYCLE SEGMENTS

Name	Life Cycle	Hazard	Exposure	Function	Economic
Agency for Toxic Substances and Diseases Registry (ATSDR) Toxicological Profiles Characterization		X	X	X	
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)		X	X		

Name	Life Cycle	Hazard	Exposure	Function	Economic
BEES (Building for Environmental and Economic Sustainability)	X	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		
CDC NHANES Biomonitoring Summaries			X		
CHE Toxicant and Disease Database		X			
Chemical Data Access Tool (US EPA)		X	X		
Chemical Hazard and Alternatives Toolbox (ChemHAT)		X	X		
Chemical Risk Information Platform (CHRIP)		X	X		
ChemIDplus		X			

Name	Life Cycle	Hazard	Exposure	Function	Economic
ChemSpider		X	X		
ChemView		X	X		
Comparative Toxicogenomics Database (CTD)		X			
Developmental and Reproductive Toxicology/Environmental Teratology Information Center (DART/ETIC)		X			
DTSC Toxics Information Clearinghouse		X	X		
eChemPortal		X			
Ecological Structure Activity Relationships (ECOSAR)			X		
Eco Materials Advisor (Granta)	X	X		X	
ECOTOX Database		X			
EIO-LCA	X	X		X	X

Name	Life Cycle	Hazard	Exposure	Function	Economic
Endocrine Disruption Exchange, Inc. (TEDX) List of Potential Endocrine Disruptors		X		X	
EnviChem (Data Bank of Environmental Properties of Chemicals, Finnish Environment Institute)		X	X	X	
European Chemicals Agency (ECHA) Dissemination Portal	X	X	X	X	
European Chemicals Agency (ECHA) Information on Chemicals		X	X		
Gabi®	X	X		X	X
Genetic Toxicology (GENE-TOX) Data Bank)		X			
GESTIS Substance Database		X	X		
Global Products Strategy (GPS) Chemical Portal		X	X		
Green Chemistry Assistant		X			
GreenScreen®		X			

Name	Life Cycle	Hazard	Exposure	Function	Economic
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			
Household Products Database		X			
IC2 Chemical Hazards Assessment Database		X			
IPCS INCHEM		X	X		
National Report on Human Exposure to Environmental Chemicals			X		
New Zealand Hazardous Substances and New Organisms Chemical Classification Information Database (HSNO CCID)		X	X		
NIOSH Health Hazard Evaluations		X			

Name	Life Cycle	Hazard	Exposure	Function	Economic
NREL U.S. Life cycle Inventory	X	X			
OECD SIDS		X	X		
OECD Substitution and Alternative Assessment Tool Selector	X	X	X	X	X
OSHA Occupational Chemical Database		X	X		
Pharos	X	X			
PRIO		X	X		
PubChem		X	X		
Quick Chemical Assessment Tool (QCAT)		X			
RISCTOX		X			
Substitution Support Portal (SUBSPORT)		X		X	X
Substitute It Now (SIN) List and SINMILARITY Tool		X			
ToxCast Database		X	X		
Toxicity Criteria Database		X			

Name	Life Cycle	Hazard	Exposure	Function	Economic
TOXLINE		X	X		
TRACI	X	X			
SimaPro	X	X		X	X
Sustainable Minds®	X	X			
US EPA Aggregated Computational Toxicology Resource (ACToR)		X	X		
US EPA EPI Suite™		X			
US EPA Integrated Risk Information System (IRIS)		X	X		
US EPA PBT Profiler	X	X			
US EPA Substance Registry Services (SRS)		X	X		

Appendix 4 — Methods and Databases for Chemical Hazard Assessment

A chemical hazard assessment requires collecting and evaluating the available and relevant information about a chemical. This appendix compiles several methodologies, tools, and databases for conducting hazard evaluation of alternatives at the product, material, and chemical level. Most of them in the list are public resources. However, the list is not intended to be comprehensive and exclusive, because we still have many unknowns about many chemicals. Because the science and toxicological information are subject to change and are continually updated, the responsible entities should select among the resources listed and other sources as necessary, and consider using the newest version of the tools and methods to accomplish the intended goal of completing the AA.

A. CHEMICAL HAZARD ASSESSMENT METHODS AND TOOLS

- **Clean Production Action.** GreenScreen® for Safer Chemicals (Version 1.3). The GreenScreen® is a chemical hazard screening method. It is used by businesses like Hewlett-Packard, governments like Washington State, and NGOs such as the Healthy Building Network in their Pharos Project. GreenScreen® aggregates criteria and related thresholds into four benchmarks. A set of human heath, environmental, and safety criteria exist at each 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, US EPA Design for Environment Alternative Assessment criteria and the European REACH legislation, while also ensuring that new and emerging science can be incorporated into the hazard assessment process.
- **Germany Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA).** Column Model for Chemical Substitutes Assessment. The model provides a simplified method to make a preliminary comparison between the risk of chemicals and products and a quick judgement on feasibility of substitution.

- **National Institute for Occupational Safety and Health (NIOSH).** Control Banding. A general technique to guide the assessment and management of workplace risks. It is a generic method that determines a control measure (such as substitution, ventilation, engineering controls, containment) based on a range of "band" of hazards (such as skin/eye irritant, very toxic, carcinogenic) and exposures (small, medium, large) based a tiered evaluation approach (qualitative, quantitative and weight of evidence).
- **OECD.** The QSAR Toolbox. The Toolbox is specifically designed to help the user to fill data gaps via the analogue approach or by building chemical categories according to the OECD Guidance on Grouping of Substances [OECD Series on Testing and Assessment No. 80. 2007. ENV/JM/MONO(2007)28].
- **Toxic Use Reduction Institute (TURI), University of Massachusetts Lowell**. Pollution Prevention Options Assessment System (P2OASys).TURI developed the P2OASys tool that assists companies in identifying potential environmental, worker and public health impacts associated with manufacturing processes and helping to choose the alternative that is most protective of worker health and environment. Companies input both quantitative and qualitative data on chemical toxicity, ecological effects, and physical properties of the chemical and of the potential alternatives. The P2OASys tool provides numerical hazard scores for a company's current process and identified alternatives. One unique characteristic of this tool is that it includes data associated with the process to help determine potential occupational exposures (estimated as low, medium, or high). Users of this tool must have expertise in occupational and environmental health and in researching chemical databases including toxicological and chemical hazard databases.
- **US Environmental Protection Agency (US EPA)**. Safer Choice Program, Design for the Environment Alternatives Assessments. This website describes the previous Design for Environmental Alternative Assessment methodology, which include a Chemicals Alternative Assessment (CAA) methodology and key hazard evaluation criteria to identify safer replacement chemicals to toxic chemicals.

