Interstate Chemicals Clearinghouse

DRAFT Alternatives Assessment Guide
Version 1.2

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IC2 Alternatives Assessment Guide v1.0

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IC2 Alternatives Assessment Guide v1.2

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Disclaimer

Team members worked collaboratively and reached consensus on the contents and approaches represented in the Guide. Specific views expressed in this document do not necessarily reflect those of all Team members, EPA, technical advisors, support staff, or IC2's members or supporting members or the agencies or companies for whom they work. Participation on the Team does not necessarily imply endorsement of the completed document or its usage. Mention of any company, process, or product names should not be considered an endorsement by any of the participants.

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Acronyms

AA	Alternatives Assessment
ATDSR	Agency for Toxic Substances and Disease Registry
ASTM	American Society for Testing and Materials
CAS Number	Chemical Abstract Services registration Number
CBA	Cost Benefit Analysis
C2CC®	Cradle to Cradle Certified®
CMR	Carcinogenic, Mutagenic or Reproductive toxic chemical
Deca-BDE	Decabromodiphenyl ether
DfE	United States Environmental Protection Agency Design for the Environment Program
DMC	Domestic Material Consumption
DMI	Direct Material Input
ECHA	European Chemicals Agency
EJ	Environmental Justice
EPA	United States Environmental Protection Agency
EPA SCIL	United States Environmental Protection Agency Safer Chemicals Ingredients List
EU	European Union
GHS	Global Harmonisation System of Classifying and Labeling Chemicals
GreenScreen®	GreenScreen® for Safer Chemicals
Guide	IC2 Alternatives Assessment Guide
IC2	Interstate Chemicals Clearinghouse
ISO	International Organization for Standardization
LCA	Life Cycle Assessment
LCC	Life Cycle Costing
LCT	Life Cycle Thinking
MFA	Material Flow Accounting
MSDS	Material Safety Data Sheet
OECD	Organisation for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
PBT	Persistent, Bioaccumulative and Toxic chemicals
P2OASys	Pollution Prevention Options Analysis System
PPE	Personal protective equipment
QSAR	Qualitative Structure Activity Relationships
RDP	Resorcinol bis-diphenyl phosphate
SDS	Safety Data Sheet
SLCA	Social life cycle assessment
SMM	Sustainable Materials Management
TPP	Triphenyl phosphate
TURI	Massachusetts Toxics Use Reduction Institute
UNEP	United Nations Environmental Programme
vBT	Very bioaccumulative and toxic substances
vPT	Very persistent and toxic substances

Overview

Purpose and Background

The Interstate Chemicals Clearinghouse (IC2) is an association of state, local, and tribal governments and supporting members from industry and the environmental community. This organization was formed to:

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

The IC2 sponsored creation of the IC2 Alternatives Assessment Guide (Guide) to:

- Foster replacement of toxic chemicals in products by selecting less hazardous, safer alternatives.
- Include all reasonable criteria to be addressed in an AA including hazard, exposure, performance, cost, availability, etc.
- Recommend the minimum data set needed to conduct an alternatives assessment (AA).
- Meet a wide range of objectives from small, medium, and large businesses, local, state, and federal governments, and other interested parties. Provide sufficient flexibility that assessors can modify an AA, including the depth to which different criteria are evaluated.

The Guide is designed to meet IC2 member needs and standardize the AA process. It allows states with similar interests to share AA results conducted by one member state. Previous experience has shown that resources are not optimized when multiple states work on the same issue without sharing expertise and results. For example, Maine, Washington, and Illinois all conducted AAs for the flame retardant decabromodiphenyl ether (Deca-BDE) using different methodologies. Resources could have been saved if one state conducted an AA and shared the results among IC2 member states.

IC2 Alternatives Assessment Guide Development

In 2011, The Washington State Department of Ecology initiated the Guide development process by drafting a scoping document and soliciting input from interested stakeholders. Eight IC2 member states, including California, Connecticut, Massachusetts, Michigan, Minnesota, New York, Oregon, and Washington, worked together on the Guide.

IC2 requested technical support from the United States Environmental Protection Agency (EPA) Design for the Environment (DfE) Program, which had extensive AA experience. In addition, Dr. Lauren Heine, then Consulting Co-Director of Clean Production Action, a non-governmental organization with extensive AA experience, was hired as a technical consultant. Team members from member states provided technical experience in toxicology, chemistry, human health, exposure, life cycle assessment, and environmental policy, all of which were instrumental in formulating a comprehensive and complete Guide.

Draft modules were posted for public comment on the Washington State Department of Ecology website. Three workshops were held with industry in March and April of 2012. These workshops were to inform industry of the progress on the Guide and to gather input on the process. Two webinars were held in August and November 2012 to provide updates and accept comments and questions. The team released a draft Guide for a 60-day public comment period from March to May 2013.

The Guide does not provide a single, specific approach for conducting an AA. Instead, it has a flexible design that can be used by AA practitioners to achieve multiple objectives that are appropriate to an AA. Up to seven modules, each evaluating a different aspect of potential alternatives, can be "plugged into" the AA. Each module can be completed to different levels, with higher levels affording greater certainty in the results but requiring greater expertise and resources.

The Guide approach is similar to a 'buffet' where all of the options are presented, and the assessor can select those modules and levels that best suit the chemical, product, or process under evaluation *as long as minimum recommendations are met*. For example, because the goal of an AA is to replace chemicals of concern with safer chemicals, all frameworks require the hazard to be emphasized in the assessment process. These issues are addressed in subsequent sections.

Because of its breadth and complexity, the Guide may appear overwhelming. It is important to remember, however, that no single AA is expected to use every method included in the Guide. The Guide provides minimum expectations for an AA and methods to meet those expectations. At specific points, the Guide also discusses how to meet other AA requirements that may be set by regulatory agencies or other organizations.

The Golden Rule and Principles

This Guide was written to follow a "Golden Rule" and an accompanying set of principles.

Principles

- **Reducing hazard**: The chemical hazard must be emphasized. When an exposure assessment is part of an AA, it should be used to improve a product only after selecting the least hazardous options.

- **Transparency:** All assumptions, data sources, data quality, decisions, etc., should be documented and explained. For example, the values selected for the relative weights of criteria used to select alternatives should be communicated and justified.
- **Flexibility:** Four modules should be included in all AAs, specifically the (1) Hazard, (2) Cost and Availability, (3) Performance Evaluation, and (4) Exposure Assessment modules. The person conducting the AA can decide if additional modules should be included.
- **Life cycle thinking:** All decisions made should reflect a broad perspective and include consideration of the full life cycle of the product. Impacts to workers, consumers, and the environment across the life cycle and the supply chain should all be considered.
- **Opportunities for green chemistry and continuous improvement:** The assessor should distinguish between results that provide clear benefits and ones that afford marginal improvements or require trade-offs. Identify all opportunities for continuous improvement and set goals for meeting them, which may include a longer-term investment in green chemistry research.
- **Consider uncertainties:** Data from peer-reviewed scientific studies are preferred over assumptions, estimates, and unpublished data. Even well-performed studies may not provide full information about a substance. There may be cases where certain animals may not be good models for toxicity, or where other adverse effects are not captured by the test method. As part of the data review, it's important to capture these uncertainties and factor them into the decision-making.

The Golden Rule

The objective of an alternatives assessment is to replace chemicals of concern in products or processes with inherently safer alternatives, thereby protecting and enhancing human health and the environment.

How have you addressed equity and environmental justice?

Throughout the guide, there are insets like this one that contain prompts to address environmental justice and equity.

Consider Environmental Justice: Include environmental justice[1] in alternatives assessment to ensure that the process:

- authentically and meaningfully consults people who have historically experienced or are currently experiencing environmental injustice;[2]
- safeguards against the introduction of new or different burdens among disproportionately impacted populations; and
- supports identifying alternatives that benefit communities harmed by the chemical under assessment.

Consider equity: Equity is a part of environmental justice and is the act of giving fair treatment to individuals. An equitable AA process should include:

- Identifying and addressing barriers that prevent an individual, organization or community from being involved in the AA.
- Seeking an alternative that addresses current burdens without creating new burdens on already impacted individuals.

[1]*According to the U.S. EPA, "**environmental justice** means the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, rules, and policies."*

[2]*Marginalized and/or underserved populations experiencing **environmental injustices** confront disproportionate exposure to toxic chemicals where they live and work, contributing to health disparities.*

Who conducts the AA

There is no fixed requirement regarding who should conduct an AA. There are many parties who may be interested in subjecting a particular chemical, product, or process to the AA process. Some examples include:

- A manufacturer or processor
- An importer or retailer
- A consortium
- An industry/government partnership
- A government entity
- An independent group

A manufacturer or retailer may voluntarily use the AA process to reduce the potential impact of their products upon human health and the environment, since they ultimately are responsible for their products. Businesses may also be required to conduct an AA by law or regulation. For example, California's Safer Consumer Products Regulations can require businesses and other responsible entities to submit AAs under certain circumstances.

In other instances, a government entity may conduct an AA. Sometimes the government entity is seeking to provide technical support to a business transitioning to safer chemicals or to support environmentally preferred purchasing within the government. In other cases, the government entity is designated as the responsible party as part of a law. For example, under certain laws, the Washington State Departments of Ecology and Health use AAs to support the regulation of certain chemicals and chemical classes in consumer products.

The responsible party is not always the assessor, or the individual or organization that conducts the AA. Specialist consultants may be contracted to act as the assessor on behalf of another organization. A consortium of related businesses may conduct an AA on behalf of their members. Sometimes, a non-governmental organization may publish an AA to promote the adoption of safer products.

Intended Audience of Guide

Assessments of the same chemical may look different if the assessors come from or represent different groups. Assessors choose a framework, modules, and levels within modules to create an appropriate AA.

Although anyone can benefit from the Guide, the current primary audience is government entities and their designees who conduct AAs. Therefore, in v1.2 the revisions to the Guide were intended to help support AA work done by governments.

IC2 member organizations typically act as the assessor for one of three reasons:

- To provide technical support to a business that is seeking alternatives that can be used instead of a chemical of concern. In this instance, the assessor will need to consider the specific needs of the business during the assessment process.
- To provide support for environmentally preferred purchasing or informed substitution within an industry. Massachusetts' Toxics Use Reduction Institute (TURI) has several good examples of this work. For these AAs, assessors will need to consider the general priorities of an institution or industry and will typically focus on those substitutions that can be readily made.
- To act under law or in support of regulations. In this instance, the government entity is required to perform an AA. The exact considerations that will need to be included in the AA will be described in the law or decided as part of regulatory action. Often, the government entity will consider the general priorities of relevant industries but will also focus on regulatory goals such as the protection of human or environmental health or the remedy of environmental injustices.

Guide v1.2 is still relevant for non-government entities that are conducting AAs. Large businesses can still use approaches that include considerations for individual businesses or industries, such as industry-approved performance testing. Smaller businesses can collaborate with government entities to conduct AAs or obtain technical assistance for their substitution decisions.

Identifying Chemicals of Concern

The chemical of concern, sometimes referred to as CoC, refers to a chemical, or occasionally class of chemicals, that has a negative impact on human and/or environmental health and is a good candidate for substitution through the AA process. Identifying the chemical of concern can be a long and involved process and is outside the scope of this document. The exact process, however used, occurs prior to beginning an AA.

Chemicals of concern can be identified through:

- Legislative mandate, including laws prioritizing environmental justice.
- Regulation, including policies prioritizing environmental justice.
- Concern from workers or communities near extraction or manufacturing sites.
- Consumer concern.
- Business concerns including greening of product lines and avoiding regulation.
- Corporate or government policies that address individual hazard properties of chemicals, such as carcinogenicity, or combinations of hazard properties, such as persistence with bioaccumulation potential and toxicity (PBT).
- Other processes.

Assessors are encouraged to collect information on why chemicals of concern were selected, since this information will support later AA work. Since elements of the Guide, such as the Stakeholder Engagement chapter, are intended to help assessors to work with communities that are disproportionately exposed to chemicals, it may be help to review the guide before the chemical of concern is identified. For example, assessors that have the flexibility to choose the chemical of concern should give those communities that have been impacted by many chemical, social, and environmental stressors an opportunity to identify high priority chemical candidates for substitution.

How to Implement the Guide

This section provides an overview of the AA process described in the Guide as well as an example of how to structure an AA and select alternatives that are preferrable to the chemical of concern. Apart from identifying chemicals of concern, all steps of the AA process are described.

The Guide enables assessors to create an AA structure and select evaluation modules that meet the needs of a wide range of users, products, and processes. Minimum expectations and recommendations are included to ensure all AAs work to replace chemicals of concern used in products or processes with safer alternatives.

How have you addressed equity and environmental justice?

Throughout the guide, there are insets like this that contain prompts to address environmental justice (EJ) and equity. These insets are meant to prompt additional thinking and assessment to avoid imposing new or different burdens on disadvantaged and/or vulnerable populations or EJ communities. This inset provides working definitions used in the Guide; applicable regulations or policies may create different definitions in specific AAs.

In the Guide, "disadvantaged and/or vulnerable populations" include those that:

- have been overburdened and disproportionately impacted by exposure to toxic chemicals and/or;
- are more susceptibility to adverse health effects from exposure to toxic chemicals, given the accumulation of an array of risk factors associated with being underserved and marginalized populations.

The term "at-risk populations," is also used by those who prefer the connotations of at-risk over disadvantaged. Both terms typically apply to a group defined by one or more specific characteristic, such as race, age, relative income, disability or immigration status, or relative proximity to extraction, manufacturing or disposal sites, which indicate greater impact from or susceptibility to toxic chemicals. These populations are often excluded from the processes and decisions that affect them.

The Guide also uses the term EJ community. An EJ community is a group of individuals that are geographically or culturally linked together. Members of these communities often are among one or more at-risk populations. Frequently, EJ communities will self-identify as a community, sometimes for the purpose of political organization and action. Assessors avoid forcing the label of an EJ community onto a group.

The alternatives assessment process allows for going beyond safer to considering not just the reduction of harm but also the benefits, including access to safer alternatives or products or jobs and economic benefit to communities. Insets like this one are included throughout the guide to help assessors better incorporate EJ considerations in their AA. At minimum, we recommend assessments identify and document potential environmental justice impacts using the best available information.

Integrating input from environmental justice stakeholders in each stage of the assessment, to the extent feasible, will be critical as *those closest to the problem are closest to the solution*. Engaging EJ communities as stakeholders in the alternatives assessment will help to ensure decisions and priorities reflect those that are the most disproportionately impacted by the chemical of concern and provide strategies to ensure uptake and adoption of the safer alternatives identified.

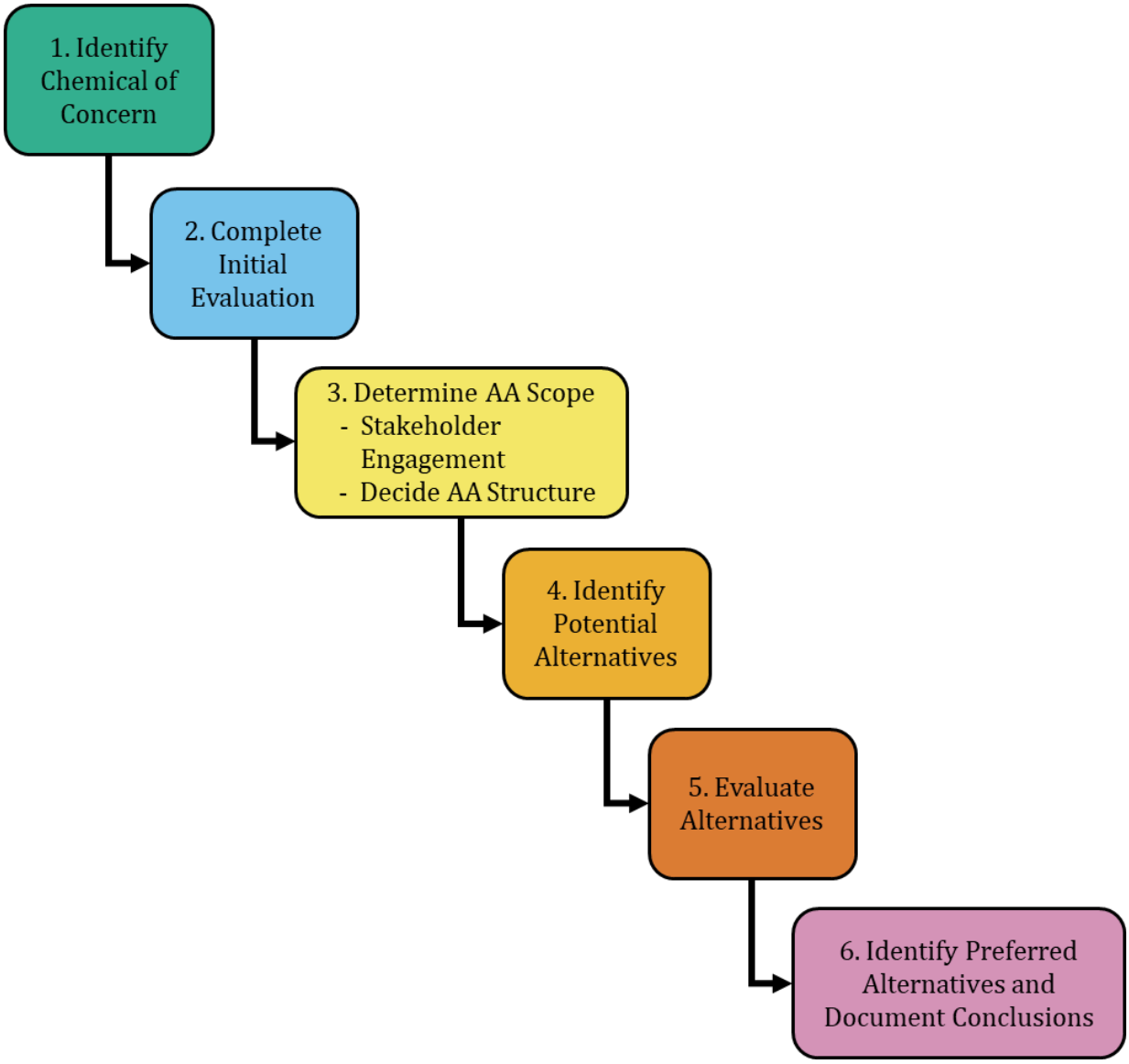
Recommended Implementation of the Guide

An AA consists of six distinct steps (

Figure 1):

1. Identify Chemicals of Concern.
2. Complete Initial Evaluation.
3. Determine AA Scope.
4. Identify Potential Alternatives.
5. Evaluate Alternatives.
6. Identify Preferred Alternatives and Document Conclusions.

Figure 1: The six AA steps.



1. Identify Chemicals of Concern

All AAs begin with identification of a chemical, product, or process that is the subject of the AA. As indicated previously, discussing strategies to identify the chemical of concern is outside the scope of this document. The Guide assumes that the chemical, product, or process of concern has already been chosen.

How have you addressed equity and environmental justice?

Were EJ communities given a role in selecting chemicals of concern or informing the selection?

A long history of systemic racism and other discriminatory practices is responsible for specific populations being disproportionately exposed to toxic chemicals across their lifecycle. These disproportionate exposures impact low-income populations, communities of color, indigenous communities, and disadvantaged communities, including refugees and immigrants. Discriminatory housing policies, zoning policies, and disinvestment have led to these populations residing near manufacturing and hazardous waste disposal facilities. People from these communities are more likely to work in industries that are users of toxic chemicals such in the agricultural, janitorial, beauty, or automobile repair sectors.