- **US Environmental Protection Agency (US EPA)**. Sustainable Futures Program. The US EPA has developed a series of risk-screening models and tools for evaluating the safety of existing and new chemicals including both hazard and exposure assessment tools. The hazard assessment tools are developed 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. These hazard assessment tools include:
  - Analog Identification Methodology (AIM): An online tool to identify publicly available experimental data on structurally related chemicals to help users determine the potential hazards of untested chemicals.
  - Ecological Structure-Activity Relationships Program (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 Quantitative Structure-Activity Relationships (QSARs).
  - Estimation Programs Interface (EPI Suite™): A software program that provides screening-level estimates of physicochemical properties (melting point, water solubility, etc.) and environmental fate properties (breakdown in water or air, etc.).
  - Non-Cancer Screening Approaches for Health Effects: A procedure of identifying health effect data from various public databases. It also provides a data preference hierarchy and screening process to review the data.
  - Oncologic: A software program designed to predict the potential carcinogenic potentials of chemicals by applying Structure Activity Relationship (SAR) analysis.
- **US Environmental Protection Agency (US EPA).** Toxicity Estimate Software Tool (TEST). The tool uses mathematical models to predict toxicity from the physical characteristics of the structure of chemicals based on QSARs methodology. The software also contains models for some physical properties such as boiling point, viscosity, density, waster solubility, vapor pressure etc.

- **Washington State Department of Ecology.** Quick Chemical Assessment Tool (QCAT, Version 2.0). QCAT is a simple chemical hazard assessment tool used to assist small and medium sized businesses evaluate and screen chemicals. It can also function as an introduction to the hazard assessment process. QCAT methodology includes detailed information on where to find data and how to interpret data. The primary goal of QCAT is to quickly identify chemicals that are not viable safer alternatives, while not to identify preferable alternatives to a chemical of concern. But it helps to prioritize alternative chemicals for a more detailed assessment.

B. DATABASES FOR COLLECTING CHEMICAL HAZARD INFORMATION

- Chemical Hazard and Alternatives Toolbox (ChemHAT). This is an internet database designed to provide hazard information on chemicals and alternatives. It is based on authoritative governmental databases that list chemicals known to harm health and environment. The chemical hazard information comes from the Chemical and Materials Library (SML) created by the Healthy Building Network for its Pharos database of chemicals and materials in building products.

- Comparative Toxicogenomics Database (CTD). CTD is a publicly available database that aims to help understanding about how environmental exposures of chemicals affect human health. It contains data describing the relationship between chemicals, genes, and human diseases.

- European Chemicals Agency (ECHA). Information on Chemicals. This is the web warehouse on hazardous properties, classification and labelling, and information on how to use chemicals safely. As from 20 January 2016, information on up to 120 000 chemicals is enriched and structured in three layers: infocard, brief profile and detailed source data.

- **Healthy Building Network.** Chemical Hazard Data Commons. This free web-based service (available to the public soon) is a tool to help find information about chemical substances and groups. It includes authoritative hazard listings, the GreenScreen® List Translator, comprehensive access to GreenScreen® assessments both public domain and licensable, plus linked searches of other databases including, PubChem, ChemIDplus, eChemPortal, HSDB, Pharos, and the ECHA Registration Dossiers.

- **European Trade Union Institute and European Environmental Bureau (Institúto Sindical de Trabajo, Ambiente y Salud, ISTAS)**. RISCTOX. RISCTOX is a comprehensive database on toxic and hazardous substances on over 100,000 chemical agents in files, which include data on classification of the substances, specific health risks, specific environmental risks, and related regulations.

- **Finnish Safety and Chemicals Agency.** Databank of Environmental Properties of Chemicals (EnviChem). The database consists of information on the toxicity of substances in relation to different species, especially aquatic organisms, together with information on the persistence and accumulation of these substances in the environment.

- **Kooperationsstelle Hamburg IFE GmbH.** Substitution Support Portal (SUBSPORT). The SUBSPORT web portal provides a compilation of prevalent criteria and existing substitution tools to compare and assess alternative substances and technologies. The portal provides a database with 34 lists of substances that are legally or voluntarily restricted or are recommended for restriction due to their hazards. It also provides a database comprising case stories from companies and literatures with general information on alternatives and detailed alternatives assessment reports by following SUBSPORT Specific Substances Alternative Assessment Methodology.

- **National Institute of Environmental Health Sciences.** Chemical Effects in Biological Systems (CEBS). The CEBS database contains data on environmental health in the context of biology and study design. It is a public resource and allows data integration across studies.

- **OECD.** The Global Portal to Information on chemical Substances - eChem Portal. An internet gateway with information about properties of chemicals, environmental fate and behavior, ecotoxicity, and toxicity. Currently, it compiles more than thirty chemical databases.

- **OECD.** Substitution and Alternative Assessment Toolbox (SAAT). A compilation of resources relevant to chemical substitution and Alternatives Assessment. Particularly the website has a filterable inventory of data sources for chemical hazard assessment.

- **The University of California, Berkeley.** The Carcinogenic Potency Database (CPDB). It is a compilation of data on chemical carcinogens. 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. It includes over 6,540 chronic long-term animal cancer test results used in support of cancer risk assessment for human.

- **US National Library of Medicine (NLM), National Institutes of Health (NIH).** PubMed. The website compiles more than 26 million citations for biomedical literatures and may include links to full text articles from PubMed Central and publisher web sites.

- **US National Library of Medicine (NLM), National Institutes of Health (NIH).** Toxicology Data Network (TOXNET). A compilation of 16 toxicology-related databases maintained by NLM. TOXNET includes data on toxicology, hazardous chemicals, environmental health, and toxic releases curated from open literature. The most used databases for chemical hazard assessment include:

    - 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. It contains over 5000 individual chemical records.

    - 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. It contains over 400,000 chemical records.

    - Developmental and Reproductive Toxicology and Environmental Teratology Information Center Database (DART): It contains literature on developmental and reproductive toxicology.

    - Household Product Database: It covers potential health effects of chemicals in more than 10,000 common household products.

- Haz-Map: It contains occupational exposure to chemicals. The database links industry, jobs, process and hazardous tasks with occupational diseases and adverse effects.

- Gene-Tox: genetic toxicology data bank. Peer-reviewed genetic toxicology test data.

- International Toxicity Estimates for Risk (ITER): It contains chronic human health risk values and cancer classifications for over 680 chemicals of environmental concern from multiple organizations worldwide.

- 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. It contains Over 500 chemical records.

- Chemical Carcinogenesis Research Information System (CCRIS): It contains chemical records with carcinogenicity, mutagenicity test results for over 8,000 chemicals. It was developed by the National Cancer Institute.

- **U.S. Environmental Protection Agency (EPA).** Aggregated Computational Toxicology Online Resource (ACToR). It compiles data from thousands of public sources on over 500,000 chemicals. It is also the portal to access US EPA's computational toxicology information, which includes:

  - Chemistry Dashboard: Chemistry data for over 700,000 chemicals and includes chemical structures, experimental and predicted physicochemical and toxicity data.

  - Toxicity Forecaster (ToxCast) Dashboard: High-throughput screening data on over 9,000 chemicals and information on approximately 1,000 assay endpoints.

  - Endocrine Disruption Screening Program in the 21st Century Dashboard: High-throughput screening data, rapid exposure estimates, high-quality chemical structures and annotations and physicochemical property data used by EPA's Endocrine Disruptor Screening Program to evaluate chemicals for endocrine-related activity.

- **Chemical product category (CPCat) and exposure databases**: Information on which chemicals can be found in categories of products (for example personal care products) and observational data from exposure studies.
- Downloadable Computational Toxicology Data and Models: High-throughput screening data, rapid exposure and dose, chemistry data and virtual tissues data and models.

- **U.S. Environmental Protection Agency (EPA).** ECOTOXicology Knowledgebase (ECOTOX). ECOTOX is a comprehensive, publicly available knowledgebase providing single chemical environmental toxicity data on aquatic life, terrestrial plants, and wildlife.

- **U.S. Environmental Protection Agency (EPA).** Substance Registry System - Regulatory listings of Chemicals. The system contains basic information of the chemical of interest, health information, program and regulatory information about this substance (including links to EPA applications/systems, statutes/regulations, or other sources that track or regulate this substance) and information about related substances.

- **U.S. Environmental Protection Agency (EPA).** Toxicity ForeCaster (ToxCast™) Data. ToxCast™ is part of the Toxicology in the 21st Century (Tox21) federal collaboration. It compiles toxicity data on over 1,800 chemicals. Its high-throughput assays and computational toxicological approach may help to rank and screen chemicals and alternatives.

Appendix 5 — [Reserved]

Appendix 6 — Exposure Tools

This list is not intended to be comprehensive nor exclusive.

TABLE 6-1 AVAILABLE EXPOSURE TOOLS

Tools/Models	Description	Data Needs/User Input	Limitations
CalTOX (Lawrence Berkeley National Lab/US EPA /Cal EPA)	Multimedia, multi-pathway model assesses human exposure from continuous releases of contaminants in soil into multiple environmental media	- Distributional data - Reliable physicochemical data - Properties of the environment or landscape receiving the contaminants -Human exposure factors	-Aggregates the exposure over different pathways but does not aggregate over multiple releases into the environment. -One source at a time -Does not include exposure from chemicals in consumer products -One year or longer exposures
ChemSTEER (Chemical Screening Tool for Exposures and Environmental Releases; US EPA)	Generates screening-level estimates for occupational inhalation and dermal exposures, and environmental releases to air, water, and land for chemicals during manufacturing, processing, and use.	-Physicochemical properties - Amounts handled and used	-Screening level only - Does not estimate exposures to the general population, consumers, or species in the environment.

Tools/Models	Description	Data Needs/User Input	Limitations
CHESAR (Chemical Safety Assessment and Reporting; ECHA)	Predicts the chemical concentration in environmental compartments, and occupational and consumer exposure. Utilizes Targeted Risk Assessment (TRA) tool from ECETOC	-Substance properties, volumes, use pattern information and a few parameters reflecting the conditions of use.	
ConsExpo (Consumer Exposure; RIVM) and ConsExpo web	Estimates exposure of humans (via inhalation, ingestion, and dermal contact pathways) to chemicals in non-food consumer products	- Physicochemical properties - Volume and surface area of rooms - Air-change rate in various rooms -Total body surface and surface of body parts of adults and children - Body weight - Exposure duration	- No aggregation in version 4, but beta version 5 considers aggregation
CSOIL (RISC_HUMAN tool; RIVM)	Estimates total human uptake of soil contaminants via exposure from soil particles, vapors, crops, and drinking water.	- Physicochemical properties - Site and soil properties - Exposure parameters describing the receptor characteristics and behavior -Toxicological data	- Distributional calculations are not supported

Tools/Models	Description	Data Needs/User Input	Limitations
ECOTRA-TRA (Targeted Risk Assessment tool; ECETOC)*	Available as an integrated exposure/risk assessment tool for workers, consumers, and the environment; and as a standalone consumer exposure estimation tool. Integrated into CHESAR tool (see above).		
E-FAST (Exposure and Fate Assessment Tool; Versar Inc./US EPA)	Screening tool to assess potential exposures from chemical discharges to air, surface water, or land. Also estimates potential inhalation and dermal exposures to consumer products.	- Physicochemical properties - Environmental fate - Different parameters for exposure to the general population, the aquatic environment, and from consumer products.	- Exposures per pathway only and not summed
EUSES 2.1 (European Union System for the Evaluation of Substances; EU/Joint Research Centre)	Assesses the risks to workers, consumers, and the environment from industrial chemicals, consumer products, and biocides. Evaluate risks to human and environment.	- Physicochemical properties - Transport and fate - Emissions rates - NOAEL and LOAEL for different toxics endpoints	- No complete aggregation

* *ECOTRA-TRA is the European Centre for Ecotoxicology and Toxicology of Chemicals Targeted Risk Assessment Tool*