When possible, we recommend collaborating with these groups when selecting chemicals of concern. If that is not possible, involve these groups as stakeholders to the extent possible and prioritize removing chemicals that cause significant harm to these communities. Prioritizing the protection of those most vulnerable protects us all.

2. Complete Initial Evaluation

The Initial Evaluation asks the question 'Is an AA necessary?' and helps the assessor determine whether the chemical of concern is truly needed in the product or process. If the chemical of concern can be eliminated without substitution while maintaining the function of the product or process, an AA is not necessary. Sometimes, an AA is required by law or regulation. In that case, or if the Initial Evaluation indicates that an AA is necessary, the assessor proceeds to the next step.

3. Determine AA Scope

Once an AA is deemed necessary, the preliminary structure and boundaries of the AA should be established. At the beginning of this stage, the assessor identifies stakeholders that could contribute to the process and works to engage them in the process. The assessor then determines an appropriate structure for the assessment, including deciding how preferred alternatives will be identified.

Stakeholder Engagement

The Stakeholder Engagement chapter discusses how to identify and include stakeholders in the AA process. Stakeholder engagement helps refine proposed initiatives to accomplish goals in ways that satisfy key stakeholder concerns. Engaging stakeholders in problem

solving about both “the what” and “the how” of various solutions can lead to better outcomes and less opposition to change. The Guide describes how assessors should use life cycle thinking to identify potential groups that are impacted by the chemical of concern or an alternative at different lifecycle stages. Assessors should document any impacts on the AA that result from stakeholder engagement.

Decide AA Structure

This chapter helps the assessor create a structure for the AA that will allow them to implement evaluation modules and use the results to identify the best alternatives to the chemical of concern. Assessors are asked to select a framework to structure the AA based on their preliminary understanding of what criteria will be used to identify preferred alternatives. Frameworks also differ in when alternatives are eliminated from the AA. An example framework is included at the end of this chapter (

Figure 2).

More details are available in the chapter "Structuring the Alternatives Assessment". This chapter also discusses how to document the conclusions of the AA, including any information that can be used to implement change based on the AA findings.

4. Identify Potential Alternatives

Once the AA has been scoped, the Other Resources

Denmark. Nordic Council of Ministers. *The Use of Decision-aid Methods in the Assessment of Risk Reduction Measures in the Control of Chemicals*. By Dr. Joonas Hokkanen and Dr. Jukka Pellinen. TemaNord 1997:622. Copenhagen: Nordic Council of Ministers, 1997. Print.

Keeney, Ralph H., and Howard Raiffa. *Decisions with Multiple Objectives: Preferences and Value Tradeoffs*. Cambridge, United Kingdom: Cambridge University Press, 1993. Print.

Ralph F. Miles, Jr., and Detlof Von Winterfeldt. *Advances in Decision Analysis: From Foundations to Applications*. Ed. Ward Edwards. New York: Cambridge University Press, 2007. Print.

University of California, Los Angeles, *Sustainable Technology and Policy Program. Developing Regulatory Alternatives Analysis Methodologies for the California Green Chemistry Initiative: Final Report.* By Timothy F. Malloy, J.D., Peter J. Sinsheimer, Ph.D., MPH, Ann Blake, Ph.D., and Igor Linkov, Ph.D.

Identifying Alternatives chapter helps the assessor identify the universe of potential alternatives to be considered during the AA process. Alternatives may be chemical substitutions or alternative materials. They could also be product redesigns or alternative products or processes that eliminate the need for the chemical of concern while still providing a similar service. In this step, the widest range of possible alternatives should be researched, including emerging technologies.

If there are many potential alternatives, the assessor can conduct an initial screen using lower levels of the Hazard Module and the Performance Evaluation Module to screen out unfavorable alternatives. Otherwise, all alternatives identified in the chapter should undergo evaluation.

5. Evaluate Alternatives

Depending on the AA structure, the assessor may be able to choose the order in which some assessment modules are implemented. However, the goals of an AA must be met, which requires prioritizing a hazard evaluation. For most applications, an adequate AA should include the Hazard, Performance Evaluation, Cost and Availability, and Exposure Assessment modules *in that order of priority*.

At this point, the assessor should also identify which, if any, of the optional assessment modules to include in the AA and why. Optional modules are considered lower priority than the other four modules. The three optional modules evaluate materials management, social impact, and lifecycle impacts.

Hazard Module

The Hazard Module helps the assessor determine what hazards exist for the chemical of concern in a product or process. The hazards associated with the chemical of concern are compared to those, if any, associated with potential alternatives. As a result of this evaluation, the most favorable alternatives are identified, i.e., those with the lowest hazard.

Performance Evaluation Module

The Performance Evaluation Module helps the assessor ensure that alternatives are technically feasible for the desired application and that any products meet performance requirements. Without this assurance, companies are unlikely to adopt specific alternatives as safer alternatives for their products or processes.

Cost and Availability Module

The Cost and Availability Module helps the assessor evaluate whether potential alternatives are cost effective and available in sufficient quantity to meet manufacturing or user needs. Any alternative that is not found both in sufficient amounts and at an adequate

cost should be identified as a less favorable alternative. The Cost and Availability Module can also help the assessor identify externalized costs, such as environmental remediation costs, that are not typically considered in the cost of a product or process.

Exposure Assessment Module

The Exposure Assessment Module evaluates potential exposures and determines whether the alternative is likely to pose a greater exposure risk to human health and the environment than the chemical of concern. It is used after the Hazard Module to reduce risk. By applying hazard screening first, one can narrow down the options to those that represent the lowest risk as having both the lowest hazard AND lowest exposure potential. These are preferred alternatives.

Materials Management Module

The Materials Management Module evaluates how a potential alternative will impact natural resources and generate waste. This module emphasizes the concepts of a circular economy and 'Cradle-to-Cradle' design. Assessors are encouraged to prioritize alternatives that are designed for material recovery and/or benign release into the environment.

Social Impact Module

The Social Impact Module evaluates whether a potential alternative will unduly shift burdens (or benefits) from one community of people to another. It evaluates impacts of an alternative on workers, communities, and societies involved in its manufacture, transport, use, and disposal.

Life Cycle Module

The Life Cycle Module gathers and evaluates information about the entire product life cycle to help avoid shifting negative impacts between lifecycle stages. It also helps the assessor to consider ways to mitigate the negative impacts of an alternative. This module is designed to be used after all other modules, as it often builds on data from preceding modules.

6. Identify Preferred Alternatives and Document Conclusions

In the previous step, the assessor uses the selected modules to evaluate potential alternatives and compare them to the chemical of concern. As a final step, the assessor must conclude whether there are favorable alternatives that could replace the chemical of concern or products that contain it. If there are multiple favorable alternatives, the assessor may need to select the most preferred alternative. The assessor must clearly communicate which alternatives are favorable or preferred and why.

When multiple favorable alternatives are identified, the assessor should adopt the least hazardous alternative whenever possible. Evaluation of additional module levels or consideration of corporate drivers and principles may also help in the final selection.

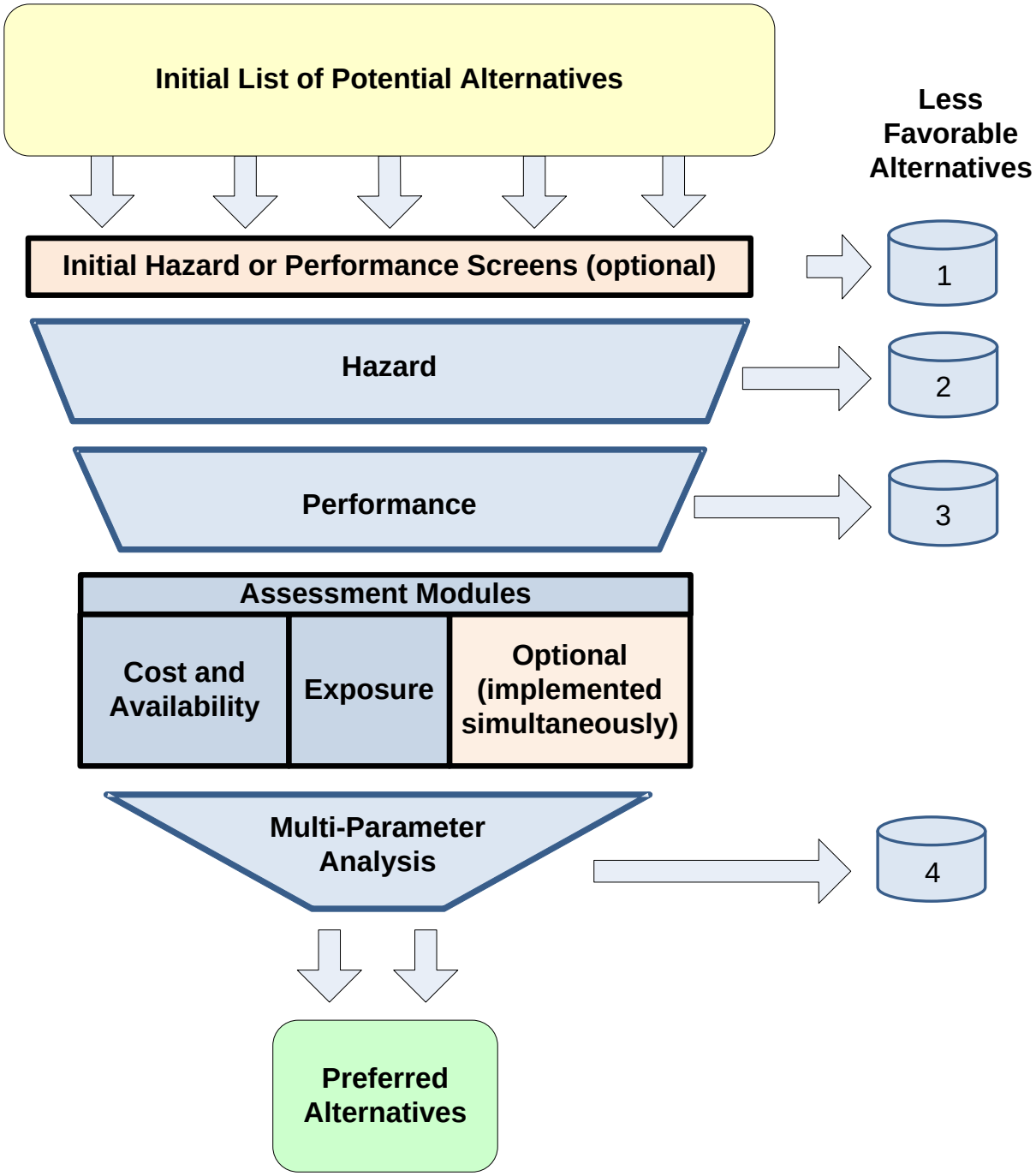
In some frameworks, the assessor removes less favorable alternatives from further consideration after each module is completed. When using one of those frameworks, the assessor may not need to do additional work to identify preferred alternatives. The assessor should still summarize why these alternatives were ultimately selected based on the findings of the modules.

If at the end of the evaluation no favorable alternative remains, it may be necessary to return to certain evaluation modules and re-evaluate alternatives deemed less favorable.

Consider the AA framework provided below, which is an example of a hybrid framework (

Figure 2). In this example, the hazard and performance evaluation modules were first used to assess alternatives and remove unfavorable alternatives that did not meet hazard and performance requirements. Cost and availability and exposure were then used to evaluate the remaining alternatives simultaneously, after which all remaining alternatives were found to be less favorable than the chemical of concern and there were no preferred alternatives.

Figure 2: Example AA framework.



Since no preferred alternatives were identified following implementation of the selected modules, the assessor should re-evaluate alternatives identified as less favorable. The assessor would begin by re-evaluating the cost, availability, or exposure considerations that results in alternatives sent to bin #4. If none of those alternatives were satisfactory as reevaluation, then the assessor could consider alternatives that had less favorable performance. Finally, if no preferred alternatives have been identified, then the assessor

could consider less favorable alternatives that were removed during the hazard evaluation. However, chemicals that are equally hazardous or more hazardous than the chemical of concern, which could be found in bin #1 or bin #2, are unfavorable alternatives and should never be selected as a preferred alternative.

Once preferred alternatives are identified, the final step of the AA process is to summarize AA findings and recommendations. This section should include:

- Any preferred alternatives that were selected along with the rationale for their selection.
- Key findings that can be shared with researchers or businesses working on developing alternatives to spur innovation, especially in green chemistry.
- Other key findings that would support the adoption of safer alternatives or could help address any concerns raised by specific stakeholders.
- Challenges or limitations that influenced decision making.
- Research needs or recommendations for a follow-up assessment if needed to find preferrable alternatives.

AA Examples and Approaches

This section presents examples of publicly available AAs and other AA methodologies that meet minimum recommendations. These examples show that both a variety of chemical products and processes have been reviewed and there is a large amount of flexibility possible within the AA process.

IC2 Alternatives Assessment Library

IC2 maintains a library of publicly available AAs from member organizations. These AAs are useful for assessors looking for examples of how AAs are performed as well as potential alternatives that could be included in future AAs. The library also includes some resources developed by member organizations to address current and historic technical needs for AAs, such as current practices to address nanomaterials in AAs.

United States Environmental Protection Agency Design for the Environment (DfE) Partnership Program

EPA's DfE Program developed the science and general processes used to conduct an AA. DfE published several complete AAs from the late 1990s through 2015. EPA has also started publishing hazard and other AA-related assessments as part of the regulatory process under the Toxic Substances Control Act.

DfE's method emphasizes chemical hazard assessments, includes an extensive stakeholder process that considers the whole product life cycle, and recognizes the need to consider

performance, cost, and exposure. The DfE methodology has inspired many tools and methods used in AA.

National Resource Defense Council's Selecting Safer Alternatives to Toxic Chemicals and Ensuring the Protection of the Most Vulnerable

In 2017, the National Resource Defense Council published a paper intended to address gaps in the AA process that can negatively impact marginalized or disproportionately impacted people, such as workers. The paper proposes considerations to help assessors avoid regrettable substitutions. Recommendations to assessors include conducting more genuine stakeholder engagement, more explicitly and transparently accounting for different trade-offs, and prioritize avoiding regrettable health impacts.

National Research Council's Framework to Guide Selection of Chemical Alternatives

In 2014, the National Academy of Sciences National Research Council published a detailed guide on informed chemical substitution. The intended goal was to address elements that the committee felt were not adequately addressed in other resources. Note, this guide does not require all AAs to include technical performance or economic feasibility criteria, which does not align with our minimum requirements.

Green Chemistry and Commerce Council Assessment of Phthalates

In 2013, the Green Chemistry and Commerce Council, now called Change Chemistry, issued the results of a project investigating alternatives to phthalates used as plasticizers in wire and cable applications. In the assessment, they released chemical hazard assessments of nine phthalate plasticizers and compiled links to technical specifications and performance information provided by plasticizer manufacturers.

Deca-BDE in Plastic Pallets, Pure Strategies, Inc.

In 2011, Pure Strategies conducted an AA for the Maine Department of Environmental Protection on the flame retardant Deca-BDE in plastic pallets. The assessment identified two alternative flame retardants on the market but recognized that development and testing would be necessary to achieve the necessary performance criteria. Production using either alternative was found to be less costly or comparable to Deca-BDE. In addition, the assessment identified traditional wood pallets, which do not need flame retardants, as a preferred alternative to plastic pallets containing Deca-BDE.

BizNGO Chemical AA Protocol

In 2011, BizNGO, a consortium of businesses and environmental groups focused on chemical issues, released an AA framework. The methodology emphasizes the importance of chemical hazard assessment in an AA and includes consideration of performance, cost, exposure, and life cycle in the protocol.

Deca-BDE in Televisions and Computers and Residential Upholstered Furniture, Washington Department of Ecology and Washington Department of Health

In 2008, the Washington Departments of Ecology and Health conducted an AA for Deca-BDE in electronic housings and residential upholstered furniture. For both types of applications, the assessment found that alternatives to Deca-BDE were already widely available and in use. The assessment evaluated the hazard, performance and cost and availability of several alternatives. Exposure was determined as irrelevant to the assessment because it was not a discriminating factor.

Five Chemicals Alternatives Assessment Study, TURI

In 2006, at the direction of the Massachusetts' Legislature, TURI assessed alternatives for five chemicals: lead and lead compounds, formaldehyde, perchloroethylene, hexavalent chromium and di(2-ethylhexyl)phthalate. An evaluation of hazard, performance, cost and availability, and exposure potential were integral to the assessment. This assessment also considered the potential effects of adopting alternative chemicals or technologies on the economic competitiveness of the Commonwealth.

Initial Evaluation

The Initial Evaluation Module determines whether an AA is needed. In some cases, a chemical of concern can be removed, without a substitute, from a product or process without causing a negative impact. In other cases, a product or process that uses or creates a chemical of concern can be discontinued. If an assessor has the authority to recommend removing a chemical of concern or the product or process it is used in, then an AA may not be needed.

Typically, a chemical of concern can be removed if one of three conditions is true:

- It was unintentionally added to or created by the product or process, and there are methods to eliminate its presence.
- It was intentionally added to the product or process but can be removed without impacting the function.
- It is used in a product or process that a business is willing to phase out or redesign.

This chapter presents guiding questions to help determine if a chemical of concern can be removed without finding an alternative. These questions are intended to guide an assessor who is conducting an AA for a specific business. However, they could also be used by an assessor who is evaluating whether a chemical of concern is necessary for a type of product or process.

If the assessor does not have the authority to decide that no AA is needed, then an initial evaluation is not necessary, although it may be a useful exercise to help identify potential alternatives for the AA.

Initial Evaluation Process

Chemicals of concern may be present for a variety of reasons. In some cases, they may be present to meet regulatory requirements. In other cases, they may be a by-product or impurity of another ingredient, or they may be a defunct ingredient that is no longer needed. It is important to understand why a chemical of concern is present in a product.

To begin the initial evaluation, ask the question: *Why was the chemical of concern added to the product?*

- If chemical was unintentionally added, continue to “Unintentionally added chemicals of concern.”
- If chemical was intentionally added, continue to “Intentionally added chemicals of concern.”
- If the reason for the chemical’s presence is unknown, investigate the product supply chain to identify possibilities. What benefit or benefits does the chemical provide either

to the manufacturing process or to the end product? Continue when you know whether the chemical of concern is intentionally added or not.

If the reason for the chemical's presence cannot be determined after further research, proceed with the AA. When identifying potential alternatives, the assessor should prioritize alternative materials, products, processes or services, since the purpose of the chemical of concern is unknown.

Unintentionally added chemicals of concern

If unintentionally added, the chemical of concern may be present for several reasons. It may be a by-product of a manufacturing process. For example, polychlorinated biphenyls, also called PCBs, can be created in the process of manufacturing pigments and dyes. It may be a naturally occurring impurity, such as when zinc deposits contain lead. Finally, it may be a contaminant, such as when lead from lead pipes contaminates water.

If the chemical can be eliminated without affecting the product's performance, a business can avoid an AA and its associated costs.