Tools/Models	Description	Data Needs/User Input	Limitations
Formaldehyde Indoor Air Model-pressed wood products (FIAM-pwp; USEPA)	Model estimates indoor air concentrations of formaldehyde emitted from pressed wood products in a variety of different indoor environments. Estimates the potential inhalation exposure.	- House information, such as house volume and internal conditions, such as temperature. - Source information, such as types and amounts of wood products. - Exposure info, such as age of source, time spent in location.	
Human Exposure Model-3 (HEM-3 version 1.3.1; USEPA)	Used for performing risk assessments for sources emitting air toxics to ambient air. It contains an atmospheric dispersion model (AERMOD) and census data.	- Accurate location coordinates - Release parameters (stack height, exit velocity, emission rate, etc)	- Addresses only inhalation

Tools/Models	Description	Data Needs/User Input	Limitations
MCCEM (Multi-chamber Concentration and Exposure Model; Versar Inc./ US EPA/ OPPT)	Estimates average and peak indoor air concentrations of chemicals released from products or materials in residential settings or other indoor environments. Also estimates inhalation exposures to these chemicals by calculating potential doses.	- Data on the indoor environment - Data on the indoor time dependent emission rates - Occupant activity pattern	- Addresses only inhalation
RAIDAR (Risk Assessment IDentification And Ranking model; Trent University)	Screening-level risk assessment model that ranks exposure potential from industrial chemicals by estimating fate and transport, bioaccumulation and exposure to humans and ecological receptors for a unit emission rate.	- Physical chemical properties - Environmental properties and degradation half life parameters	
SHEDS (Stochastic Human Exposure and Dose Simulation; US EPA)	Estimates chemical exposure distributions in human populations from different exposure pathways (inhalation, skin contact, and dietary and non-dietary ingestion.		

Tools/Models	Description	Data Needs/User Input	Limitations
USEtox (UNEP/SETAC)	Calculates interim and recommended characterization factors for human and freshwater ecotoxicological impacts of chemicals in life cycle impact assessment - Nonpolar non-ionic organic chemicals and metals	- Physicochemical data - Environmental parameters	
WPEM (Wall paint Exposure model; US EPA)	Estimates indoor air concentration released from wall paint over time - Workers and consumers	- Painting scenario - Paint and chemical info - Occupancy and exposure information	- Single chamber model used - Only one chemical modeled at a time - 100% uptake is assumed - Closed building

TABLE 6-2A TARGET GROUPS FOR TOOLS IN TABLE 6-1

Tools	Human Children	General Population	Environment
CalTOX		X	X
ChemSTEER		X	X
CHESAR	X	X	X
ConsExpo			
CSOIL	X	X	
ECETOC-TRA		X	X
E-FAST	X	X	X
EUSES 2.1		X	X
FIAM-pwp			

Tools	Human Children	General Population	Environment
HEM-3		X	X
MCCEM	X	X	
PROMISE			
RAIDAR		X	
SHEDS	X		
USETOX		X	x
WPEM			

General population: Exposure routes are via environmental emissions/releases

Environment: Consists of ecological receptors

TABLE 6-2B HUMAN CONSUMER AND WORKER EXPOSURE ROUTES FOR TOOLS IN TABLE 6-1

Tools	Consumer Inhalation	Consumer Ingestion	Consumer Dermal	Worker Inhalation	Worker Ingestion	Worker Dermal
CalTOX						
ChemSTEER				X		X
CHESAR	X	X	X	X	X	X
ConsExpo	X	X	X			
CSOIL						
ECETOC-TRA	X	X	X	X		X
E-FAST	X	X	X			
EUSES 2.1	X	X	X	X		X
FIAM-pwp	X					
HEM-3	X					
MCCEM	X	X				
PROMISE	X					
RAIDAR						
SHEDS						
USETOX						
WPEM	X			X		

Consumer: Exposure via direct use

Appendix 7-1 — SCP Factors and typically Used Life Cycle Impact Categories

This is a list of SCP factors and the corresponding life cycle impact assessment (LCIA) categories typically used in LCA. Use the hyperlinks below to go directly to the SCP Factor of interest.

SCP FACTORS

ADVERSE ENVIRONMENTAL IMPACTS

SCP Factor	SCP Subfactor	SCP Subfactor parameters	LCIA Impact Categories
Adverse air quality impact	California Toxic Air Contaminants	--	
		Carbon dioxide	Greenhouse gases
	Greenhouse gases	Hydrofluorocarbons	Greenhouse gases
		Methane	Greenhouse gases
		Nitrogen trifluoride	Greenhouse gases
		Nitrous oxide	Greenhouse gases
		Perfluorocarbons	Greenhouse gases

SCP Factor	SCP Subfactor	SCP Subfactor parameters	LCIA Impact Categories
Adverse air quality impact	Greenhouse gases	Sulfur hexafluoride	Greenhouse gases
		Other global warming potential gases	Greenhouse gases
	Nitrogen oxides	--	Greenhouse gases
	Particulate matter	--	Particulate Matter
	Stratospheric ozone depletion substances	--	Ozone Depletion Potential
	Sulfur oxides	--	Acidification
	Tropospheric ozone forming compounds	--	Photochemical Smog
Adverse ecological impacts	On aquatic, avian or terrestrial animal, plant organisms, or microbes	--	Eutrophication Acidification Aquatic Toxicity Terrestrial Toxicity
	On aquatic and terrestrial ecosystems	--	Eutrophication Acidification Aquatic Toxicity Terrestrial Toxicity
	Biological or chemical contamination of soil	--	Terrestrial Toxicity
	Environmental endpoints under Article 4, Chapter 54	--	Eutrophication Terrestrial Toxicity

SCP Factor	SCP Subfactor	SCP Subfactor parameters	LCIA Impact Categories
Adverse soil quality impacts	Compaction or other structure changes	--	Land Use
	Erosion	--	Land Use
	Loss of organic matter	--	Land Use
	Soil sealing	--	Land Use
Adverse water quality impacts	Increase in biological oxygen demand	--	Eutrophication
	Increase in chemical oxygen demand	--	Eutrophication
	Increase in temperature	--	
	Increase in total dissolved solids	--	
	Introduction/Increase in California CWA priority pollutants	--	
	Introduction/ Increase in California CWA pollutants	--	
	Introduction/ Increase in chemicals with MCLs	--	
	Introduction/Increase in chemicals with Notification Levels	--	
	Introduction/Increase in chemicals with public health goals for drinking water under California Safe Drinking Water Act	--	

SCP Factor	SCP Subfactor	SCP Subfactor parameters	LCIA Impact Categories
Exceedance of an enforceable California or federal regulatory standard relating to the protection of the environment	--	--	

ADVERSE PUBLIC HEALTH IMPACTS

Human Toxicity: Although "Human Toxicity" is a category in LCIA, it does not directly compare with the SCP factors under adverse public health impacts. It is very broad, does not specify toxicological endpoints, and is a population-based average at the regional, national, or global level.