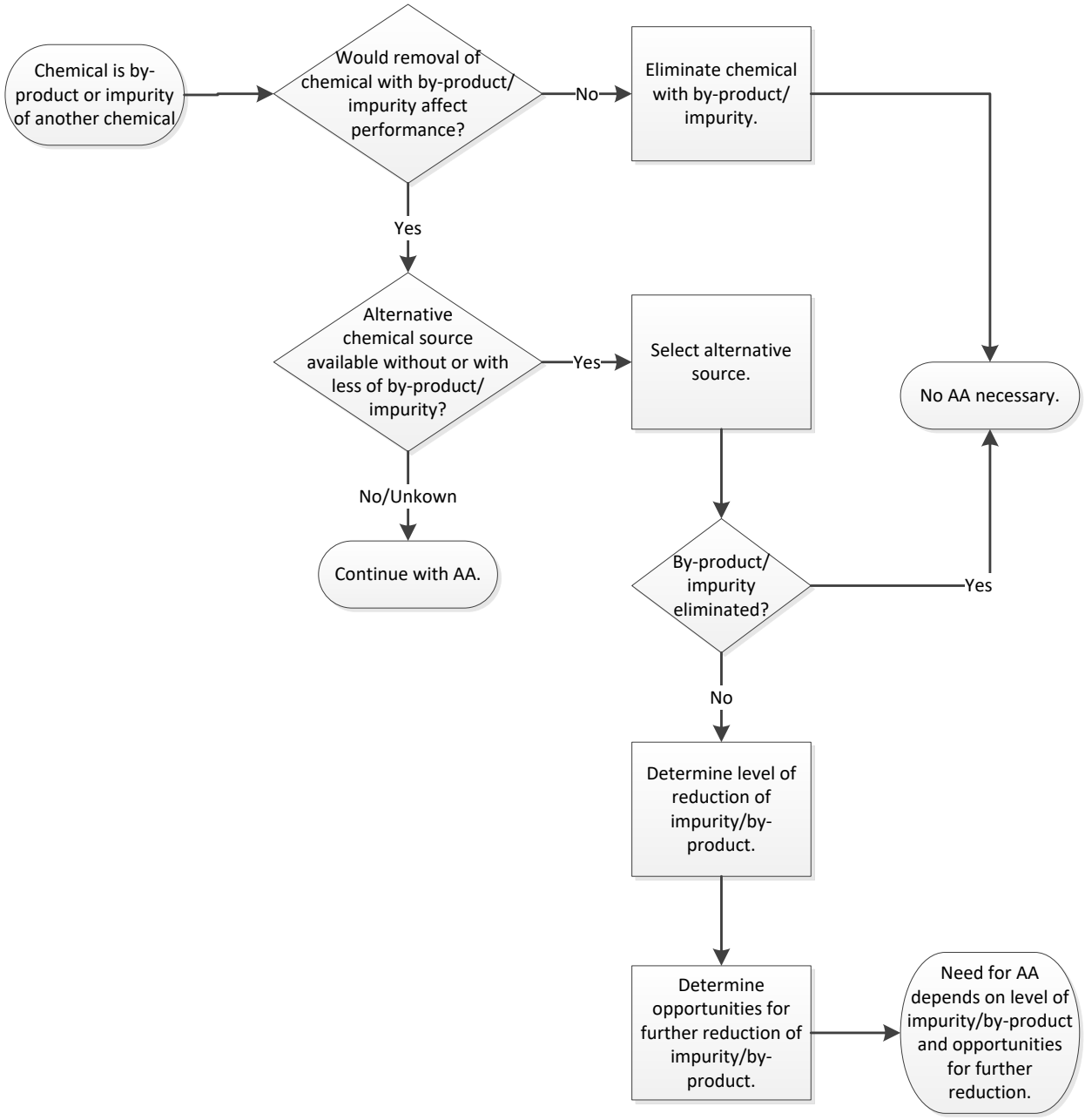
1. Is the chemical of concern an impurity or the by-product of a manufacturing process?
   A. If yes, would removing the chemical with the impurity or the chemical that generates the by-product affect product performance?
      - If no, document the decision and eliminate the chemical. No AA is necessary.
      - If yes, continue to the next question.

   B. Are other chemical sources available without the by-product, impurity, or contaminant?

Example 1: Caustic soda produced in a mercury cell process may contain traces of mercury. Caustic soda produced with an alternative process will not contain mercury.
Example 2: Reactions used in the production of detergent surfactants can form 1,4-dioxane as a by-product. Dioxane may be removed by means of vacuum stripping at the end of the polymerization process.

      - If yes, select alternate sources. Was the by-product or impurity eliminated?
        - If yes, document the results. No AA is necessary.
        - If no, determine the level of reduction of the by-product or impurity. Do opportunities exist for further reduction? The need for an AA depends on level of reduction.
      - If no, continue with the AA.

Figure 3: Identifying unintentionally added chemicals of concern.



Intentionally added chemicals of concern

In some cases, a chemical of concern will be added to a product or process even after it no longer serves a useful purpose. The chemical of concern could be added to meet a regulatory requirement, or it could be added to meet a previously required function that is no longer needed.

1. Do local, state, federal, or national legislation require addition of the chemical of concern?
    - Is the chemical of concern specifically required by a regulation?
    - Is using the chemical of concern the ONLY way to meet regulatory requirements?
    - Does the regulation specifically prohibit the use of an alternative?
        - If the answer is yes to all of the questions above, document information used to reach the conclusion and identify that an AA cannot be performed.
        - If no to ANY of the above questions, continue to the next question.

Example: A manufacturer of medical radiation screening equipment may be required by regulation to provide radiation protection. Lead shielding may be the only substance and method that can be used to meet this regulatory requirement. An AA may still be done in this specific application to determine if a better alternative exists.

Example: Deca-BDE is one of many substances that is used to meet regulatory flame-retardant requirements in furniture. Although most manufacturers used Deca-BDE to meet the regulatory requirement, an AA is necessary to determine which of the regulatorily required alternatives has the lowest impact upon human health and the environment.

2. Determine the function of the chemical in the product or manufacturing process.
    - Is the function performed necessary for the success of the product?
        - If no, eliminate the chemical. No AA is necessary.

Example: A major sportswear manufacturer found that several intentionally added toxic chemicals in its rubber formulations were historical artifacts and did not enhance performance of the product. Rather than conduct an AA, the chemicals were eliminated from the product.

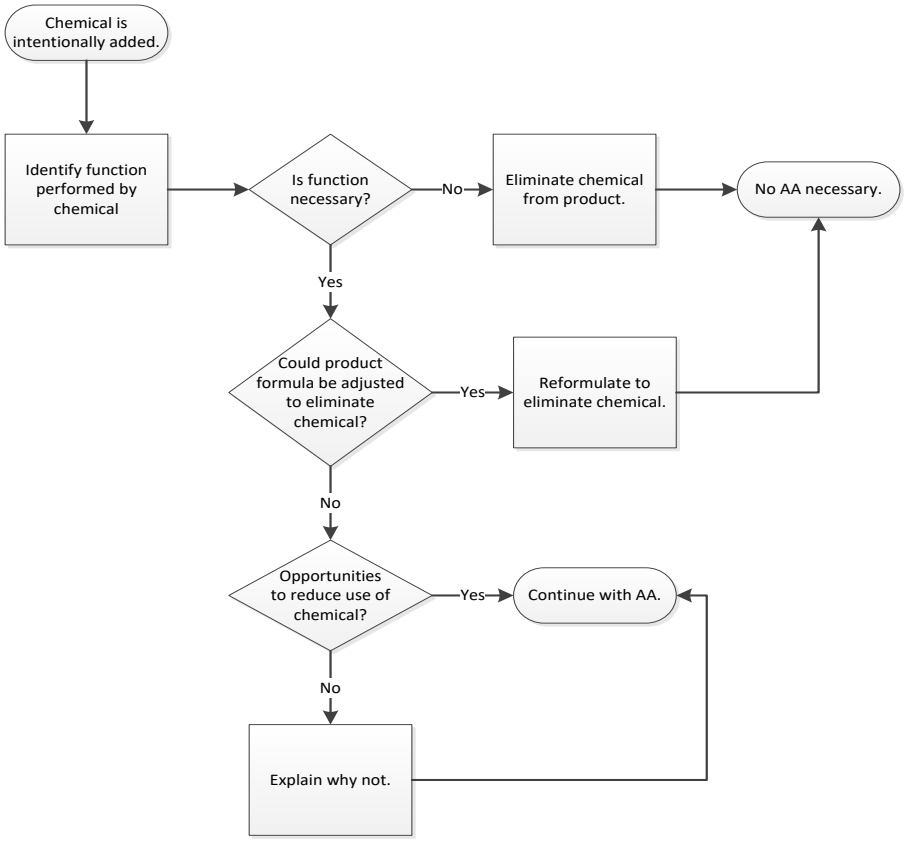
        - If yes, continue to the next question.
    - Could the toxic chemical be eliminated from the product formula without adding any new chemicals?
        - If yes, reformulate the product and document the decision. No AA is necessary.
        - If no, continue to the next question.
    - Are there opportunities to reduce the amount of the chemical used?

Example: A major sportswear company was able to reduce total zinc content in rubber formulations by 80 percent and leachable zinc content by more than 90 percent.

        - If yes, continue the AA to see if the chemical can be eliminated completely.
        - If no, continue to the next question.
    - Is it possible that an alternative could be used in place of the toxic chemical?
        - If no, explain why no alternative is thought to exist. Document information used to reach the conclusion and identify that the AA is complete.
        - If yes, continue with the AA.

Many of these decisions are internal to an organization. There are a few tools available to help with these decisions, some of which are sector-specific.

Figure 4: Intentionally Added Chemicals.



Product redesign or phase-out

Even if a chemical of concern is intentionally added, an AA may not be needed if the product or process that contains the chemical of concern can be removed or redesigned. These questions may only be relevant to assessors that are working with a specific business.

1. Look at a business portfolio of products and services. Does the business portfolio include other products that cover the same product type?
    - If yes, ask if the business is willing to phase out the phase out the product containing the chemical of concern?
        - If yes, document decision and phase-out the product containing the chemical of concern.
        - If no, continue to the next question.
    - If no, continue to the next question.

2. Has the product containing the chemical of concern reached maturity and should it be considered for sunset?
   - If yes, sunset the product. Document the decision. No AA is necessary.
   - If no, continue to the next question.
3. Will the business prioritize redesigning the product in the next product innovation cycle?
   - If yes, submit the product for redesign and development informed by Green Chemistry Principles.[1] Rather than replacing a chemical of concern with a safer alternative, redesign considers all aspects of a product. If redesign occurs, an AA should not be necessary.
   - If no, continue with the AA.

Tools

The following resources may be useful when identifying the function of the chemical of concern in a product or process, or when searching for alternatives.

- Material declarations may be requested from suppliers by manufacturers.
- Safety Data Sheets may be requested from suppliers by manufacturers.
- CleanGredients
- Chemsec Marketplace
- SpecialChem
- UL Prospector (formerly Innovadex)
- German Federal Institute for Occupational Safety and Health Substitution Support Portal

[1] The Green Chemistry Principles document was created by the Expert Committee on Sustainable Chemistry.

Stakeholder Engagement

The goal of stakeholder engagement within an AA is to ensure concerned parties can understand what decisions are being made and why, can provide input into the process, and can potentially assist with decision-making. This chapter uses a life cycle thinking approach to ensure stakeholders throughout the product or process life cycle can participate in the AA process.

Stakeholder engagement is an important part of any AA. Identifying key stakeholders through life cycle thinking can help assessors better understand how the chemical of concern may impact people or the environment. Engaging stakeholders in problem solving can lead to dynamic discussions and improved outcomes. Stakeholder engagement can lead to greater buy-in and less opposition to change.

In this chapter, we describe a process that assessors can use to identify and engage with potential stakeholders. The first step, performed before the AA begins and ideally before the chemical of concern is selected, is to identify stakeholders throughout the chemical of concern's life cycle. It is important to consider potential stakeholders at all stages and to acknowledge when a stakeholder was not engaged. Although the sections focus on best practices for engaging EJ communities, the practices are also applicable to engaging with any stakeholder.

The second step is to document contributions from stakeholders in the AA and how those contributions influenced the AA. Stakeholders may help identify alternatives, contribute to the analysis, or raise concerns about aspects of the AA. Assessors should not presume to know the concerns of specific stakeholders without hearing from those stakeholders either directly or through trusted proxies. Engaging stakeholders is necessary to help refine the assessment and successfully implement safer alternatives.

An important aspect of stakeholder engagement in the AA process is transparency in all decision-making. While different stakeholders may share a desired outcome, they may have different and often opposing positions on how to achieve an outcome. In those instances, it is important to acknowledge when a solution is reached that is acceptable to all but does not fully meet the desires of all. Even when agreement is not possible, transparency enables all parties to understand how the decision was reached.

Identifying Stakeholders

The term stakeholder can refer to any individual, community or organization that may be impacted, positively or negatively, by the decisions made in the AA. They are typically impacted because they interact with the chemical of concern or an alternative in some way. Example stakeholders can include companies involved in manufacturing, distribution, or

retail, their workers, communities that live near manufacturing or disposal sites, and people who use relevant products. Stakeholders may be involved at different stages of the life cycle and need different levels of support to engage with the AA.

Stakeholders can contribute to all parts of an AA. As such, assessors are encouraged to begin identifying stakeholders and reaching out to them early in the process. Assessors should also view stakeholder engagement as a continuous process. If stakeholders are interested in contributing to an AA that is already underway, the assessor should attempt to incorporate them into the process as much as possible.

Box: Use of the Word Stakeholder

In this guide, we use the word stakeholder to denote any person or group that has an interest in the outcome of the AA. Some actively avoid the label stakeholder due to its historic relationship with settler colonialism, where stakeholders were those who would stake a claim to land that was often in dispute or outright stolen from indigenous peoples. Since we have not identified clear consensus on a replacement word, we will continue to use the word stakeholder generically in this guide.

However, we strongly encourage assessors to be mindful of the impact of this word and others with similar marginalizing legacies and be prepared to work with groups to find substitute language as appropriate.

We encourage assessors to use life cycle thinking to identify key stakeholders early in the AA process. Given the complex and global nature of most supply chains, it will likely not be possible for an assessor to engage all stakeholders that are impacted by the chemical of concern. However, it is still important to identify these people to the extent possible. Even when a stakeholder cannot be reached or is not interested in engaging in this process, the assessor can still consider impacts to that stakeholder during the AA process.

Life Cycle Thinking

Life Cycle Thinking (LCT) is a conceptual model typically used to support a Life Cycle Assessment, although LCT can be applied in its absence. According to the United Nations Environment Programme (UNEP)'s Life Cycle Initiative, "LCT is about going beyond the traditional focus on production site and manufacturing processes to include environmental, social and economic impacts of a product over its entire life cycle." [2] LCT can be used by assessors to methodically evaluate the ways different people or environments will interact with a product or process, and with the associated chemicals, from cradle-to-grave or

[2] What is Life Cycle Thinking? 2023 [cited 2023 October 10]. Available from: https://www.lifecycleinitiative.org/activities/what-is-life-cycle-thinking/.

cradle-to-cradle. In the Guide, LCT is also applied in the Life Cycle Assessment, Materials Management and Exposure Assessment Modules.

Assessors can use LCT to obtain a holistic picture of who may be impacted by the outcome of an AA. After all, the key stakeholders impacted by raw material extraction may be different from key stakeholders impacted by product manufacture, use, or disposal. Understanding the life cycle of a product or chemical of concern can help an assessor determine who the key stakeholders are in an AA.[3]

By connecting with potential stakeholders throughout the life cycle, the assessor can create an AA that considers alternatives that are safer at all lifecycle stages. LCT can also help assessors prioritize environmental justice considerations when engaging stakeholders. This may help assessors avoid burden shifting, where the alternative improves the impact of the production, pollution, and disposal of chemicals for some people, but does not help or worsens conditions for historically marginalized and overburdened communities.

Stakeholder Engagement and EJ

EPA defines EJ as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation and enforcement of environmental laws, regulations, and policies.[4] The Guide's recommendations are based on this definition, but there are other definitions developed by other international, national, state, and local governments that may be relevant to a specific AA.

How have you addressed equity and environmental justice?

Have state/local policies regarding environmental justice been addressed? Consult those policy provisions and requirements as during the conduct of the AA.

Several states have EJ policies or requirements as do some cities; more policies are likely to be adopted in the coming years. The AA and its process should be in alignment with relevant environmental justice policies. The National Conference of State Legislators has tracked relevant environmental justice state laws and policies.

With the increased focus on ensuring that EJ communities are involved in decision-making processes, it is important to identify these communities early in the AA process. EJ communities often have significant numbers of low-income people, Black, Indigenous, and/or other People of Color, and/or vulnerable populations, such as non-native English

[3] Ibid.

[4] US EPA. Learn About Environmental Justice. 2023 [cited 10 October 2023]. Available from: https://www.epa.gov/environmentaljustice/learn-about-environmental-justice

speakers, the elderly, children, and those with pre-existing health conditions. Due to exposure to toxic chemicals, these communities often disproportionately experience:

- adverse human health impacts.
- adverse environmental impacts.
- climate change-related impacts.
- other adverse impacts.

As stakeholders, EJ communities have almost certainly faced negative impacts from the chemical of concern. They are also more likely to encounter any negative impacts from the alternatives that are adopted. It is imperative to consider their input when performing an AA to ensure that potential chemical substitutions are in fact safer for all and not just moving to a different but equally burdensome impact to an EJ community.

Best Practices for Engagement with Environmental Justice Communities

A thoughtful approach to community engagement has the power to build trust between individuals and government or industry[5]. Strong relationships will allow an assessor to truly understand how communities and the public have been affected by toxic chemicals and whether an alternative option will further contribute to the existing burdens of the region or help alleviate them.

The Guide focuses on EJ communities because they often face many barriers that prevent them from participating in decision-making processes like AAs. However, since the focus is on identifying and removing barriers to participation, the assessor may also use these best practices as appropriate to better engage with other stakeholders.

When engaging with stakeholders, it is important to use a variety of methods to reach as many stakeholders as possible, particularly stakeholders that come from EJ communities and represent EJ considerations. Best engagement practices include:

- Understanding who is most affected by chemicals of concern and potential alternatives. This will likely require the assessor to research how these substances are created, used, and disposed of before beginning stakeholder engagement.
- Establishing long-term, collaborative relationships with stakeholders whenever possible.
- Traveling to stakeholders and holding meetings where and when stakeholders already congregate.
- Providing the necessary resources to bridge language and cultural barriers through:

[5] Metropolitan Area Planning Council. *Community Engagement*. 2023 [cited 10 October 2023]. Available from: https://www.mapc.org/our-work/services-for-cities-towns/community-engagement/

    - Translation of written materials, and
    - Use of interpretation, including sign language if required, for in-person meetings. Interpreters should be able to understand and work within the cultural context(s) of a specific community. Often this can be achieved by hiring someone from within the community to act as an interpreter.
- Identifying and addressing barriers that may prevent interested stakeholders from engaging. Beyond language access, barriers could include:
    - The location or time-of-day stakeholder meetings are held.
    - The length of time stakeholders are expected to participate, both in individual meetings and in the process as a whole.
    - Transportation or internet connectivity issues.
    - Lack of child-care options.
    - Lack of compensation, including monetary compensation, for input.
- Ensuring that stakeholders have accessible and factual information on the AA process, the chemical of concern, and potential alternatives. Accessible here means understandable to the audience, which may require creating multiple version of the same information.
- Answering questions and concerns truthfully and accurately, and in a manner that is accessible to all stakeholders.
- Clearly describing when and how stakeholder input may or may not be used within the AA. Ensuring that stakeholders can find out how information was or was not used.

It is important that the assessor clearly communicate to all stakeholders when and how their input may be used, ideally before a stakeholder or community of stakeholders commits to participating in the process. Representatives from community groups, especially EJ communities, may be representing their community in several active issues. Assessor should provide enough information about the AA that communities can make informed decisions about how best to engage, if at all.

Many of these best practices were developed in projects that have diverse but geographically similar stakeholders. AA assessors will likely need to engage with stakeholders located in geographically disparate communities. To help build relationships with stakeholders, practitioners are encouraged to seek out and engage with organizations or individuals that are trusted within a specific community. These trusted intermediaries can help assessors develop an engagement strategy that will best meet the needs of that community. They can also potentially provide input to the assessor if the broader community is unable or uninterested in participating in the AA process.

Approaches to Engagement

Stakeholder involvement in an AA can vary significantly in how much information and influence stakeholders are given. At the most basic level, stakeholders can merely be kept informed about AA progress and findings. At a high level of involvement, stakeholders can be given final decision-making authority as to what constitutes a preferrable alternative. While we recommend that AA practitioners go beyond merely informing stakeholders, we also recognize that most assessors do not have the authority to give stakeholders final decision-making power.

As detailed in this chapter, we recommend at minimum that AA practitioners engage with stakeholders to hear concerns about the chemical of concern, its relevant product or process, and its potential alternatives. There are many methods assessors can use to hear stakeholder concerns including:

- Advisory committees.
- One-on-one meetings.
- Listening sessions.
- Surveys.
- Public comment periods.
- Review interviews, surveys, community-based research, or other literature produced by or about a specific stakeholder.

As an example, advisory committees have been used in AAs conducted by EPA a part of their Design for the Environment program (Appendix: EPA DfE Program Stakeholder Engagement). Although stakeholders are not explicitly included when selecting the chemical of concern or as part of the final decision-making process, they are involved in all aspects of AA research.

The Guide does not recommend one engagement method over others. Depending on the level of engagement the assessor can commit to, the current stage within the AA process, and who the assessor is engaging with, different engagement methods may be more effective. Assessors may be able to get advice on appropriate methods from trusted community members or outreach specialists. Whatever methods are used to engage with stakeholders should be documented in the AA.

Engagement Process

To help assessors engage with stakeholders through the AA process, we have created a stepwise approach. We recommend that assessors review these steps as early as possible in the process, ideally before a chemical of concern is identified.

1. Identify key stakeholders. This list can be updated throughout the AA process.

- If a chemical of concern has not been chosen, prioritize communities that are currently or were recently disproportionately impacted by chemical manufacturing, use, or disposal.
- If a chemical of concern has been selected, use a life cycle thinking model to identify potential stakeholders. When considering the full life cycle of a chemical of concern, consider EJ groups, community representatives and other stakeholders associated with manufacturing, transport, storage, and product use and disposal.

2. Develop a stakeholder engagement strategy. The strategy should address the following questions:
   - What are the outreach and engagement goals for the AA?
   - What resources, such as staff, money, and time, can be committed to stakeholder engagement?
   - What are the anticipated accomplishments of the AA? How might they be acted upon?
   - What role will stakeholders be allowed to play in the AA process? Will they only be asked for input or will they be able to make decisions? Will some stakeholders have more opportunities to participate than others, such as on an advisory board?

3. Contact potential stakeholders. Often, this will entail identifying and building relationships with groups or individuals who are trusted within a broader stakeholder group. These individuals can help the AA assessor understand the needs of the stakeholder group, including what resources would support specific stakeholder group engagement.

4. Seek input on how stakeholders are affected by the chemical of concern and potential alternatives. Pertinent stakeholders should be approached to understand their perspectives and to consider those perspectives in the evaluation of alternatives.
   - Approaches for soliciting input could include interviews, questionnaires, scoping discussions, or similar means.
   - The approach chosen will depend on the stakeholder and his or her level of knowledge relative to the product or process under evaluation. Consider what additional resources are needed to remove barriers to participation.
   - Whenever possible, provide opportunities for stakeholders to give additional input.
   - If stakeholders cannot be engaged with, document the reason why. Seek out research or other literature from trusted sources that document potential concerns from these stakeholders.

5. Use input to identify potential concerns for evaluation.
   - Have those concerns been validated for the chemical, product, or process under evaluation?

- If yes, mark the appropriate place within the AA where these concerns should be included. Continue the evaluation.
- If no, document the decision reached and the information used to reach the conclusion. Continue the evaluation.

6. Can the concerns identified be addressed or mitigated?
   - If yes, list actions taken to address these concerns and document how these actions will eliminate or mitigate concerns. Present actions to stakeholders for review and comment. Continue the evaluation.
   - If no, document the decision reached and the information used to reach the conclusion. Continue the evaluation.

7. Are any of the concerns identified serious enough to identify the alternative as unfavorable? The rationale for this conclusion must be documented and accessible to stakeholders. For example, did stakeholders identify a critical performance requirement that the alternative did not meet or a new exposure route that indicates individuals at one or more stages of the alternative life cycle would experience negative health impacts?
   - If yes, have these conclusions been offered for stakeholder review and comment and do the stakeholders concur?
     - If yes, document information used to reach the conclusion and the results of the stakeholder review and comment. Continue the evaluation.
     - If no, document the reasons for failure to accept stakeholder input and make it available to stakeholders. Continue the evaluation.
   - If no, continue evaluation.

8. Did stakeholders raise other considerations that should be included in the AA? Examples could include other potential alternatives to assess or information about an alternative's performance or availability.
   - If yes, have these conclusions been offered for stakeholder review and comment and do the stakeholders concur?
     - If yes, document information used to reach the conclusion and the results of the stakeholder review and comment. Continue the evaluation.
     - If no, document the reasons for failure to accept stakeholder input and make it available to stakeholders. Continue the evaluation.
   - If no, continue the evaluation.

9. Incorporate stakeholder input into the final decision-making process. Document how and when input influenced decisions.

Resources

National Resource Defense Council: The paper "Selecting Safer Alternatives to Toxic Chemicals and Ensuring the Protection of the Most Vulnerable." was written to address gaps in the AA process that negatively impact marginalized or disproportionately impacted people. Recommendations are included to help assessors conduct more genuine stakeholder engagement and transparently account for different trade-offs made in the AA.

Agency for Toxic Substances and Disease Registry (ATDSR): EJ Index is a census tract-based mapping tool that ranks the cumulative impacts of environmental injustice on health based on 36 environmental, social, and health factors (many overlapping with EJScreen factors), grouped into 3 overarching modules and 10 different domains.

EPA: EJScreen is a mapping tool that may help users identify areas with potential environmental quality issues related to 13 EJ indexes. The mappable indices and indicators include PM2.5, ozone, diesel PM, air toxics cancer risk, air toxics respiratory hazard index, toxic releases to air, traffic proximity, heart disease, asthma, cancer, and more.

Council on Environmental Quality: Climate and Economic Justice Screening Tool is a census tract-based mapping tool of indicators in 8 categories: climate change, energy, health, housing, legacy pollution, transportation, water and wastewater, and workforce development. The tool aims to identify "disadvantaged communities" although race is not factored into this tool's definition of "disadvantaged."

Appendix: EPA DfE Program Stakeholder Engagement

When the program conducted AAs, EPA's Design for the Environment Program included an extensive stakeholder engagement process as an integral part of identifying and assessing alternatives for chemicals of concern. "Convening stakeholders" was the third step in DfE's process, after determining the feasibility and collecting information on chemical alternatives.

DfE used input from many perspectives to inform the project scope, identify alternatives, and facilitate manufacturer and user adoption of safer chemicals. Stakeholders were drawn from the entire supply chain and all life cycle stages of the chemical of concern. Involvement throughout the project helped to ensure that stakeholders contributed to, understood and supported the outcome, enhanced credibility, and promoted the adoption of the safer alternatives.

Typical stakeholders included:

- Chemical manufacturers
- Product manufacturers
- Non-governmental organizations
- Government agencies
- Academics
- Retailers
- Consumers
- Waste and recycling companies
- Chemical and technology innovators

DfE began an AA by convening all interested stakeholders in a face-to-face meeting where issues were discussed and interested parties provided input on the scope. Once the scope was clarified, stakeholder committees were formed to provide guidance to DfE. Stakeholder committees included a Steering Committee, which helped oversee progress, a Technical Committee to provide information on potential alternatives, etc. Completed AA sections were released to stakeholders for review and comment.

Through literature review and discussion with stakeholders, DfE collected information about viability on a range of potential alternatives. They focused on finding alternatives that were functional with minimum disruption to the manufacturing process. To identify the most likely alternatives, DfE also included viability demonstrations by chemical and product manufacturers.

Once the hazard assessment was completed, DfE prepared a report containing the AA results to inform stakeholders, the public, and decision makers. The report provided contextual and supplemental information designed to aid in decision-making and could include descriptions of manufacturing processes, use patterns, and life cycle stages that might have posed special exposure concerns. The report could also contain a description of the cost of use and the potential economic impacts associated with alternative selection and information on alternative technologies that might have resulted in safer chemicals, manufacturing processes, and practices.

Structuring the Alternatives Assessment (Frameworks and Decision Making)

This chapter describes how to structure an AA such that the assessor can identify preferred alternatives through a distinctive process that is transparent to an outside observer. When choosing a structure for an AA, the assessor must consider what defines a preferred alternative and the boundaries of the assessment scope. Two organizations seeking alternatives for the same chemical in the same product or process may structure their AAs differently to accommodate different priorities.

While this chapter is designed to allow assessors to incorporate their organization's priorities, all the AA structures described here will prioritize identifying alternatives that:

- Pose less of a health concern than the chemical of concern.
- Pose less of an environmental or ecological concern than the chemical of concern.
- Either perform as effectively as the chemical of concern or meet identified performance requirements.
- Meet some baseline of economic viability.

The broad structure of an AA is imposed by a framework, which provides a clear process to collect and compare large amounts of data, and a decision method, which provides a structure for analyzing data and selecting preferred alternatives. A separate decision method may not be needed if the selected framework has a decision method built-in. Three frameworks and three decision methods are included in this chapter.

This chapter also discusses how an assessor can identify a preliminary list of decision criteria, which are the considerations that will be used to select a preferrable alternative. An assessor can use this list of decision criteria along with project scope information to select individual evaluation modules. Those modules are then inserted within the selected framework and decision method.

Finally, the chapter includes a brief discussion on concluding an AA. Because the ultimate purpose of AAs is to support the replacement of toxic chemicals in products with safer alternatives, it is important that an AA include concluding remarks. In these remarks, assessors can acknowledge points of uncertainty within their analysis, discuss potential alternatives that could be preferred alternatives with slight alterations, or identify potential places for future alternative improvement.

Introduction to the AA Structure

All AAs use the same general structure, which is outlined here as a five-step process. Based on the responses to the questions in each step in the process, the assessor can identify appropriate decision criteria, frameworks, and decision methods for their AA. The assessor should consult with whoever will implement the findings of the AA in steps one and two, to increase the likelihood that preferred alternatives will be adopted.

1. *Define the issue* –What decision will be made based on the assessment? Who will make the decision? How will the decision be implemented?
    - Will the AA identify one preferred alternative, rank all alternatives from most to least preferred, or list any and all alternatives that are found to be good enough?
    - Is this assessment seeking an alternative for a specific business? Or is this an assessment intended to find any alternatives available to an industry?
2. *Identify the decision criteria* – How will the assessment identify preferred alternatives? Which modules, at which levels, will be used to evaluate alternatives?
    - What would make an alternative preferable to what is currently used? What characteristics are most important for an alternative to have?
    - Four modules are recommended at minimum. Do those modules account for all the characteristics identified or are more needed?
    - What level of uncertainty is acceptable for each characteristic? Does that influence the level selected for each evaluation module?
    - What trade-offs are acceptable to the decision makers?
3. *Identify the decision-making framework and decision method* – How will data be collected and used to evaluate and select preferred alternatives?
    - What resources are available to conduct the AA? What is the limiting resource?
    - How big is the pool of potential alternatives? Will the AA need a mechanism to prioritize some alternatives over others?
    - Does the relative priority of the decision criteria, or the number of decision criteria, indicate anything about the best AA framework?
4. *Collect information regarding the criteria* – Is qualitative and/or quantitative data available for each selected module that address decision criteria?
    - What is the quality of the data?
    - Are there criteria where data is missing for some or all of the alternatives?
5. *Compare the alternatives to the original chemical of concern*. Is there an alternative that meets all the decision criteria?
    - Does changing the relative weight of the criteria change whether a preferable alternative is identified?
    - Is there at least one alternative that meets the minimum decision criteria recommended in the Guide?

Role of Stakeholder Engagement

The Stakeholder Engagement chapter discusses ways to identify and engage with individuals or communities that may have an interest in the outcome of an AA. Stakeholders can contribute at all steps of the AA process, including identifying candidate chemicals of concern before an AA begins.

In some AAs, assessors may include stakeholders during conversations about AA structure and even allow stakeholders to decide how decisions will be made. In other cases, issues of legal or other decision-making authority may prevent this type of engagement. Assessors are encouraged to include stakeholders in the structuring process whenever possible. Stakeholders have valuable contributions to all elements of this process.

Assessors usually talk to stakeholders when collecting information regarding decision criteria (step four). We also strongly encourage assessors to talk to stakeholders when identifying and prioritizing decision criteria (step two). Because stakeholders have often interacted with the chemical of concern or the relevant product or process, they often have insight into what characteristics an alternative will need to be a successful replacement. Stakeholders may also be involved in substituting alternatives, so considering their input early in the process increases the likelihood safer alternatives are adopted.

How have you addressed equity and environmental justice?

Involving stakeholders from likely affected EJ communities in the decision-making process promotes transparency and can help prevent environmental injustices. These perspectives can provide valuable insights into solutions and the potential social and environmental consequences of decisions that may not be apparent to those charged with making decisions. Refer to the Stakeholder Engagement chapter to guide how to best seek their input.

Document how environmental justice considerations were incorporated into the decision criteria and explain how these considerations ultimately influenced the decision-making process. Integrating environmental justice into the decision criteria and making the process transparent helps to ensure that environmental justice considerations are not only acknowledged but actively addressed in the AA.

Choosing Decision Criteria and Evaluation Modules

The goal of an AA is to select at least one alternative that is preferrable to a chemical of concern. As part of the AA process, an assessor must decide what the characteristics of a preferred alternative are. In this chapter any characteristics that will be used in the AA to identify a preferred alternative are referred to as decision criteria.

Identifying and Prioritizing Decision Criteria

At minimum, all AAs should include the following decision criteria to identify a preferred alternative:

- Poses less of a health, environmental, or ecological concern than the chemical of concern.
- Meets identified performance requirements.
- Is obtainable or can be manufactured within a reasonable timeframe.

The minimum decision criteria could be modified to be more specific or stringent. Some examples include:

- Is not a known asthma-causing agent.
- Meets an established technical performance standard used within the industry.
- Can be purchased for an amount that falls within some specified monetary range.

Additional desired characteristics could also lead to new criteria not included in the minimum, such as choosing an alternative that requires less energy to create or has a smaller carbon footprint. Other examples of decision criteria are found in Appendix B: Initial Screen for Decision Methods.

Once these criteria are identified, the assessor should attempt to establish the relative weight of the different characteristics. The assessor should first consider what the highest priority is for their assessment. Though not required, AA practitioners are strongly encouraged prioritize identifying alternatives that pose the lowest health concerns.

Next, the assessor should attempt to establish the relative priority of the other criteria. If there is no alternative that meets all the criteria, what are acceptable trade-offs? What characteristics are nice-to-have but not necessary to continue to provide the same service within a society as the current product or process? Relative prioritization might change during the AA process, especially if the issue being addressed by the AA is not well-defined. However, as a reminder, trade-offs should not lead to accepting an alternative that does not meet the minimum criteria.

Finally, the assessor may wish to consider if any additional decision criteria could benefit AA implementation by encouraging the adoption of preferred alternatives. These decision criteria may not influence alternative selection or may be low-priority decision criteria. However, if they are included in the AA process then the assessor can efficiently collect information to support implementation during the evaluation process.

How have you addressed equity and environmental justice?

Ask: Who is determining and defining the relative weight of each criterion? Who is being prioritized? Are there other perspectives that are missing? For example, do the weighting criteria prioritize financial benefits to manufacturers over the benefits to those that have been disproportionately impacted by the chemical of concern? Do the weighting criteria favor cost over potentially transformative new solutions that would benefit fenceline communities?

Selecting Evaluation Modules

All AA frameworks should incorporate evaluation modules. Each module in this guide contains decision criteria that enable separation of the potential alternatives into "bins:" favorable, less favorable, unfavorable, or unknown and therefore unfavorable for that specific module. Within each module, different levels describe slightly different methods that will be used to address the chosen decision criteria. Although assessors decide which modules to use and at what level, the Guide does include minimum recommendations.

The assessor should consider their decision criteria hierarchy when deciding whether to use a module and at what level. Higher levels in a module typically require more resources, expertise, and access to information. A higher priority criterion could indicate that a higher level in the relevant evaluation module would be useful. For example, if one decision criterion is to identify alternatives that adequately perform on a specific American Society for Testing and Materials (ASTM) performance test, then the assessor should select a Performance Evaluation Module Level that uses industry performance tests.

When choosing what level to use for a module, the assessor should also consider how acceptable uncertainty will be for each decision criterion.

Because decision criteria will vary among organizations, the evaluation modules selected for an AA may also vary. The thought process used, including all assumptions and rationales, must be explicit so decisions made can be clearly understood by all readers. The AA process should not be used to justify the continued use of chemicals of concern but rather to search for safer alternatives.

Selecting a Framework

AA frameworks impose a stepwise process on the evaluation of alternatives. They help the assessor compare large amounts of sometimes conflicting data and select preferred alternatives. We describe three commonly used frameworks in this chapter, although others exist. Assessors should employ the framework that gives the most robust, dependable results based on their decision-making needs.

- **Sequential**: Selected evaluation modules are applied in a set order one at a time. Any potential alternatives deemed unfavorable in a module are progressively "screened out." Only the most favorable alternatives proceed to the next module.
- **Simultaneous**: Data from all selected modules are evaluated simultaneously for all potential alternatives. Once the data are collected, the potential alternatives are compared simultaneously using a selected decision method.
- **Hybrid**: Select fundamental evaluation modules (minimally including Hazard Evaluation) are first performed sequentially, with unfavorable alternatives screened out. Data from remaining modules may then be evaluated simultaneously.

Although it is possible to change AA frameworks during the AA process, we strongly encourage assessors to carefully choose a framework based on the anticipated needs of the AA. Some elements of an AA that can influence framework selection are:

- The resources available for the AA.
- The number of potential alternatives the AA is likely to evaluate.
- The decision criteria that will likely be used to select alternatives.
- The decision method that will be used to select alternatives.

The influence of resources, staff, and time will not be discussed in detail in this guide. It is up to the assessor to think carefully about how resources and project timelines will impact what types of evaluation and decision-making can be accomplished in the AA. For example, if an assessor believes there will be many potential alternatives to evaluate but resources are limited, then the sequential framework can help quickly narrow down options.

Alternatively, if there are few alternatives and the evaluation modules are not resource intensive to perform, the simultaneous framework will give the assessor the most data to make a decision. This framework can also be helpful for an organization that strongly prioritizes a decision criterion that is not one of the minimum recommendations, like maximizing ingredient sustainability. In that example, the simultaneous framework would enable the assessor to collect information the sustainability of all alternatives during a life cycle assessment and then look for sustainable alternatives that meet other criteria during the final evaluation.

Minimum Requirements for All Frameworks

We recommend certain evaluation modules be included in any of the AA frameworks to ensure the baseline decision criteria will be met. The following four evaluation modules should be included in all AAs.