SCP Factor	LCIA Impact Categories
Carcinogenicity	See comment above regarding Human Toxicity
Developmental toxicity	See comment above regarding Human Toxicity
Reproductive toxicity	See comment above regarding Human Toxicity
Cardiovascular toxicity	See comment above regarding Human Toxicity
Dermatotoxicity	See comment above regarding Human Toxicity
Endocrine toxicity	See comment above regarding Human Toxicity
Epigenetic toxicity	See comment above regarding Human Toxicity
Genotoxicity	See comment above regarding Human Toxicity
Hematotoxicity	See comment above regarding Human Toxicity
Hepatotoxicity and digestive system toxicity	See comment above regarding Human Toxicity
Immunotoxicity	See comment above regarding Human Toxicity
Musculoskeletal toxicity	See comment above regarding Human Toxicity
Nephrotoxicity and other urinary system toxicity	See comment above regarding Human Toxicity
Neurodevelopmental toxicity	See comment above regarding Human Toxicity
Neurotoxicity	See comment above regarding Human Toxicity

SCP Factor	LCIA Impact Categories
Ocular toxicity	See comment above regarding Human Toxicity
Ototoxicity	See comment above regarding Human Toxicity
Reactivity in biological systems	See comment above regarding Human Toxicity
Respiratory toxicity	See comment above regarding Human Toxicity
Exceedance of an enforceable California or federal regulatory standard relating to the public health	See comment above regarding Human Toxicity

ADVERSE WASTE AND END-OF-LIFE IMPACTS

SCP Factor	LCIA Impact Categories
Volume or mass generated	Mass flow data from product system model
Any special handling needed	Process knowledge
Effects on solid waste and wastewater disposal and treatment	Mass flow data from product system model
Discharge to storm drains or sewer adversely affecting wastewater treatment facilities	Mass flow data from product system model

MATERIALS AND RESOURCE CONSUMPTION IMPACTS

SCP Factor	LCIA Impact Categories
Renewable resources consumption	Water Use
Nonrenewable resources consumption	Resource Depletion

Appendix 7-2 — LCA Tools

The following table shows LCA tools (Horvath, et.al., 2011) with a link to its URL, stage, focus, cost (free or access fee), phases (segments[67]), processes, indicators, geography, and timeframe. The LCA focus identifies the tool's intended system of analysis (e.g., transportation, buildings, end-of-life, etc.). The phases and processes categories present the direct, indirect, and supply chain processes that are included in the tool's scope. Indicators show the energy inputs, emission outputs, costs, and impacts evaluated by the various LCA tools.

[67] *LCA uses the term "phase" and the SCP AA uses the term "segment."*

Name	LCA Stage	LCA Focus	Free/Fee	Life Cycle Phases	Processes	Indicators Evaluated	Geography	Relevant Analysis Time Period
Athena	LCI, LCIA	Buildings Cradle-to-grave	Free and Fee Tools	Material production, construction, transportation activities, maintenance and replacement, demolition for buildings.	Material production through end-of-life (excluding use phase)	Free version captures GHG emissions. Fee version does impact assessment including energy, air emissions, water emissions, land emissions, and resource use.	US and Canada	
BEES	LCI, LCIA, LCCA	Buildings Cradle through use	Free	Materials-based LCA for buildings.	Material production through end-of-life	Inputs: Energy and water. Outputs: Many other emissions to air, water, and land	US	

Name	LCA Stage	LCA Focus	Free/Fee	Life Cycle Phases	Processes	Indicators Evaluated	Geography	Relevant Analysis Time Period
CA GREET 2.0	LCI	Transportation Well-to-wheel	Free	Fuel Production. Vehicle Operation. Vehicle Manufacturing.	Transportation Fuels (Including petroleum-based, biofuels, hydrogen, and electricity). Light duty auto and truck vehicle operation and manufacturing.	Energy, GHG, VOC, CO, NO_X, PM, SOX.	California	1990 to 2020
E3 Database	LCI, LCIA, LCCA	Transportation Well-to-wheel	Fee	Fuel Production. Vehicle Operation.	Transportation fuels. Vehicle Operation.	Energy, GHG, NO_X, SO_2, CO, NMVOC, Dust/PM, Costs.	Europe	
EASEWASTE	LCI, LCIA	End-of-life	Free	Waste generation, collection, treatment, disposal, and transport.	Waste collection and processing.	Resource, energy, and land inputs. Greenhouse gas, acidification, nutrient enrichment, ozone depletion, photo-chemical ozone formation, ecotoxicity, human toxicity, stored toxicity, and spoiled groundwater.	Europe	Released in 2008

Name	LCA Stage	LCA Focus	Free/Fee	Life Cycle Phases	Processes	Indicators Evaluated	Geography	Relevant Analysis Time Period
EIO-LCA	LCI	General Cradle-to-gate	Free	Material production through use including supply chains.	Material production through use including supply chains.	Inputs: Energy. Outputs: economic value, GHGs, Criteria Air Pollutants, Hazardous Waste, and Toxic Releases.	Databases for the US, Canada, Germany, Spain, and China.	For the US, 1992 & 1997 are free. 2002 available for a fee.
Gabi	LCI, LCIA	General Cradle-to-grave	Fee	Ability to build LCA and include any phase	Ability to build LCA and include any process	Energy, many other emissions	Several databases which include Europe, US, and Japan	LCI parameters can be specified
GHGenius 3.15	LCI, LCCA	Transportation Well-to-wheel	Free	Fuel Production. Vehicle Operation. Vehicle Manufacturing.	Transportation fuels (including petroleum-based, biofuels, hydrogen, and electricity). Light and heavy-duty vehicle operation and manufacturing.	Energy, GHG, CO, NO_X, NMOC, SO_2, PM.	Canada, US, Mexico, India	

Name	LCA Stage	LCA Focus	Free/Fee	Life Cycle Phases	Processes	Indicators Evaluated	Geography	Relevant Analysis Time Period
GREET 2016 revision 1	LCI	Transportation Well-to-wheel	Free	Fuel Production. Vehicle Operation Vehicle. Manufacturing.	Transportation fuels (Including petroleum-based, biofuels, hydrogen, and electricity). Light duty auto and truck vehicle operation and manufacturing.	Energy, GHG, VOC, CO, NO_X, PM, SOX, Black carbon	US	1990 to 2020
MSW-DST	LCI	End-of-life	Free	Raw material acquisition through use for waste material remanufacturing considerations.	Waste management options.	Energy, GHG, criteria pollutants, and +30 other pollutants.	US	
NREL U.S. Life cycle Inventory	LCI	General	Free	Various. Repository of government life cycle reports of various processes.	Various.	Various.	US	Varies for each process report.

Name	LCA Stage	LCA Focus	Free/Fee	Life Cycle Phases	Processes	Indicators Evaluated	Geography	Relevant Analysis Time Period
SimaPro	LCI, LCIA	General Cradle-to-grave	Fee	Ability to build LCA and include any phase	Ability to build LCA and include any process	Energy, many other emissions	Several databases which include Europe, US, and Japan	LCI parameters can be specified
TRACI	LCIA	Emissions impacts	Free	Life cycle Impact Assessment.		Ozone depletion, smog formation, global warming, acidification, eutrophication, human health cancer, human health noncancer, human health criteria pollutants, eco-toxicity, fossil fuel depletion, land use, water use.	US	

Name	LCA Stage	LCA Focus	Free/Fee	Life Cycle Phases	Processes	Indicators Evaluated	Geography	Relevant Analysis Time Period
WaRM	LCI	End-of-life	Free	Waste disposal options. Can evaluate material extraction and production by evaluating recycling and material reuse assessments.	Landfilling with no recovery, flaring, and LFGE. Material reuse, recycling, composting, and incineration.	GHG emissions.	US	
WRATE	LCI, LCIA	End-of-life	Fee	Waste collection, transport, treatment, and disposal activities.	Waste collection and processing.	Abiotic resource depletion, freshwater aquatic ecotoxicity, acidification, eutrophication, global warming potential, human toxicity.	UK, Ireland	

Appendix 8 — [Reserved]

Appendix 9 — [Reserved]

Appendix 10 — [Reserved]

Appendix 11 — Information Quality Evaluation in Other Frameworks

Some frameworks and methods used in other fields (e.g., Life Cycle Assessment and Chemical Safety Assessment) to evaluate information quality may be of value to help move the regulated community towards a systematic way to communicate the merit of their supporting information. This Appendix provides more details and references on such frameworks and methods for evaluating the quality of information. Furthermore, these approaches may help the responsible entity to weigh the considerations of reliability and validity in their information collection strategy or decision to choose from different information sources to substantiate AA outcomes during performance of AAs.

I. DATA QUALITY EVALUATION FOR LIFE CYCLE ASSESSMENTS

Pedigree Matrix of Data Quality Indicators

A pedigree matrix used for Life Cycle Assessment (LCA) data quality, with a rating score from "1" (good quality) to "5" (poor quality) assigned for each of five Data Quality Indicators (DQIs), is shown in Table 11A-1. The objective of the pedigree matrix approach is to point at possibilities for improvement in data quality and to trace back sources of uncertainty. The indicators in the pedigree matrix provide a good starting point for data quality evaluation, such as "reliability" relate to the sources, acquisition methods, and verification procedures used to obtain the data. However, the practitioners need to realize obtaining the rating scores of data quality remains a challenging task under the SCP regulatory framework and may not be necessary. The limitations of rating scores include: they cannot be integrated into a single score for interpretation of overall data quality; the quality criteria come from multiple disciplines such as economics, toxicology, life cycle data; most of the rating scores are of subjective nature.

TABLE 11A-1 ECOINVENT 3.0 DATA QUALITY PEDIGREE MATRIX (WEIDEMA, ET.AL., 2013)

Indicator Score	1	2	3	4	5 (default)
Reliability	Verified[68] data based on measurements[69]	Verified data partly based on assumptions or non-verified data based on measurements	Non-verified data partly based on qualified estimates	Qualified estimates (e.g., by industrial expert)	Non-qualified estimate
Completeness	Representative data from all sites relevant for the market considered, over an adequate period to even out normal fluctuations	Representative data from > 50% of the sites relevant for the market considered, over an adequate period to even out normal fluctuations	Representative data from only some sites (<<50%) relevant for the market considered or > 50% of sites but from shorter periods	Representative data from only one site relevant for the market considered or some sites but from shorter periods	Representativeness unknown or data from a small number of sites and from shorter periods

[68] Verification may take place in several ways, e.g., by onsite checking, by recalculation, through mass balances or cross-checks with other sources.

[69] Measurement includes calculated data where the basis for calculation is measurements (e.g., emissions calculated from measured inputs to a process). If the calculation is based partly on assumptions, the score should be two or three.

Indicator Score	1	2	3	4	5 (default)
Temporal correlation	Less than 3 years of difference to the period of the dataset	Less than 6 years of difference to the period of the dataset	Less than 10 years of difference to the period of the dataset	Less than 15 years of difference to the period of the dataset	Age of data unknown or more than 15 years of difference to the period of the dataset
Geographical correlation	Data from area under study	Average data from larger area in which the area under study is included	Data from area with similar production conditions	Data from area with slightly similar production conditions	Data from unknown or distinctly different area (North America instead of Middle East, OECD-Europe instead of Russia)
Further technological correlation	Data from enterprises, processes, and materials under study	Data from processes and material under study (i.e., identical technology) but from different enterprises	Data from processes and materials under study but from different technology	Data on related processes or materials	Data on related processes on laboratory scale or from different technology

Spread Assessment Pedigree Approach

The Center of Environmental Science (CML) in Leiden University released a research report (van den Berg, et.al., 1999), which presented a systematic quality assessment in LCA studies. Guided by Funtowicz and Ravetz's NUSAP (Numeral Unit Spread Assessment and Pedigree) framework to assess uncertainty and quality (Funtowicz, et.al., 1990), the authors in CML proposed to assess the overall quality of an LCA study from three quality parameters: spread (reliability), assessment (validity), and pedigree (plausibility). Table 11A-2 presents the characteristics that describe each of these three data quality indicators in the Spread-Assessment-Pedigree Approach.