1. Hazard (Hazard Module).
2. Performance (Performance Evaluation Module).

3. Cost and Availability (Cost and Availability Module).
4. Exposure (Exposure Assessment Module).

The lowest level recommended should be used for these evaluation modules at minimum. Several modules have an initial screen built in that may be used before initiating the AA or completing the evaluation module. These preliminary screens are not sufficient to meet the minimum requirements.

How have you addressed equity and environmental justice?

How might the structure of the AA impact the examination of environmental justice? For example, if a cost analysis is performed first in a sequential framework, which may not account for life cycle thinking, assessors may exclude more transformative alternatives that could have tremendous long-term benefits and offset large negative external costs to EJ communities. Document the justification for using a specific framework so that others can understand how environmental justice concerns were examined in the AA process.

Sequential Framework

The sequential framework evaluates alternatives in a specific order that prioritizes assessing those alternatives that have reduced hazards and meet baseline performance requirements. Alternatives that fail a module are not considered further unless no preferred alternatives are identified. By removing alternatives that have clearly identified concerns, AA practitioners can conserve limited resources and prioritize potentially favorable alternatives for further evaluation.

Several modules include an initial screen that may be used to quickly eliminate alternatives that have clear, serious concerns. For example, the Hazard Module includes a screening method that compares alternatives against lists of known toxic chemicals. More information on screening opportunities is found in each individual module.

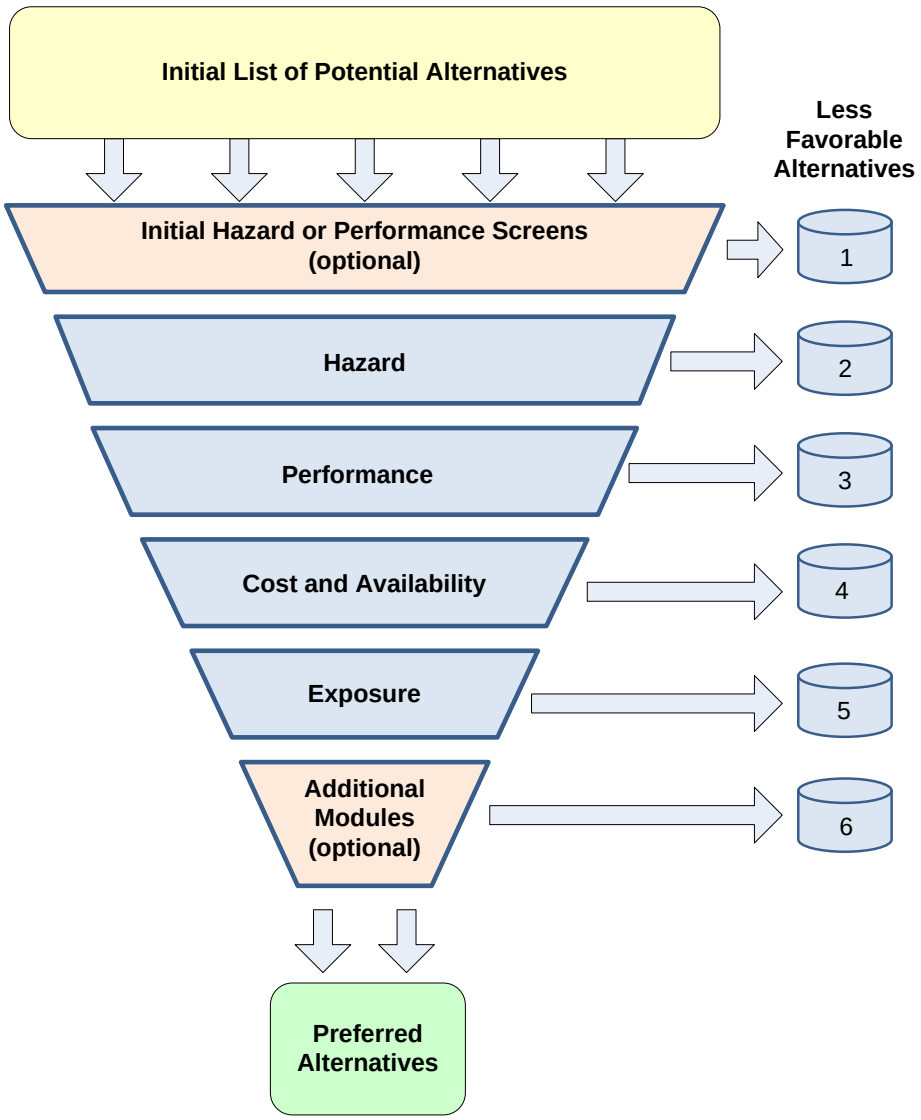
Assessors should use the specific module order listed in the minimum requirements in the sequential framework. The Hazard Module is implemented first to ensure that only alternatives with reduced hazards continue with the assessment process.

Favorable alternatives identified in the Hazard Module are then evaluated using the Performance Evaluation Module. Those alternatives with acceptable performance are then evaluated in the Cost and Availability Module. Any remaining alternatives are then evaluated in the Exposure Assessment Module.

Once the minimum recommended evaluations are complete, additional modules may be selected and implemented. If successful, the alternative or alternatives identified at the end

of the process are the preferred alternatives based upon the combined assessment. This process is shown in **Figure 5**.

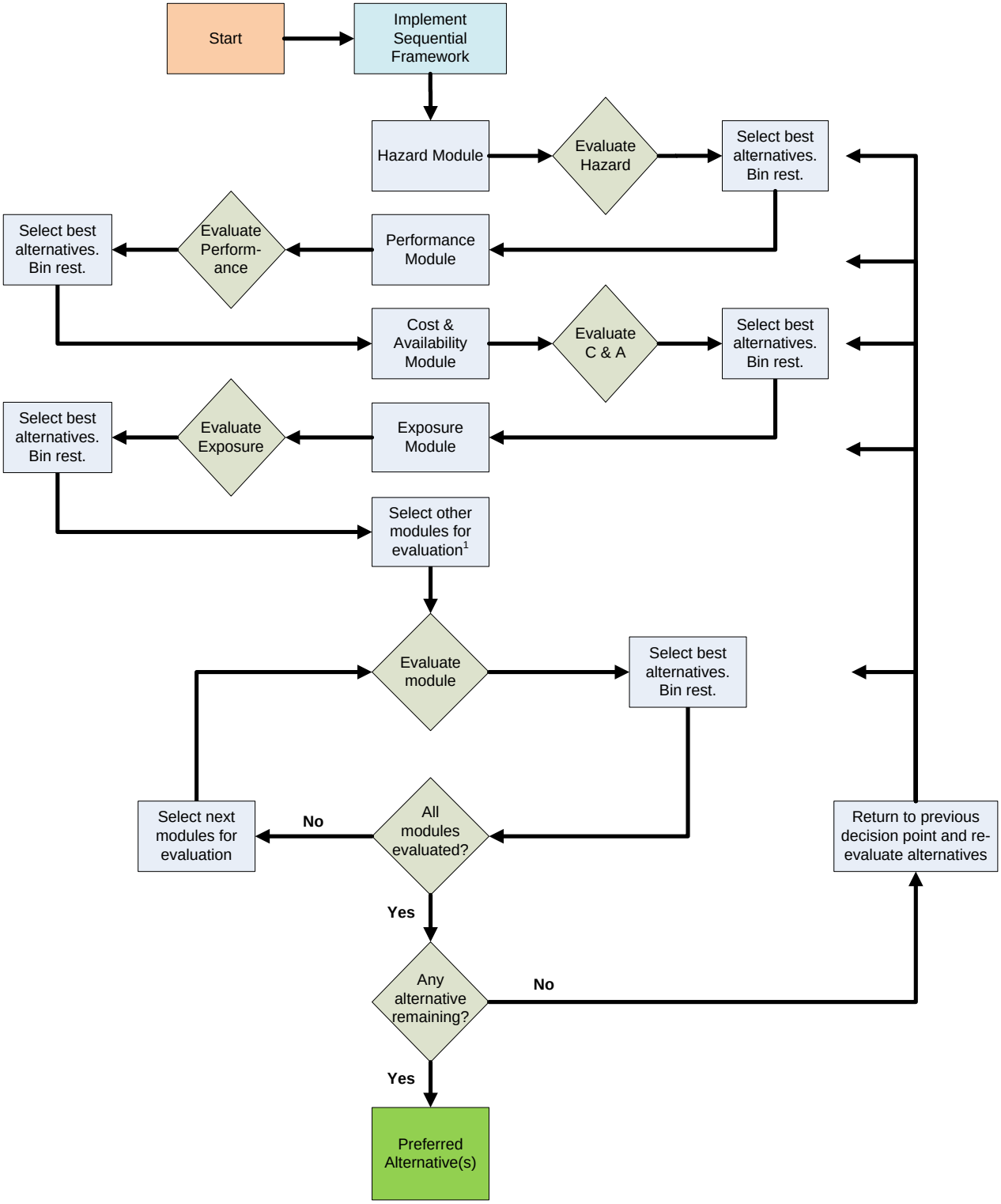
Figure 5: Sequential Framework.



If no preferred alternatives are identified, then the assessor can revisit the evaluation modules in reverse order to see if any binned alternatives are acceptable with further review (

Figure 6). When revisiting a module, the assessor should reconsider whether any alternatives that were identified as less favorable could in fact meet the decision criteria used in the module. If the assessor agrees with the previous decision that they cannot, the decision and reasoning is documented and the assessor steps back to the previous module assessment. The process continues until a favorable alternative is identified or all alternatives have been eliminated from consideration.

Figure 6: Process Diagram for the Sequential Framework.



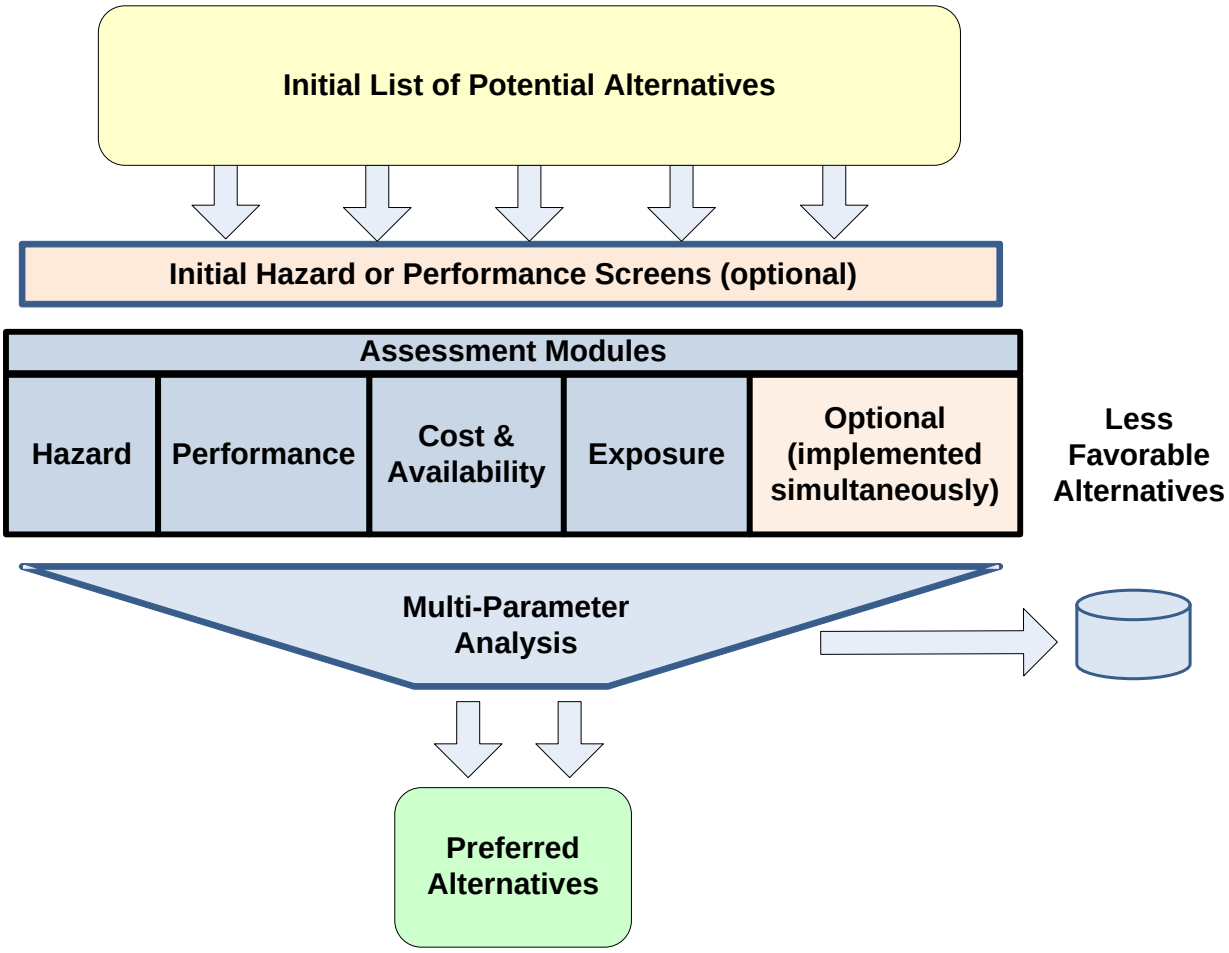
[1] The modules that remain are Stakeholder, Materials Management, Social Impact and Life-cycle. The user may select the modules, their order and the level of complexity for a specific alternatives assessment. This decision process should be documented.

If the Sequential Framework is selected, the assessor may not need an additional decision method since the Sequential Framework applies a specific form of an iterative decision method. In many cases, an AA that uses Sequential Framework will produce a single preferred alternative.

Simultaneous Framework

In the Simultaneous Framework, data from all selected modules are evaluated simultaneously for all potential alternatives (**Figure 7**). A decision method is then used to identify preferred alternatives (Appendix A: Decision Methods). The Simultaneous Framework provides a great deal of flexibility to the assessor and allows an AA to be tailored to address a specific product or process under evaluation.

Figure 7: Simultaneous Framework.



The four modules recommended as minimum requirements should be included in the Simultaneous Framework. Selection of additional modules and the degree of evaluation within each module is left to the assessor but must be documented and justified prior to implementation. Module order in this framework is assumed to be unimportant.

We recommend using the preliminary decision criteria to help choose evaluation modules and a decision method. Depending upon the decision method (Appendix A) selected, it may be necessary to also conduct an Initial Screen (Appendix B) to determine which criteria should be included as endpoints in the decision process. These decisions must be documented and explained.

Once the endpoints have been determined, all alternatives are evaluated by all selected modules. Once the data has been collected on all the alternatives for all modules, a comparison is made against all endpoints to determine the optimal alternative.

Analysis of all the data generated in the Simultaneous Framework can be challenging. Prioritizing various trade-offs is an important consideration as data gaps are identified. Numerous decision methods exist that can assist this process. More information on the methods is found in Decision Methods (Appendix A).

Regardless, the assessor will need to prioritize which criteria may be the most important. The relative weight placed on the results from specific modules used in the assessment should reflect the relative weight of the different decision criteria.

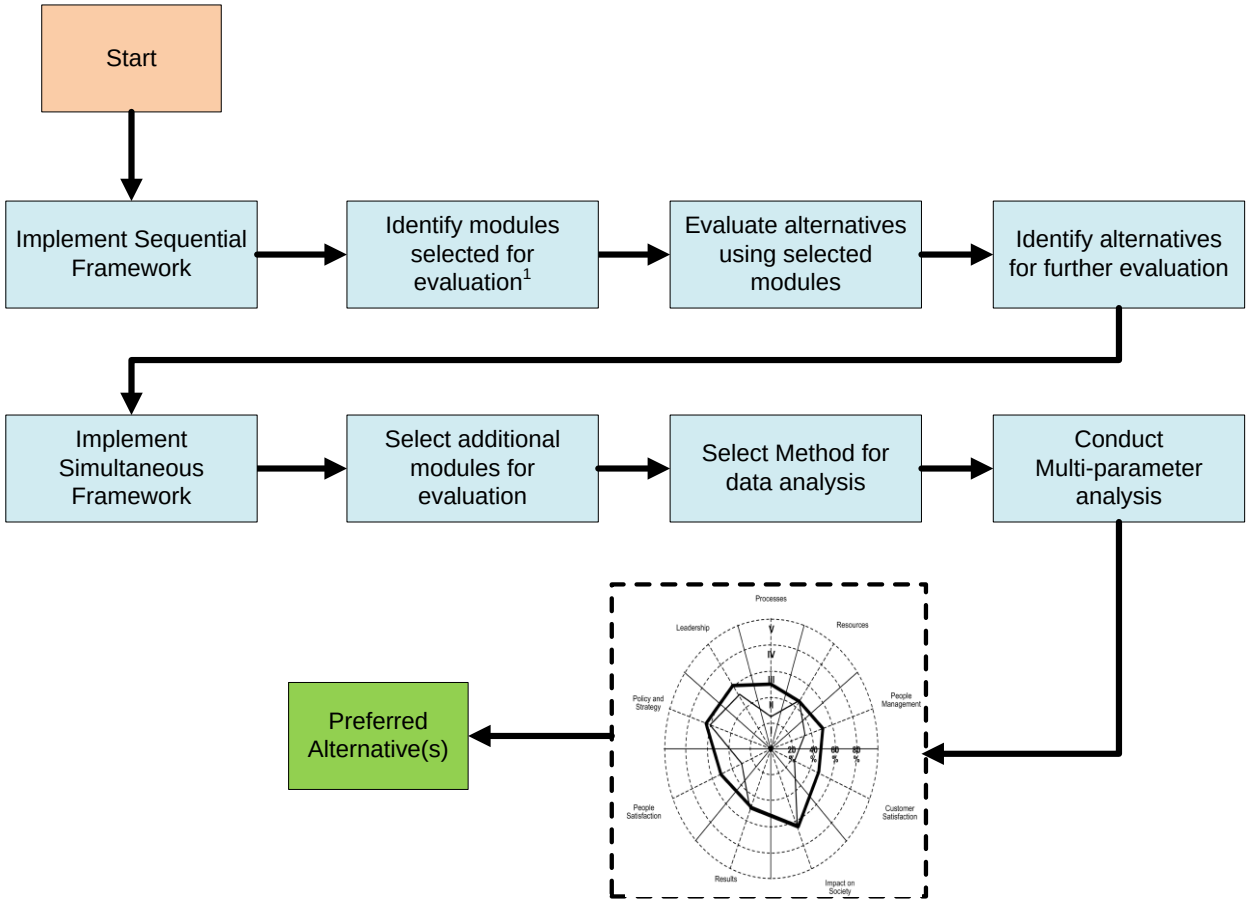
For example, two alternatives may have the same degree of reduced toxicity and exposure. However, when the life cycle module and performance modules are factored into the decision, one alternative is found to have higher energy consumption but better performance while the other has decreased performance but significantly reduced energy consumption. The decision methodology will have to identify which of considerations is of a higher concern to differentiate the two alternatives. Regardless of the decision method used, all decisions need to be documented and explained.

Hybrid Framework

The Hybrid Framework (**Figure** 8) consists of a combination of the Sequential and Simultaneous decision approaches. In the Hybrid Framework, the alternatives are first prioritized using the Sequential Framework. The point at which the process stops is left to the assessor. At a minimum, the first module (Hazard) is recommended for the sequential portion of this framework.

Once the alternatives have been prioritized using the Sequential Framework, the most favorable alternatives are subjected to the Simultaneous Framework. Assessors should use the preliminary decision criteria to help choose additional evaluation modules and a decision method for this part. Depending upon the decision method selected (Appendix A), it may be necessary to conduct an Initial Screen (Appendix B) to determine which criteria should be included as endpoints in the decision process. These decisions must be documented and explained.

Figure 8: Process Diagram of the Hybrid Framework.



[1] The sequential approach must be implemented at least through the Hazard Module. Any evaluation after the Hazard Module may be subjected to the Multi-attribute approach.

Once the endpoints have been determined, if appropriate, all alternatives are evaluated by all selected modules. The data from these remaining modules are evaluated using one of the three decision methods and the most favorable alternatives are selected. The relative weight placed on results from specific modules used in the Simultaneous Framework must reflect the values identified previously. Analysis of all data can be challenging, and prioritization of trade-offs is an important consideration. As with the Simultaneous Framework, all decisions must be transparent and documented including the weights and priorities assigned to the different criteria and the justification for these decisions.

Selecting a Decision Method

Decision-making is the final step in the AA process. During decision-making, the assessor will take data from each evaluation module that was used during the AA and use that data to identify acceptable alternatives. At minimum, this process will consist of passing or

failing an alternative after comparing it to some standard of acceptability developed from each decision criterion and the relevant evaluation module. As decision-making increases in complexity, it can require creating carefully weighted scores for each alternative and the original formulation so that they can be compared. For most AAs, decision-making will also require some uncertainty analysis.

Several methods exist to address complex decisions where many decision criteria have been identified. Complex decisions can be broken down into more manageable decisions in which pairs of criteria are compared in a stepwise fashion. The criteria are then aggregated and these groups of criteria are compared with each other. In other applications, large numbers of criteria are compared simultaneously in a multi-criteria analysis. The Guide includes three methods:

- **Simple Comparison:** The assessor uses only those decision criteria where there is a clear distinction between the chemical of concern and the alternatives to identify any clearly superior alternatives. If multiple alternatives are clearly superior, the assessor can apply the remaining decision criteria to select a preferred alternative, if desired.
- **Iterative Comparison:** The assessor evaluates each alternative using each evaluation module or decision criteria in a stepwise manner. Alternatives are first evaluated using the highest-priority criterion. Alternatives that meet that criterion are then evaluated using the second highest-priority criterion, and so on until no criteria remain or only one alternative is left.
- **Simultaneous Comparison:** The assessor uses multiparameter analysis to evaluate all data simultaneously. Weight is applied to different criteria based on determined priority.

These options are described in more detail in Appendix A.

Influence of Decision Criteria on Decision Method Choice

The comparison step can be straightforward when only the minimum decision criteria are used. If the goal is to identify alternatives that have these characteristics, then the assessor will likely use the iterative or simple comparison methods. The comparison quickly becomes complex when comparing options with a range of pros and cons based on many criteria or if the assessor wishes to create a ranked list of all alternatives.

Typically, when comparing more than a very few simple criteria, the assessor will establish some form of hierarchy among the relevant criteria. Any preliminary discussions of acceptable trade-offs that occurred when the decision criteria were identified will be helpful when establishing this hierarchy. Although the ranking of criteria can be inherent in the process, transparency requires an explicit discussion of how and why the different

criteria rank in importance to the decision and whether this ranking reflects the values of the decision-maker and concerned stakeholders.

To select a decision method, consider the number of decision criteria identified and their relative priorities within the assessment. If there are only a few criteria and they all are of similar priority when identifying alternatives, then the Simple or Iterative Methods might be adequate. If the criteria have a clear hierarchy, then the Iterative Method can be used. If the relative priority is unclear, then the Simultaneous Method will allow the assessor to perform a sensitivity analysis to see which decision criteria most influence the ranked list.

Documenting Outcomes and Conclusions

The final step of the AA process is to summarize AA findings and recommendations. Any preferred alternatives should be listed here along with the rationale for their selection. This section should also be used to document other key findings that would be useful when implementing the findings of the AA, or if further research or a follow-up assessment is needed to find preferrable alternatives.

Some AAs identify alternatives that will be acceptable to some product or process users, but not all. These alternatives are often changes in the products or processes that individuals or companies could achieve but that might not be practical for an entire market to adopt. They can also be potentially transformative options that provide the same service but with a dramatically different product or process. Documenting these alternatives will help promote the adoption of safer alternatives by providing diverse substitution options.

For example, WA DOE performed an assessment of alternatives to PFAS in single-use food service items. In their AA, Washington concluded that switching to reusable food service items like reusable trays was a preferred alternative for some restaurants and cafeterias. However, this option could not work for businesses that could not clean service items. Washington highlighted this alternative in their AA conclusions so that organizations that could use reusable items would consider it as an option.

In other AAs, no safer alternatives are identified even when only the minimum decision criteria are used. When that occurs, it is very likely that another AA will be needed to look at new research or new alternatives. To support that future work, the conclusions of the current AA can identify which criteria most alternatives failed and why. This information could directly inform a plan to conduct research and development or to continue searching for a safer alternative. The conclusion could also mention exposure controls that should be used until safer alternatives are identified.

Finally, the conclusions can also highlight improvements to preferred alternatives that would make them less hazardous or easier to use. These conclusions can be used to identify

opportunities to improve alternatives and accelerate the substitution of hazardous materials through green research and development.

How have you addressed equity and environmental justice?

Have you documented findings that can be used to support environmental justice? In several evaluation modules, assessors are asked to document information about alternatives that would be useful for future work. Future work could include both research to improve the safety or performance of alternatives and actions that organizations could take to support the implementation of safer or transformative alternatives. Assessors should include this information in their concluding remarks, to increase the likelihood others will act upon the findings.

Appendix A: Decision Methods

Simple Comparison Method

This 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.

1. To optimize risk reduction, compare the human health and environmental hazards and exposure routes associated with the product and the proposed alternative.
    - Identify the potential hazards associated with the original product and its alternatives and identify the relevant criteria.
        - Do any of the potential hazards affect human health?
            - If yes, document information used to reach the conclusion and include hazards as relevant criteria. Continue the evaluation.
        - Do any of the potential hazards affect the environment or nonhuman receptors? This includes impacts to water, air, soil, etc.
            - If yes, document information used to reach the conclusion and include environmental and ecological hazards as relevant criteria. Continue the evaluation.
        - Do any of the potential hazards impact the effectiveness of the product or alternatives?
            - If yes, document information used to reach the conclusion and include effectiveness as a relevant criterion. Continue the evaluation.

        - If no to all of the above, identify the information used to reach the conclusion and identify that hazard is not a discriminating decision criterion in this assessment.

- Identify the potential exposure associated with the original product and its alternatives and identify the relevant criteria.
    - Do any of the potential impacts affect human exposure?
        - If yes, document information used to reach the conclusion and include exposure as relevant criteria.
    - Do any of the potential impacts affect the environment or exposure to nonhuman receptors?
        - If yes, document information used to reach the conclusion and include environmental and ecological impacts as relevant criteria.
    - Do any of the potential impacts involve effectiveness of the product or alternatives?
        - If yes, document information used to reach the conclusion and include effectiveness as a relevant criterion. Continue the evaluation.
        - If no to all of above, document the information used to reach this conclusion and identify that hazard is not a discriminating decision criterion in this assessment. Continue the evaluation.

2. Quantify the values of the relevant criteria for each of the alternatives.
    - Is quantitative information available for the criteria values?
        - If yes, document the available information. Continue the evaluation.
        - If no, document the information is not available and identify the criteria as unknown. Continue the evaluation.
    - Is qualitative information available for the criteria values?
        - If yes, document the available information.
        - If no, can the information be generated through modeling? If yes, document available information. Continue the evaluation.

3. Create a matrix depicting the relevant criteria, the chemical of concern and alternatives, including the values for the criteria.
    - Are any of the alternatives inferior to the chemical of concern regarding health and exposure?
        - If yes, document information used to reach the conclusion. Exclude these alternatives from further consideration.
        - If no, continue the evaluation.
    - Are any of the alternatives superior to the original condition regarding health and exposure?

    - If yes, document information used to reach the conclusion. These alternatives should be preferred over the chemical of concern.
    - If no, these alternatives should remain under consideration.
- Are any of the alternatives inferior to the chemical of concern regarding environmental and ecological impacts?
    - If yes, document information used to reach the conclusion. These alternatives may be excluded from further consideration.
    - If no, these alternatives should remain under consideration.
- Are any of the alternatives superior to the chemical of concern regarding environmental and ecological impacts?
    - If yes, document information used to reach the conclusion. These alternatives should be preferred over the chemical of concern.
    - If no, these alternatives may remain under consideration.
- Are any of the alternatives inferior to the chemical of concern regarding effectiveness?
    - If yes, document information used to reach the conclusion. These alternatives may be excluded from further consideration.
    - If no, these alternatives should remain under consideration.
- Are any of the alternatives superior to the chemical of concern regarding effectiveness?
    - If yes, document information used to reach the conclusion. These alternatives should be preferred over the original.
    - If no, these alternatives may remain under consideration.

4. Identify any alternatives that are clearly superior or inferior to the original chemical or product.
    - Are any of the alternatives superior with regard to all three of the guiding criteria of health and exposure, environmental and ecological impacts, or effectiveness?
        - If yes, the alternative is clearly superior to the original and may be eligible for selection. Document information used to reach the conclusion and proceed with assessment.
        - If no, are any of the alternatives superior or neutral with regard to the three guiding criteria of health and exposure, environmental and ecological impacts, or effectiveness?
            - If yes, such an alternative is superior to the original and may be eligible for selection. Document information used to reach the conclusion and proceed with assessment.
            - If no, then all of the alternatives are inferior and may be rejected.

5. For those alternatives that pass the previous criteria, are there any additional concerns identified in the remaining criteria in the AA method? Create a matrix depicting the relevant criteria, the chemical of concern, and alternatives, including the values for the criteria.
    - Are any of the alternatives superior regarding social impact, life cycle, material flow management, cost and availability for any data evaluated?
        - If yes, such an alternative is superior to the original and may be eligible for selection. Document information used to reach the conclusion and proceed with assessment.
        - If no, are any of the alternatives neither superior nor inferior regarding the remaining criteria?
            - If yes, alternative may be considered equivalent to original and may be eligible for selection. Document the information used to reach the conclusion and continue evaluation.
            - If no, all alternatives are inferior and may be rejected. Continue the evaluation.

6. Uncertainty Analysis:
    - Is any important information missing from any stage of this evaluation?
        - If yes, can anything be done to fill in the data gap?
            - If yes, fill in the data gap and restart the data analysis procedure.
            - If no, document information used to reach the conclusion and indicate that the alternative selected may not be optimal. Additional review may be necessary when new data comes available. Analysis complete.
        - If no, the evaluation is complete.

Iterative Comparison Method

This method describes an iterative comparison of alternatives using a hierarchy of criteria, which have been determined by the assessor, to define preferences among criteria to facilitate comparison. This type of approach is typically used for screening by eliminating those options that do not achieve minimum thresholds for each criterion. If all the alternatives are rejected in an initial analysis, the assessor can adjust the hierarchy of criteria and selected thresholds and reiterate the assessment.

- Conduct an Initial Screen to determine relevant assessment factors (

1. Appendix B: Initial Screen for Decision Methods).

2. Based upon the results of the Initial Screen, quantify the values of the relevant criteria for each of the alternatives. Document the information and rationale used for all determinations.
   - Is quantitative or qualitative information available for the criteria values?
     - If yes, document the available information. Continue the evaluation.
     - If no, can the information be generated through structure analysis or other models?
       - If yes, document the available information. Continue the evaluation.
       - If no, continue the evaluation.

3. Develop a hierarchy of criteria based on assessor values, including, but not limited to: corporate constraints, product limitations, chemical policy ideals, applicable regulations and requirements, available threshold information, and stakeholder input. Document the information and rationale used for all determinations.
   - Rank the criteria in order of importance from highest to lowest.
   - Identify threshold conditions for criteria.
   - Document the information and rationale used to establish criteria preferences and thresholds.

4. Compare criteria values to threshold values for criteria in order of importance, eliminating those alternatives that do not achieve the desired threshold values. Document the information and rationale used for all determinations.
   - Are any alternatives remaining that met all criteria thresholds?
     - If yes, any remaining alternatives should be considered eligible for implementation.
     - If no, excluded alternatives may be re-evaluated beginning with those that failed the least important criteria. If necessary, the assessor may reconsider the criteria hierarchy and or threshold values during the re-evaluation.

5. Uncertainty Analysis:
   - Is any important information missing from any stage of this evaluation?
     - If yes, can anything be done to fill in the data gap?
       - If yes, fill in the data gap and restart the data analysis procedure.
       - If no, document the information used to reach the conclusion and indicate that the alternative selected may not be optimal. Additional review may be necessary if new data comes available. The evaluation is complete.
     - If no, the evaluation is complete.

Simultaneous Comparison Method

This approach 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.

1. Conduct an Initial Screen to determine relevant assessment factors.

2. Based upon the results of the Initial Screen, quantify the values of the relevant criteria for each of the alternatives.
   - Is qualitative or quantitative information available for the criteria values?
     - If yes, document the available information.
     - If no, can the information be generated through structure analysis or other models?
       - If yes, document the available information. Continue the evaluation.
       - If no, document the result and continue the evaluation.

3. Develop or determine relative weights for criteria.
   - Do standardized weighting values exist for identified criteria?
     - If yes, are the standardized weights valid for the situation at hand?
       - If yes, continue the analysis with standardized weights.
       - If no, develop valid weights. Continue the evaluation.
     - If no, continue the evaluation.
   - Are calculated weights appropriate for the criteria and alternatives?
     - If yes, continue the analysis with calculated weights.
     - If no, develop valid weights.
   - Are resources available to employ surveys of experts and stakeholders to derive weights?
     - If yes, develop surveys, derive weights and continue the analysis with derived weights.
     - If no, seek less resource-intensive options.
   - Are other rating models available and appropriate for the analysis?
     - If yes, continue the analysis with modeled weights.
     - If no, develop weights using assessor preferences.

4. Normalize criteria values and apply weights. Employ multi-criteria decision analysis software to evaluate all criteria and alternatives simultaneously.
   - Include sensitivity analysis to evaluate the influence of weighting on the outcome.

5. Uncertainty Analysis:
   - Is any important information missing from any stage of this evaluation?
     - If yes, can anything be done to fill in the data gap?

        - If yes, fill in the data gap and restart the data analysis procedure.
        - If no, document the information used to reach the conclusion and indicate that the alternative selected may not be optimal. Additional review may be necessary when new data comes available. Analysis complete.
    - If no, the evaluation is complete.

Appendix B: Initial Screen for Decision Methods

Identify the potential impacts associated with the original product and its alternatives and identify relevant criteria. Document all the information or assumptions used to include and define criteria.

- Do any of the potential impacts affect water quality?
  - If yes, define and include water quality criteria.
  - If no, identify that water quality is equivalent for the alternatives being assessed and is not a factor in the evaluation.
- Do any of the potential impacts affect air quality?
  - If yes, define and include air quality criteria.
  - If no, identify that air quality impacts are equivalent for the alternatives being assessed and is not a factor in the evaluation.
- Do any of the potential impacts affect soil quality?
  - If yes, define and include soil quality criteria.
  - If no, identify that soil quality is equivalent for the alternatives being assessed and is not a factor in the evaluation.
- Do any of the potential impacts affect greenhouse gas emissions?
  - If yes, define and include greenhouse gas criteria.
  - If no, identify that greenhouse gas emissions are equivalent for the alternatives being assessed and is not a factor in the evaluation.
- Do any of the potential impacts affect life cycle considerations?
  - If yes, define and include life cycle criteria.
  - If no, identify that life cycle considerations are equivalent for the alternatives being assessed and are not a factor in the evaluation.
- Do any of the potential impacts involve effectiveness of the product or alternatives?
  - If yes, define and include effectiveness criteria.
  - If no, identify that effectiveness is equivalent for the alternatives being assessed and is not a factor in the evaluation.
- Do any of the potential impacts affect costs associated with the product or alternatives?
  - If yes, define and include cost criteria.
  - If no, identify that costs are equivalent for the alternatives being assessed and are not a factor in the evaluation.
- Do any of the potential impacts affect social impact considerations?
  - If yes, define and include social impact criteria.

- If no, identify that social impact criteria are equivalent for the alternatives being assessed and are not a factor in the evaluation.

- Do any of the potential impacts affect materials management considerations?
  - If yes, define and include materials management criteria.
  - If no, identify that materials management are equivalent for the alternatives being assessed and are not a factor in the evaluation.

Other Resources

Denmark. Nordic Council of Ministers. *The Use of Decision-aid Methods in the Assessment of Risk Reduction Measures in the Control of Chemicals*. By Dr. Joonas Hokkanen and Dr. Jukka Pellinen. TemaNord 1997:622. Copenhagen: Nordic Council of Ministers, 1997. Print.

Keeney, Ralph H., and Howard Raiffa. *Decisions with Multiple Objectives: Preferences and Value Tradeoffs*. Cambridge, United Kingdom: Cambridge University Press, 1993. Print.

Ralph F. Miles, Jr., and Detlof Von Winterfeldt. *Advances in Decision Analysis: From Foundations to Applications*. Ed. Ward Edwards. New York: Cambridge University Press, 2007. Print.

University of California, Los Angeles, *Sustainable Technology and Policy Program*. *Developing Regulatory Alternatives Analysis Methodologies for the California Green Chemistry Initiative: Final Report.* By Timothy F. Malloy, J.D., Peter J. Sinsheimer, Ph.D., MPH, Ann Blake, Ph.D., and Igor Linkov, Ph.D.

Identifying Alternatives

This chapter describes the process of identifying a list of potential alternatives that will be considered during the AA. Alternatives may include chemical substitutions or alternative materials. Alternatives can also include changing the products or processes to eliminate certain chemicals while providing the same service as the original. Assessors should consider the widest range of possible alternatives that could work to provide a specific service or create a product, including emerging technologies. In subsequent modules, the list of possible alternatives is narrowed based on technical, economic, and health and safety considerations.

This chapter assumes that the chemical of concern is a potential candidate for substitution and cannot be easily removed from a product or process without redesign. If these statements have not been confirmed, complete the Initial Evaluation.

Identifying Functional Substitutes

Assessors are encouraged to use the concept of "functional substitution" to help identify a broad assortment of potential alternatives. Functional substitution is described in Tickner et al. (2015) as "the application of information on function to identify, evaluate, and select safer alternatives that achieve a particular result."[6] The idea of functional substitution expands on the idea of functionality previously discussed in the Initial Evaluation by encouraging assessors to identify more alternatives than just drop-in chemical replacements.

Viable alternatives can include chemicals, materials, products, or processes that provide either the same end use function or the same service within society. Drop-in chemical replacements are any that provide the same chemical function as the chemical of concern. End-use-function alternatives are those that can replace the function of a chemical of concern in a product or process. In contrast, service alternatives can be significantly different products and processes that serve the same role within society. A good example provided in Tickner et al. is replacements for bisphenol-A, or BPA, in thermal receipt paper:

- A chemical function substitute would be another chemical that could replace BPA, like bisphenol-S.
- An end-use function substitute would be to redesign thermal receipt paper to eliminate the need for BPA, or to switch to non-thermal printing.

[6] Tickner et al. (2015). "Advancing Safer Alternatives Through Functional Substitution." *Environ. Sci. Technol.* 2015, 49, 2, 742–749. DOI: 10.1021/es503328m

- A service function substitute would be to switch to electronic receipts instead of printing.