TABLE 11A-2 QUALITY INDICATOR DESCRIPTIONS FOR THE SPREAD-ASSESSMENT-PEDIGREE APPROACH

Quality Parameter	Data Type	Description
Spread (Reliability)	Model Reliability	• Reproducibility of transformation • Reproducibility of computation
	Input Data Reliability	• Uncertainty • Completeness • Variability
Assessment (Validity)	Model Validity	• Linearity • Goal and scope match • Scope properly elaborate in functional unit, allocation methods, and characterization models • Potential vs. actual effects • Disregarding local circumstances • All relevant empirical mechanisms included • Models behind equivalency factors
	Input Data Validity	• Representativeness • System boundaries

Quality Parameter	Data Type	Description
Pedigree (Plausibility)	Procedural Aspects	• Data verification • Sensitivity analysis • Dominance analysis • External plausibility • Parts of model tested • Comparison of outcome with similar models • Status of software provider
		•

ISO Standard 14044: Environmental Management – Life-Cycle Assessment – Requirements and Guidelines

International Standard for Life Cycle Assessment (LCA), ISO 14044 (2006, Section 4.2.3.6) (ISO, 2006), outlines the guidelines for acceptable data quality for LCA. The data quality evaluation should address the following:

- Time-related coverage: age of the data and minimum length of time over which data should be collected
- Geographical coverage: geographical area from which data for unit processes should be collected to satisfy the goal of the study
- Technology coverage: specific technology or technology mix
- Precision: measure of the variability of the data values for each data expressed (e.g., variance)
- Completeness: percentage of flow that is measured or estimated
- Representativeness: qualitative assessment of the degree to which the data set reflects the true population of interest (i.e., geographical coverage, period, and technology coverage)
- Consistency: qualitative assessment of whether the study methodology is applied uniformly to the various components of the analysis
- Reproducibility: qualitative assessment of the extent to which information about the methodology and data values would allow an independent practitioner to reproduce the results reported in the study
- Sources of the data

- Uncertainty of the information (e.g., data models and assumptions)

The Standard also requires practitioners to specify data quality requirement when conducting LCA and document approaches to address missing data.

US EPA Guidelines for Assessing the Quality of Life-Cycle Inventory Analysis (EPA 1995)

In 1995, US EPA published a guideline document titled *Guidelines for Assessing the Quality of Life-Cycle Inventory Analysis* that outlined an approach for assessing and documenting Life Cycle Inventory (LCI) data quality. The guideline document summarized a step-by-step LCI data development process that include the following: defining study scope and boundaries, developing an LCI data collection plan, undertaking data collection and quality assessment, evaluating model sensitivity and results, and documenting and referencing study results. Data Quality Indicators (DQIs) are quantitative or qualitative terms defining data characteristics that serve as benchmarks against which data quality can be assessed. The guideline defined a set of DQIs applicable for assessing LCI data quality, as follows:

- Acceptability: the degree to which the data source has been peer reviewed, evaluated against an accepted standard, or checked for errors through expert judgment.
- Bias: the level of systematic error that causes the mean values of a data set to be consistently (over repeated samples) higher or lower than the corresponding "true" parameter values.
- Comparability: the degree to which different methods, data sets, or decisions agree or can be represented as similar or equivalent.
- Completeness: the amount of data available for the analysis compared with the amount of data needed or desired.
- Description of Data Collection Methods and Limitations: the level of information describing the method of data collection, including any limitations associated with the data collection method.
- Precision: the degree of spread or variability, expressed numerically if possible, in a set of data values or measurements compared to the mean of the data values.
- Level of reference: the degree to which data values reference the original data source.
- Representativeness: the degree to which the data represent what the analyst is trying to describe or depict.

Table 11A-3 provides an example of how to organize and document LCI data quality assessment into a worksheet based on these predefined DQIs.

TABLE 11A-3 EXAMPLE WORKSHEET OF LCI DATA QUALITY ASSESSMENT

Data Parameter	Description
Data Sources:	Development Document for Effluent Limitations Guidelines, New Sources Performance Standards, and Pretreatment Standards for the Pulp, Paper, and paperboard and the Builders' Paper and Board Mills Point Source Categories. US EPA, Office of Water, 1982.
Data Quality Goals:	• Effluent data for each compound will be typical for most US paperboard manufacturers. • Data must capture long-term trends in effluent releases.
Data Assessed:	Primary water effluent considered for this data source include: 5 day-Biochemical Oxygen Demand (BOD5), Total Suspended Solids (TSS), pentachlorophenol (PCP), trichlorophenol (TCP), and zinc.

DQI	Relevance of DQI (A)	Data Quality Rating (B)	Comments
Acceptability	High	High	(A) It is important for the data to have undergone review by an independent party. (B) The data received extensive review, including being subject to an extensive QA/QC methodology.

DQI	Relevance of DQI (A)	Data Quality Rating (B)	Comments
Bias	High	High	(A) Bias in aggregated data can result from over-reliance on data from a new technology, a specific region of the country, or from specific processing method. (B) Data were collected from over 600 mills covering many technologies, processes, and geographic areas. The data were segregated into specific subcategories to avoid overlapping process technologies. Long-term sampling programs were employed which mitigate problems from cyclic variations (e.g., seasonal, business cycle.)
Comparability	High	High	(A) It is important for the data to be comparable to long-term measures of industry effluent. (B) Several test sites were selected for long-term analysis to provide a comparable measure. Data values compared well to these standards.

DQI	Relevance of DQI (A)	Data Quality Rating (B)	Comments
Completeness	Medium	High	(A) Representativeness is deemed more important than completeness in this analysis. (B) There is considerable data in this data source on the target primary water effluent from 600 mills.
Description of Data Collection Method and Limitations	High	Medium	(A) Given the broad universe of ills this data sources captures, it is important for collection methods and limitations to be well documented. (B) An extensive description of the data collection methods used is provided in the text. Specific data quality limitations for each mill are not identified.
Precision	Medium	Medium	(A) Exact values are not needed; reasonable approximations are adequate for the study. (B) Few statistical measures are provided to assess the precision of the data. While single values are provided for each mill from which the variation across mills can be assessed, there is no consideration of the variation in the data collected.

DQI	Relevance of DQI (A)	Data Quality Rating (B)	Comments
Level of Reference	Low	High	(A) Thorough referencing of the data source is not critical given the wealth of effluent data collected form the 600 mills. (B) The document is thoroughly referenced.
Representativeness	High	High	(A) It is important for the effluent data in this report to reflect typical releases. (B) Although the data are dated 1982, it is the most recent comprehensive collection (from 600 mills) and is deemed to be representative of the industry.

II. DATA QUALITY EVLAUATION FOR CHEMICAL SAFETY ASSESSMENT

OECD HPV Chemicals Program

The OECD High Production Volume (HPV) Chemicals Program provides an initial chemical hazard assessment. In this Program, The OECD Manual for Investigation of HPV Chemicals (OECD, 2005) suggests data quality evaluation in terms of three aspects, defined by Klimisch, Andreae, and Tillman (1997) along the following lines:

- Reliability: evaluating the inherent quality of a test report or publication relating to preferable standardized methodology and the way the experimental procedure and results are described to give evidence of the clarity and plausibility of the findings;
- Relevance: covering the extent to which data and tests are appropriate for a specific hazard identification or risk characterization; and
- Adequacy: defining the usefulness of data for hazard/risk assessment purposes. When there is more than one study for each endpoint, the greatest weight is attached to the study that is the most reliable and relevant. Robust study summaries are prepared for the highest quality or “key” studies.

Among these above terms, the OECD Manual focuses on determining the reliability of data. This essentially relates to methods and approaches of the study, particularly for ecotoxicity and human health endpoints data. The Manual suggests the use of sound scientific judgment when considering relevance and adequacy. These two aspects relate to the availability of information and how information is summarized and documented.

EU REACH Regulation Guidance Documents

REACH represents the EU's Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals. ECHA (European Chemicals Agency) developed and published a series of guidance documents to assist implementation of REACH. Guidance on Information Requirements and Chemical Safety Assessments (ECHA, 2011c) summarizes the data quality for chemical safety/risk assessment from three aspects: relevance, reliability, and adequacy. The definitions of these terms are the same definitions by Klimisch et.al. (1997) and the OECD HPV Program. Through the evaluation of these aspects, the data quality can be determined and used as supporting evidence for decisions made in the assessment.

1) The relevancy of the available data is evaluated qualitatively based on the following questions:

    - Whether the data are based on the appropriate species in the study
    - Whether the testing substance is representative of the substance as being registered
    - Whether relevant routes of exposure are studied
    - Whether the appropriate doses/concentration are used
    - Whether the critical parameters used for a specific endpoint are justified and considered adequately

2) The reliability of information can be scored numerically from 1-4, defined by Klimisch et al. (1997) (See Table 11A-4).

TABLE 11A-4 RELIABILITY SCORING SYSTEM

Data Score	Description
1 - Reliable data without restrictions	"studies or data [...] generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline [...] or in which all parameters described are closely related/comparable to a guideline method."

Data Score	Description
2 - Reliable data with restrictions	"studies or data [...] (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable."
3 - Not reliable	"studies or data [...] in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g., non-physiological pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment."
4 - Not assignable	"studies or data [...] which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.)."

3) This document explains the adequacy, i.e., validation of two types of data: non-human and human data. Non-human data include both non-testing data (e.g., QSAR data and grouping/read across data) and in-vitro data. For example, the document cites the OECD principles for QSAR validation, "to facilitate the consideration of a QSAR model for regulatory purpose, it should be associated with the following information:

    - a defined endpoint
    - an unambiguous algorithm
    - a defined domain of applicability
    - appropriate measure of goodness-of-fit, robustness and productivity
    - a mechanistic interpretation, if possible (OECD, 2007)

IPCS Harmonization Project

The International Program on Chemical Safety (IPCS) is a joint venture of the United Nations Environment Program (UNEP), the International Labor Organization (ILO) and the World Health Organization (WHO). The overall goal of IPCS Harmonization Project is to harmonize global approaches on chemical risk (including both hazard and exposure) assessment by developing

international guidance documents. One of the IPCS Harmonization Project publications defines data quality in chemical exposure assessment by the following four indicators (WHO, 2008c):

- Appropriateness: the degree to which data are relevant and applicable to a specific exposure assessment.
- Accuracy: the degree to which measure, calculated or modeled values correspond to the true values of what they are intended to represent.
- Integrity: the degree to which the data collected and reported are what they purport to be.
- Transparency: the clarity and completeness with which all key data, methods and processes, as well as the underlying assumptions and limitations, are documented and presented.

III. HARMONIZATION OF KEY TERMS TO CHARACTERIZE INFORMATION QUALITY

As we discussed earlier, the Guide and other information quality evaluation use different terms synonymously to characterize the merit or quality of information. Due to the similar underlying aspects to evaluating the merit of information, the key terms from various frameworks may be harmonized to communicate the merit of information for the purpose of the Guide.

Table 11A-5 provides a mapping of the key terms used in this AA evaluation approach with the corresponding terms used by others. For example, in the context of EU's REACH Guidance and OECD's HPV Chemicals program, relevance, reliability, and adequacy are used to evaluate data quality for chemical hazard/risk assessments. In the AA under the SCP context, we combined these considerations to two essential components to describe reasonableness based on specific needs for AA evaluation: reliability and validity. The reason for diverging from terms used for other data quality frameworks is to make it more accessible to the Guide's target audience, which includes groups that do not necessarily have strong background knowledge of LCA or chemical hazard/risk assessment. Meanwhile, the terms reliability and validity still comprehensively cover all the important data quality considerations for different types of assessments in the AA process (e.g., chemical specific data for impact assessment or process specific data for life cycle impact assessment). Furthermore, the consideration of plausibility makes the scope of AA evaluation more comprehensive and covers non-technical aspects that are not covered by reliability and validity.

TABLE 11A-5 HARMONIZATION AND MAPPING OF KEY TERMS TO CHARACTERIZE THE REASONABLENESS.

Terms used in the Guide	Terms used in the SCP regulations	Terms used in ECHA/OECD Guidance for chemical assessment	Terms used in ISO 14044(2006) for LCA	Terms used in Ecoinvent® LCA pedigree matrix
Reliability	Reliable information	Reliability	Precision	Reliability
Reliability	Independently confirmed, corroborated, or replicated		Sources of data	
Reliability	Independently reviewed by qualified disinterested parties		Reproducibility	
Validity	Relevant for the purpose	Relevancy	Representativeness	Temporal correlation
Validity	Study design appropriate to the hypothesis and sufficient		Time-related coverage	
Validity			Geographical coverage	Geographical correlation
Validity			Technology coverage	Technological correlation
Validity	---	Adequacy	Uncertainty	
Plausibility	Level of rigor/quality control	---	Consistency	---
Plausibility	---	---	Completeness	Completeness

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