By using a broad definition of a function to identify alternatives, more potential alternatives can be assessed. Because many drop-in replacements for chemicals of concern are structurally similar to the original chemical and therefore may be similarly hazardous, looking for non-chemical substitutes may also increase the likelihood of identifying safer alternatives. Once an assessor generates an initial list of alternatives, more specific functional criteria can be used to eliminate some options.

Process

To generate the most comprehensive list of possible alternatives, we recommend the assessor start by brainstorming all possible alternatives. Screening questions can then be used to eliminate alternatives that will not be successful based on the needs of the organization conducting the assessment. Finally, if needed, the assessor can apply initial screens from the Hazard and Performance Evaluation Modules to narrow the starting list of alternatives for the AA.

1. Identify all functionally equivalent alternatives

Start by brainstorming the functions of the chemical of concern in the product or process under assessment.

- What functions does the chemical of concern providing in the product or process?
- What functions does the product or process provide to the purchaser or end user?
- What services does the product or process provide within a larger system or to society?

Once these questions are answered, the assessor can look for specific alternatives that meet one of the above functions. The Guide lists several Tools that assessors can use to look for alternatives. The following questions can also guide the brainstorming process:

- Does published literature document a successful material, product, or process redesign to avoid using the chemical of concern?
- Are there similar products offered for sale that use an alternative? If so, is it possible to identify what alternative was used?
- Do other manufacturers advertise their product as free of the chemical of concern? If so, is it possible to identify what alternative was used?
- Do chemical manufacturer(s) offer alternatives? Is an alternative listed on 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?
- Are there technical resources available that identify chemicals, materials, or design changes with similar functionality?
- Does a chemical or material supplier offer an alternative?
- Have you searched the internet for alternatives?
- Have other AAs identified possible chemicals?
- Have state, local, federal, or international organizations identified alternatives?

How have you addressed equity and environmental justice?

Have alternatives been identified that could provide benefits to disadvantaged and/or vulnerable populations, especially non-chemical alternatives that could offer new ways of achieving the same service function as the chemical of concern?

Ask stakeholders to suggest potential alternatives. When the scope of alternatives considered is limited to chemical replacements, assessors often need to navigate hazard trade-offs because most chemicals in commerce today are not "benign by design". Use this phase of an AA to identify the opportunities to evaluate more transformative alternatives. Refer to the Stakeholder Engagement chapter for further guidance.

If the assessor is working with a specific company to identify alternatives for their product or process, then the assessor can also ask:

- Does the company's supplier or a competitor offer an alternative?
- Does a company's competitor offer a product or process that uses an alternative?
- Can changes potentially be made to the company's manufacturing process or product design to allow the use of an identified alternative?

Based on the above questions, list all possible alternatives for review by subsequent modules.

Example Alternatives

Example 1: Lead wheel weights can be replaced with less toxic materials, including safer metals and other non-metallic alternatives.
Example 2: Barrier fabrics between upholstery fabric and foam in upholstered furniture are an alternative to flame retardants in the foam.
Example 3: Aminocarboxylate chelating agents, which persist in the environment, can be replaced with easily biodegradable chemicals.
Example 4: Detergents were reformulated to eliminate phosphates.

A Note on Nanomaterial Alternatives

Nanomaterial alternatives are increasingly used in products. Man-made nanomaterials are defined by International Organization for Standardization (ISO) as "materials in any external dimension in the nanoscale or with an internal surface structure at the nanoscale, which is 1 to 100 nanometers."[7] These materials typically have fundamentally different properties compared to the bulk, non-nanoscale, versions of the same material.

Many nanomaterials are given the same Chemical Abstract Services Registration (CAS) Number as the corresponding bulk material but have distinct physical, chemical, and hazard characteristics. As such, a nanomaterial alternative may need to be evaluated separately from the bulk material alternative, especially in the Hazard, Performance Evaluation, Exposure Assessment, and Materials Management Modules.

2. Screen alternatives to remove obvious failures

Once an initial list of alternatives is created, the assessor should consider whether certain circumstances preclude the adoption of an alternative. Depending on who is conducting the alternative and where products are used or manufactured, some alternatives will not be adopted even if an AA were to identify them as preferrable to the chemical of concern.

- Is the alternative restricted by local, state, federal or international legislation, which makes its use infeasible?
    - If so, document this information and eliminate this alternative from consideration.
    - If not, continue the evaluation.
- Is this AA being performed on behalf of a specific company?
    - If yes, answer the next question.
    - If not, move to the next step.
- Work with stakeholders at the specific company to identify whether there are any types of alternative that the company will not consider adopting. For example, if the company makes thermal receipt paper, are they able to consider service function alternatives that no longer use thermal paper?
    - Depending on the response, eliminate any alternatives that the company will not consider. These alternatives could be included in the AA conclusions as possible options for other AAs (see Documenting Outcomes and Conclusions for more details).

[7] ISO. (2008). International Organization for Standardization. Technical specification ISO/TS 27687:2008(E): Nanotechnologies Terminology and definitions for nano-objects—Nanoparticle, nanofibre and nanoplate.

3. Perform Optional Initial Screens

An assessor can winnow the list of potential alternatives by conducting an initial screen using the lowest levels of the Hazard and Performance Evaluation modules. For example, chemicals screened using the Hazard Module and identified as equal or potentially greater hazard as the chemical of concern can be eliminated from further consideration. Similarly, chemicals that do not perform to the requirements identified in Level 1 of the Performance Evaluation Module may also be identified as unfavorable and removed from further consideration. For more information on potential screening mechanisms, see the Hazard and Performance Evaluation modules.

The advantage of these screens is they concentrate potentially limited resources on the most viable alternatives. Any alternatives removed from consideration should be documented along with the data used to reach these conclusions in the final AA report.

Hazard Module

The hazard module provides a framework to assess the possible hazards for the chemical of concern and the alternatives being considered. Many different hazard criteria may be used to evaluate and compare chemicals, products, and processes. This module describes three evaluation levels ranging from a basic assessment of the minimum hazard criteria, through increasing detail and broadening scope, ending with an expanded and verified extended hazard evaluation.

To help reduce the resources needed for the hazard evaluation, we also recommend the assessor complete two initial steps before the hazard evaluation. The first step helps the assessor identify the minimum hazard criteria that will be used in the alternatives assessment. In the second step, the assessor screens alternatives against authoritative lists to identify known hazardous substances that should be removed from the assessment (Table 1). If the initial screening does not identify hazard documented on authoritative lists, further analysis is needed to identify undocumented hazards.

Table 1: Hazard Module Evaluation Levels.

Initial Steps	*Initial Steps:* Identifies minimum hazard criteria for assessment. Then, uses readily available authoritative lists of hazard criteria to evaluate whether an alternative should be removed from the evaluation.
Level 1	*Basic Evaluation:* Uses hazard evaluation methods to at minimum compare chemicals, products, or processes for identified minimum hazard criteria.
Level 2	*Extended Hazard Evaluation:* Uses established hazard evaluation methods to conduct a thorough hazard evaluation that has been verified by a third party.
Level 3	*Comprehensive Hazard Evaluation:* Expands upon Level 2 by eliminating data gaps and expanding the number of hazard criteria used in the analysis.

Introduction

Hazard refers to the inherent properties of a substance, mixture of substances or processes that, under production, usage, or disposal, make it capable of causing adverse effects to humans, animals, and the environment. Hazard can be measured for several human and environmental traits. Information on each trait may come from epidemiological studies, experimental data, or toxicity modeling results. Modeled data is based on extrapolations from known information about similar chemicals. For most chemicals in commerce today, data is available for only a limited number of hazard traits, resulting in data gaps. Generally, as the amount and quality of data increases, so does confidence in the evaluation.

Function of Hazard Evaluation

As concerns have increased about the widespread use of toxic chemicals in products and their effects on human and environmental health, there is increased interest in replacing chemicals of concern with safer alternatives. When eliminating chemicals of concern, businesses have occasionally replaced them with chemicals of equal or greater hazard resulting in 'regrettable substitution.'

A well-documented example of a regrettable substitution is the replacement of chlorinated solvents in the auto repair industry with hexane. In response to increasing regulation of methylene chloride, several manufacturers switched from chlorinated solvents to hexane in brake cleaners, even though hexane had been shown to cause nerve damage as early as 1964.[8] A few years after the substitution, workers in auto repair shops in California began to report health concerns that were eventually tied to hexane.[9]

Manufacturers did not learn from this experience, however, and replaced hexane with another halogenated solvent, n-propyl bromide, which is a known reproductive and developmental toxicant. The National Toxicology Program later identified n-propyl bromide as 'reasonably anticipated to be a human carcinogen.'[10]

Examples such as this have emphasized the need for methods to compare chemicals of concern with potential alternatives to promote safer substitutions. Although no chemical can be guaranteed to be a truly safe alternative, the above example demonstrates the need to evaluate hazard data for chemicals in products. By evaluating available data and selecting chemicals with the lowest impact on human health and the environment, businesses substantially reduce the likelihood of selecting a regrettable substitute.

How have you addressed equity and environmental justice?

Although the hazard assessment approach is focused on evaluating the intrinsic hazard properties of a chemical, it is important to carry an environmental justice lens into the assessment. Alternatives that are safer for disadvantaged and/or vulnerable population, who often already face higher health burdens from chemical exposure, will be safer for all. When possible, linking the health experience of EJ communities with known negative health impacts can help assessors to avoid alternatives that would cause

[8] Yamada S, 1964. An occurrence of polyneuritis by n-hexane in the polyethylene laminating plants. Jpn J Ind Health, vol.6, p. 192.

[9] University of California-Berkeley, 2010. Preventing Toxic Exposures-Workplace Lessons in Safer Alternatives, Joan Lichterman, Holly Brown-Williams, Linda Delp, Margaret Quinn and Julia Quint authors, Vol. 5, No. 1.

[10] National Toxicology Program, 2021. 15th Report on Carcinogens [Internet]. 1-Bromopropane: CAS No. 106-94-5. Available from: https://www.ncbi.nlm.nih.gov/books/NBK590752/

new or different burdens to those communities. Inset boxes have been added at strategic points in this module where assessors can use an EJ lens to enhance their hazard evaluations and comparisons.

Methods to Evaluate Hazard

The Hazard Module is compatible with multiple methods to evaluate and compare hazard traits. The level of complexity for the user varies from reviewing authoritative lists of chemical hazards that were created by expert groups to generating and evaluating new toxicological data for specific chemicals of interest.

Authoritative Lists of Hazards

Several government bodies and expert groups have performed comprehensive hazard assessments of chemicals and published lists of chemicals of concern for various hazard traits. These lists can be used alongside chemical hazard classifications from countries using the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) to quickly identify hazard traits associated with specific chemicals.

In addition to authoritative lists, many screening lists of chemicals are publicly available. Screening lists are either 1) lists developed by authoritative bodies to target chemicals for additional scrutiny, which are often generated by models or screening tests, or 2) lists developed by non-governmental bodies or experts not sanctioned by a government. If a chemical is under assessment, precautionary avoidance may be warranted.

The authoritative lists include only a limited set of the approximately 350,000 chemicals registered for production or use around the world.[11] Many chemicals have not been tested. Therefore, these lists only provide a starting point for identifying chemicals of concern. It is important to assess the available toxicological literature on unlisted chemicals and to use modeling tools and analogs to determine whether the weight of evidence indicates that a substance is a chemical of concern.

EPA DfE and Safer Choice Program

EPA's DfE Program pioneered work in the field of AAs in the late 1990s. DfE developed a set of hazard criteria that can be used to compare chemical substitutes. Revised criteria were released in 2011. These criteria form the basis of many chemical hazard assessment methodologies that are still in use.

[11] Wang Z, et. al, 2020. Toward a Global Understanding of Chemical Pollution: A First Comprehensive Analysis of National and Regional Chemical Inventories. *Environ. Sci. Technol.* vol. 54, pg. 2575–2584.

In addition, DfE established a voluntary product evaluation and labeling program for industrial, institutional, and consumer products, called the Safer Choice Program. EPA maintains a list of preferable chemicals identified by the safer products labeling program, called the EPA Safer Chemicals Ingredient List (EPA SCIL), that meet the DfE hazard criteria. Safer Choice products are made with ingredients that meet these criteria.

Comparative hazard evaluation methods

As interest has grown in understanding and comparing chemical hazards, several organizations have developed methods to score and compare substances based on available toxicological, physical, and chemical data. Many of these methods are publicly available and are used by licensed practitioners to evaluate chemicals, products, or processes, typically for a fee. Several examples are discussed as part of Level 1 and Level 2 of this module. Common human and environmental hazard traits used by DfE and other hazard evaluation methods are included in the Appendix: Common Hazard Traits.

Initial Step: Determine Minimum Hazard Criteria for the AA

Before conducting a hazard evaluation, the assessor should complete two initial steps. The first step is to decide what the minimum hazard criteria will be for this AA. This decision will be based on the assessor's knowledge of the chemical of concern and the product or process under assessment. The second step, which is discussed in the next section, is an initial screening of alternatives to quickly eliminate any that are unlikely to be less hazardous than the chemical of concern.

The minimum hazard criteria are the combination of hazard traits that will be used to evaluate substances and any rules about allowable data gaps. This guide provides recommended hazard traits for each level as a starting point. Additionally, published hazard evaluation methods should include a recommended set of hazard traits that are considered, often including which hazard traits are acceptable data gaps. However, based on the chemical of concern and the product or process under assessment, an experienced AA practitioner may want to add or modify an existing hazard trait, or change a data gap from acceptable to unacceptable, to better meet the needs of their AA.

For example, many hazard evaluation methods do not require data on endocrine disruption. While this may be an acceptable data gap when assessing some products and processes, this may be an important trait for other products that are inhaled, ingested, or absorbed during use, such as personal care products

Alternatively, a chemical under evaluation may have multiple hazard traits that contribute to its status as a chemical of concern. Some of these hazard traits may not be evaluated if the recommended hazard traits for Level 1 or Level 2 are the only traits used. Identifying alternatives that have reduced hazard in those traits associated with the chemical of

concern may decrease the chance that the alternatives are regrettable substitutes. For example, the EPA Significant New Alternatives Policy program focuses on identifying alternatives to ozone-depleting substances. The ozone depleting and global warming potential of alternatives are evaluated alongside other toxicity traits.

Since the selected hazard traits will play a central role in identifying safer alternatives, the assessor is encouraged to consult technical experts and stakeholders before deciding whether to modify the recommended hazard criteria. Individuals who frequently use the product under assessment, or who are impacted by its manufacture, transport or disposal may also have insight into additional hazard traits that should be included.

Experienced AA practitioners are encouraged to consider including hazard traits that negatively affect EJ communities. These communities are often disproportionately impacted by health hazards such as asthma or neurotoxicity that may not be included in the minimum hazard criteria.[12,13] It is worth remembering that certain EJ communities are also highly impacted by substances with combinations of hazard traits. For example, Tribes and EJ communities living in Alaska are especially vulnerable to highly persistent and mobile substances, which concentrate in the Arctic. If potential alternatives are all likely to be highly persistent, assessors may also want to evaluate mobility to avoid selecting an alternative that may contribute to hazards for those communities.

How have you addressed equity and environmental justice?

When possible, safer alternatives should not exacerbate existing health burdens in EJ communities. Convene potentially impacted community stakeholders (refer to the Stakeholder Engagement chapter for guidance) to understand priority health concerns impacting their community. Additional information resources including reviews of the public health literature and environmental justice screening tools should also be used.

Are there priority health concerns for EJ communities that are connected to specific hazard traits that should be included in the minimum hazard criteria?

Expertise Required to Determine the Minimum Hazard Criteria

No level can provide 100% certainty that an alternative is truly safer than the chemical of concern. However, as the number of hazard traits evaluated and the number of sources examined increase, confidence in the accuracy of the assessment outcome also increases.

[12] Landrigan P, Rauh V, Galvez M, 2010. Environmental Justice and the Health of Children. *Mt Sinai J Med.,* vol.77, pg.178–187. DOI: 10.1002/msj.20173

[13] Johnston J, Cushing L, 2020. Chemical Exposures, Health, and Environmental Justice in Communities Living on the Fenceline of Industry. *Curr Environ Health Rep*., vol.7, pg.48-57. doi: 10.1007/s40572-020-00263-8.

For users with little expertise in hazard evaluation, we recommend deciding whether to use a Level 1, Level 2, or Level 3 evaluation, and then use the recommended hazard traits for that level. Other assessors can use the recommended hazard traits for a specific level as a starting point and modify as appropriate.

Process

There are many hazard traits that can be included in the hazard evaluation. The hazard traits that we recommend be included for Levels 1-3 are summarized in Table 2**.**

Table 2: Recommended Hazard Traits for Levels 1-3.

Recommended Hazard Traits	Levels		
	1	2	3
Human Health			
Carcinogenicity	x	x	x
Mutagenicity and Genotoxicity	x	x	x
Reproductive Toxicity	x	x	x
Developmental Toxicity	x	x	x
Acute Mammalian Toxicity	x	x	x
Systemic Toxicity & Organ Effects – repeated exposure	x	x	x
Systemic Toxicity & Organ Effects – single exposure		x	x
Endocrine Activity		x	x
Neurotoxicity		x	x
Skin Sensitization		x	x
Respiratory Sensitization		x	x
Skin Corrosion or Irritation			x
Eye Irritation or Damage			x
Aspiration			x
Environmental			
Acute aquatic toxicity	x	x	x
Chronic aquatic toxicity	x	x	x
Persistence	x	x	x
Bioaccumulation	x	x	x
Mobility			x
Domesticated animal toxicity			x
Wildlife toxicity			x
Loss of genetic diversity, including biodiversity			x
Impairment of waste management organisms			x
Eutrophication			x

Table 2: Recommended Hazard Traits for Levels 1-3.

Recommended Hazard Traits	Levels		
	1	2	3
Greenhouse gas emissions			x
Ozone depletion potential			x
Waste generation			x
Physical			
Flammability	x	x	x
Reactivity		x	x
Explosivity			x
Corrosivity			x
Oxidizing properties			x
Self-reactivity			x
Aerosolization/dustiness			x
Vibration/noise			x

Once a hazard evaluation level and hazard evaluation methodology have been selected, the assessor can then consider whether hazard traits or allowable data gaps should be modified at all.

What data gaps are allowable will depend on the hazard evaluation level and method selected. For example, in Level 1, we recommend using the minimum hazard traits described by the Organisation for Economic Cooperation and Development (OECD).[14] We consider this set of traits to be the minimum needed to identify a less hazardous alternative in any assessment. Assessors should therefore be cautious about removing any of these traits from their assessment.

1. Select a hazard evaluation level and review the recommended minimum hazard criteria in Table 2. Is there evidence that these criteria should be modified for this assessment?
   - If yes, document the rationale and proceed to question 2.
   - If no, then this initial step has been completed.

2. Consider the known or likely hazards of the chemical of concern and the product or process under assessment. You may need to identify known hazards of the product or process at all lifecycle stages.

[14] OECD, 2021. Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives. Retrieved from: https://www.oecd.org/chemicalsafety/risk-management/guidance-on-key-considerations-for-the-identification-and-selection-of-safer-chemical-alternatives.pdf

- Based on known or likely hazards identified, are there any hazard traits that should be added to the recommended criteria to identify less hazardous alternatives?
    - If yes, document the reason for adding these hazard traits to the hazard criteria and proceed.
    - If no, proceed.
- Based on known or likely hazards identified, are any of the recommended traits unnecessary to identify less hazardous alternatives?
    - If yes, document the reason for not including those hazard traits in this analysis. You will need to consult with toxicologists or hazard evaluation specialists to confirm this decision will not undermine the selection of safer alternatives.
    - If no, proceed to question 3.

3. Consider which hazard traits, if any, are allowed to be data gaps in the evaluation. Should the list of allowable data gaps be modified?
    - If yes, document the reason for modifying which data gaps are permitted for this evaluation. You will need to consult with toxicologists or hazard evaluation specialists to confirm this decision will not undermine the selection of alternatives.
    - If no, then this initial step has been completed.

Initial Step: Screen Against Hazard Lists

Performing an initial screen on alternatives using authoritative lists can quickly eliminate chemicals of concern without a more comprehensive assessment. This screen can be done quickly using screening tools or more slowly by consulting individual authoritative lists and chemical, material, and product Safety Data Sheets (SDS).

Expertise Required to Screen Against Hazard Lists

Performing a screen against hazard lists requires little technical review or expertise and only a basic understanding of the hazard traits. The assessor determines whether a chemical appears in hazard lists established by recognized experts in each field. If a chemical appears on one of the authoritative lists at a sufficient level of concern, it is an unfavorable alternative and removed from further consideration. For example, when using a GreenScreen ListTranslator, substances that are assessed and have the score of List Translator-1 (LT-1) are frequently screened out because a full hazard evaluation would likely score them as chemicals of concern.

What resources and knowledge are required to use screening tools?

An assessor with limited chemical or toxicology background can screen out alternatives. Assessors can access SDSs obtained from manufacturers to perform the screening by looking for certain GHS-aligned hazard statements. Additionally, automated tools, which screen chemicals using multiple authoritative lists, may currently be accessed for free in a limited capacity.

What degree of confidence does screening provide?

Screening alternatives against authoritative lists will tell the assessor if a chemical has been identified by a limited number of sources as being hazardous. This can be useful in narrowing the scope of a more comprehensive assessment.

If a chemical does not appear on a specified list during screening or does not have listed hazards on an SDS, no conclusions can be drawn regarding the chemical's hazard traits. Further assessment is required.

Process

We provide two approaches to complete the hazard list screening. The first uses automated screening tools, while the second uses SDSs. We encourage the assessor to use both approaches in the same assessment, to make sure all likely hazardous alternatives are removed from further consideration.

Automated Screening Tools

Clean Production Action has created a tool called the GreenScreen® List Translator for use with chemical hazard assessments. Currently, GreenScreen® List Translator compares alternatives against authoritative lists for multiple hazard traits. When a chemical is present on a list, the hazard trait(s) and hazard criteria for the list are then compared to the GreenScreen® to translate the listing into a GreenScreen® hazard trait (called a hazard endpoint) and hazard level. The combination of hazard traits and hazard levels are then compared to the GreenScreen® Benchmark-1 criteria to assign a List Translator score to the chemical. Substances that are scored as LT-1 would likely be scored as chemicals of concern in a full hazard evaluation.

Automated versions of the GreenScreen® List Translator are currently available for a fee or with the creation of a free account. Healthy Building Network incorporated GreenScreen® List Translator into its Pharos Database, which can be accessed for an annual fee. The Pharos Database searches additional hazard lists, restricted substance lists, and regulatory lists and provides information on whether a chemical is found on any of those lists and whether that may be associated with a potential hazard. 3E also provides an

automated version of the GreenScreen® List Translator as part of Toxnot, which can be accessed through a limited free account, or unrestricted for a monthly fee.

An automated hazard list screening service is also available as part of the Enhesa platform, which includes both ToxPlanet and SciveraLENS®, both of which can be accessed through an annual subscription. Other commercial chemical management software products may include some authoritative or restricted substance list reviews, such as UL SmartWercs and 3eco, including those mentioned in the additional levels, such as SciveraLENS® GHS+.

EPA created the Cheminformatics Hazard Comparison Dashboard, a collection of analysis modules under development to provide more information for chemical hazard evaluations. The Hazard Comparison Dashboard module can be used as an automated screening tool and is available for free through the EPA website. Other elements of the Hazard Comparison Dashboard and other modules are still under development as of 2024 and should only be used with caution by experience AA practitioners. Any assessors who wish to use the Hazard Comparison Dashboard as an automated screening tool are encouraged to read the Vegosen and Martin (2020) paper that describes its development.[15]

Many automated list screening tools will also flag if a full hazard evaluation has already been completed for a substance. They may also note when alternatives are found on positive lists, such as the EPA Safer Chemicals Ingredients List, that include a full hazard evaluation. These evaluations can often be used in a Level 1 or Level 2 hazard evaluation. The assessor should note any of these flags for the subsequent hazard evaluation.

How have you addressed equity and environmental justice?

Hazards associated with the chemicals used to manufacture an alternative or the chemical of concern (i.e., the "embedded chemistry") should be considered when assessing whether an alternative is safer from a life cycle perspective. Such chemicals have their own hazard profile. If alternatives can only be produced using hazardous chemicals, then they may not be safer alternatives for workers at and communities near manufacturing facilities.

However, data on the embedded chemistry and/or process are often unavailable due to lack of transparency. If the embedded chemistry of the alternatives can be identified, then the assessor should attempt to evaluate the hazards of these chemicals. If information is unavailable, the assessor should document that absence. Data gaps for embedded chemistry should not be used to discount alternatives, but they should be flagged to guide future data transparency efforts.

[15] Vegosen L and Martin T. 2020. An automated framework for compiling and integrating chemical hazard data. *Clean Techn. Environ. Policy*, vol.22, pg.441-458. doi: 10.1007/s10098-019-01795-w.

Once a screening tool has been selected, we recommend using the following process to screen alternatives:

1. Identify chemical information. Include CAS Numbers and any chemical synonyms. Note: CAS Numbers may not distinguish between bulk and nanomaterial substances with the same chemical composition and structure. Additional information may be needed to confirm the automated tool is screening a nanomaterial substance.
2. Is the substance on any of the specified authoritative lists for a high level of concern?
   - If yes, bin the alternative found on these lists as unfavorable and document the information used to reach the conclusion.
   - If no, continue the analysis. The potential alternative should be included in the hazard evaluation.
3. Note any toxicity concerns for the potential alternative. If the assessor proceeds with a more comprehensive assessment, this initial research will become part of that assessment.
4. Note if a hazard evaluation has already been published for the alternative. Some tools will include publicly available evaluations or note when alternatives are found on positive lists. These evaluations and lists may be used during the Level 1 or Level 2 hazard evaluations.

Safety Data Sheets

Manufacturers, distributors, and importers are required to provide an SDS for all hazardous chemicals in their inventory. This document is designed to provide information to downstream users on the hazards and safe handling of the substance. Assessors can also use SDSs to quickly screen out substances that have known hazard traits.

Not all SDS are sufficiently detailed to support screening work. There are several indicators, identified in trainings from TURI, that can help identify usable SDS:

- The SDS used should be the most recent version. The assessor should contact the supplier to confirm they have the most recent version.
- The SDS publication date should be after 2015. In 2015, the Occupational Safety and Health Administration (OSHA) adopted standards to align hazard statements with GHS.
- The document should not be called a Material Safety Data Sheet (MSDS). MSDS refers to documents published before OSHA alignment with GHS.
- The SDS lists proprietary constituents in the formulation. Sufficient detail is provided to confirm the SDS is relevant to the alternative under assessment, such as CAS Numbers or information about substance purity or average size or shape.
- Hazard traits like endocrine disruption, environmental hazards, neurotoxicity or climate impacts are included in the SDS.

Once a usable SDS has been obtained, the following process can be used to determine if the alternative has hazard traits that make it a nonviable alternative:

1. Does the SDS for the substance contain any of the GHS statements that indicate it is a high level of concern?
   - If yes, bin the substance found on these lists as an unfavorable alternative and document the information used to reach the conclusion.
   - If no, continue the analysis. The potential alternative should be included in the hazard evaluation.
2. Note any other toxicity concerns for the potential alternative that were included on the SDS. If the assessor proceeds with a more comprehensive assessment, this initial research will become part of that assessment.

Level 1: Basic Evaluation

Level 1 is a basic evaluation that uses publicly available information to assess those hazard traits that were identified in the initial screen as the minimum hazard criteria for the alternatives assessment. It then uses a tool to score each alternative and the chemical of concern to enable a basic comparison.

Who should use this tool?

The basic evaluation is designed to be used by individuals who have limited resources or expertise with AAs. This may include businesses or governments with limited resources or government programs that are providing technical assistance to companies moving to safer alternatives. It may also be useful for practitioners who have many potential alternatives they want to screen against a few hazard traits before performing a more comprehensive hazard evaluation.

What resources and knowledge are required to use this tool?

The Guide includes criteria to help assessors determine whether a hazard evaluation method or tool is suitable. For a Level 1 assessment, only tools that are based on hazard evaluation methods that meet the Level 1 criteria should be used. These tools do not require significant expertise in hazard evaluations, toxicology, or chemistry. Some of these tools do not require the assessor to enter in hazard information for an alternative. Those that do use resources like SDSs and authoritative hazard lists and have detailed instructions for how to use the tool.

Tools used in Level 1 are not required to have a robust process for accounting for data gaps or a process to review data that was generated automatically. Therefore, results from a Level 1 evaluation should only be used if data are available for all the necessary hazard

traits that were identified as part of the minimum hazard criteria. A Level 2 or Level 3 evaluation may be necessary if insufficient data was available to complete a basic evaluation. Some of the tools recommended in Level 1 can also meet the criteria for a Level 2 or Level 3 evaluation, if additional criteria like a system for third-party review of hazard evaluations, can be met.

What degree of confidence does Level 1 provide?

The basic evaluation only requires that the assessor consider the minimum hazard traits identified for the AA. It is possible the assessor could miss hazard concerns that would be identified in a more thorough evaluation. This level only requires that the method use a limited number of data sources and does not require review by a toxicologist. Level 1 may not be able to appropriately score complex mixtures of chemicals or inorganic chemicals. However, the Level 1 assessment goes beyond only screening against hazard lists and can be used to identify safer alternatives that have sufficient hazard data.

Process

Each hazard evaluation should include minimum hazard criteria, a process for scoring chemicals based on individual hazard traits, and a process for identifying and removing chemicals of high concern. Chemicals of high concern are typically one or more of the following:

- Persistent, bioaccumulative and toxic (PBT).
- Very persistent and very bioaccumulative (vPvB).
- Very persistent and toxic (vPT) or very bioaccumulative and toxic (vBT).
- Pose a high level of hazard for priority human health effects, such as carcinogenicity, mutagenicity, or reproductive toxicity (CMR).

To be considered an appropriate Level 1 hazard evaluation method, the method should meet all the following criteria:

- **Published methodology:** The method used to evaluate hazard traits, chemicals, products, and processes should be available to the assessor in enough detail that they can evaluate whether the tool meets the requirements of a Level 1 evaluation.
- **Equivalency to established hazard classification methods:** The hazard evaluation method and hazard traits considered should be comparable to those established by GHS.
- **Hazard trait transparency:** The method should evaluate human and environmental health hazard, environmental fate and ecotoxicity traits. Which traits are evaluated should be clearly stated.
- **Hazard trait suitability:** The hazard traits evaluated in the method should at minimum include all the minimum hazard criteria identified for this assessment.

Although the IC2 does not recommend any one basic hazard evaluation method, we have included a few example methods that currently meet these criteria. A few of these examples, as noted below, may also meet the criteria for a Level 2 Extended Hazard Evaluation if the assessor is able to access certain additional information about the evaluation.

Pollution Prevention Options Analysis System (P2OASys)

P2OASys is a free tool created by TURI. The tool allows users to manually enter hazard data for a chemical and then creates a score. Hazard data is typically taken from authoritative hazard lists and SDSs. This tool does not account for data gaps as part of its chemical scoring system and does not require an expert to prepare or review the data.

EPA Safer Choice

The EPA Safer Choice program is a product certification program run by the EPA. EPA maintains a publicly available list of products that have been certified under the Safer Choice Standard, formerly called EPA DfE Standard. The hazard evaluation process used to certify Safer Choice and DfE products meets the criteria for a Level 1 evaluation. If an alternative under consideration is a Safer Choice or DfE product, then that alternative can be identified as a less hazardous alternative.

SciveraLENS® GHS+

SciveraLENS® GHS+ is part of the Enhesa platform and can be used for a basic evaluation. For an annual fee, users can query a hazard evaluation database or input data for a new chemical, which will then go through an automated process to evaluate and score the chemical. Staff toxicologists can review and verify the auto-generated score for accuracy. This tool is recommended for Level 1 Basic Hazard Evaluations because the process accounts for data gaps but does not always describe the rationale for hazard trait score assignments. If an assessor has access to that additional information and the expertise to evaluate decisions, then Scivera LENS® GHS+ may be used for Level 2 Extended Hazard Evaluations as well.

GreenScreen® for Safer Chemicals

Clean Production Action, a non-profit organization, created the GreenScreen® for Safer Chemicals (GreenScreen®) in 2007. Chemicals receive a GreenScreen Benchmark™ score based on the combination of the hazard assessments of 19 hazard traits. Some groups will pay to make GreenScreen® assessments publicly available. Those publicly available evaluations will meet the Level 1 criteria provided all the minimum hazard criteria were all included. If an assessor has the expertise to review the GreenScreen®, or can pay a third party to review, then GreenScreen® may be used for Level 2 Extended Hazard Evaluations as well.

ChemFORWARD

ChemFORWARD is a hazard evaluation method created by a non-profit of the same name. The method is based on the Cradle to Cradle Certified® (C2CC®) Material Health Assessment methodology. ChemFORWARD evaluates chemicals using human and environmental health and environmental fate hazard traits taken from the Material Health Assessment and GHS. Some groups will pay to make ChemFORWARD hazard evaluations publicly available. Those publicly available evaluations will meet the Level 1 criteria provided all the minimum hazard criteria were all included.

Stepwise Process

The following stepwise process should be performed for the chemical of concern and each alternative. Step 1 may be skipped if it was completed when identifying alternatives or during the initial screen against hazard lists.

1. Identify chemical information. Include CAS Numbers and any chemical synonyms. Note: CAS Numbers may not distinguish between bulk and nanomaterial substances with the same chemical composition and structure. Additional information will be needed to confirm the automated tool is screening the nanomaterial substance.
2. Select a hazard evaluation tool. Does the tool meet all the criteria for a Level 1 hazard evaluation?
   - If yes, follow the method described by the tool to complete the hazard evaluation. Note this may be as simple as searching for the chemical within a database.
   - If no, do not attempt to use this method. Look for a different method that meets the criteria.
3. Look at the final hazard evaluation for the alternative. Is there information available for each hazard trait?
   - If yes, record the final score produced by the hazard evaluation tool and move to Final Step: Comparing Hazard Scores.
   - If no, remove the chemical from consideration in the AA unless additional information is found, or a more detailed evaluation is performed, such as an Extended Hazard Evaluation.

Level 2: Extended Hazard Evaluation

An extended hazard evaluation uses publicly available methods based on globally recognized methods for classifying and assessing chemical hazards, such as EPA DfE and GHS. This evaluation goes beyond the minimum hazard traits recognized by OECD to evaluate other commonly compared human health and physical hazard traits such as

respiratory sensitization, endocrine disruption, and chemical reactivity. These methods also include some consideration of data gaps and data quality.

The use of publicly available methods makes chemical hazard evaluation and subsequent comparison to the chemical of concern transparent and reproducible. Because these methods also include processes for third-party review and periodic reassessment of chemical hazards, they provide an increased level of confidence in the evaluation.

Who should use this tool?

Assessing chemical hazards using an extended hazard evaluation requires skill in toxicology, chemistry, computer modeling, and other scientific areas. However, these methods all include processes for experts to both perform the analyses and act as third-party reviewers. An assessor who does not have the necessary expertise could hire experts to evaluate and score chemicals or perform a third-party review of any evaluations.

What resources and knowledge are required to use this tool?

Conducting a Level 2 hazard evaluation requires a commitment of both time and resources, which can be costly. Using an extended hazard evaluation method requires a high level of technical expertise. Specialists in toxicology, chemistry, computer modeling such as (Q)SAR[16], and other scientific areas are needed to generate data, evaluate sources, review technical information, and assign scores to the chemicals that have undergone the screening process. This expertise is particularly necessary when information from peer-reviewed journal articles and computer modeling are used to fill in data gaps.

What degree of confidence does Level 2 provide?

A Level 2 evaluation can provide a higher degree of certainty because the hazard assessment is more detailed and comprehensive than Level 1. These evaluations are also performed by professionals with training and expertise in toxicology or chemistry and chemical hazard assessments. Data gaps may still exist. And some degree of uncertainty will exist because of the evolving nature of science. Therefore, all chemicals and products should be subjected to periodic review, to evaluate the impact of improvements in data and scientific understanding upon the final score.

[16] (Q)SAR = Quality Structure Activity Relationships. (Q)SARs are computer modeling results that predict the toxicity of chemicals based upon structural similarities with chemicals possessing known toxicity concerns.

Process

The extended hazard evaluations recommended in Level 2 all have published methods that are transparent and comprehensive. Assessors must follow the published method of the selected evaluation tool.

To be considered an appropriate Level 2 hazard evaluation, the method should meet all the following criteria:

- **Equivalency to established hazard classification methods:** The hazard evaluation method, minimum hazard criteria, and hazard traits considered should be comparable to those established by DfE and GHS.
- **Hazard trait transparency:** The method should evaluate human and environmental health hazard, environmental fate and ecotoxicity traits. Which traits are evaluated should be clearly stated.
- **Processes to address data gaps and data quality:** The method should provide some guidance around data quality and factor the severity of data gaps in the overall score for the chemical, product, or process. Chemicals that are severely lacking in data should not be assumed safer than the chemical of concern.
- **Method transparency:** The method and criteria used to evaluate hazard traits, chemicals, products, and processes must be publicly available in sufficient detail that an experienced hazard assessor could replicate the method.
- **Processes for re-assessment and third-party review:** The method should include provisions for assessments to be conducted or reviewed by third-party experts who have experience in conducting extended hazard evaluations. The method should also include a process for periodic re-assessment of chemicals or an expiration date for completed evaluations.

Although the Guide does not recommend any one extended hazard evaluation method, there are a few example methods that currently meet these criteria.

GreenScreen®

GreenScreen® evaluates chemicals and their potential degradation products against a wide range of human health and environmental toxicity and environmental fate endpoints and physical/chemical properties to determine safer alternatives to chemicals of concern. In the hazard assessment, 19 hazard traits are evaluated and used to assign an overall benchmark score to the substance. The GreenScreen® method identifies the most serious data gaps and adjusts the score based on the number and severity of data gaps.

The GreenScreen® method is free and publicly available to all assessors. However, assessors that have not been trained and licensed to use GreenScreen® should work with a Licensed GreenScreen Profiler, a toxicology firm that provides assessment services for a fee

for clients, to obtain GreenScreen® assessments. For further details, assessors should refer to the GreenScreen® website.

Cradle-to-Cradle Material Health Assessment

C2CC® is a globally recognized consumer product certification. Products are evaluated for Material Health in addition to other sustainability metrics. As part of the overall score, products are assigned a Material Health level of Bronze, Silver, Gold, or Platinum. Chemicals and products are assessed by accredited third parties and reviewed by Cradle to Cradle Products Innovation Institute. Comparing alternatives to the chemical of concern only using C2CC® would be difficult because the details of Material Health Assessments are not published, just the score. Assessors interested in using Material Health Assessments will need to carefully review the C2CC® methodology to determine how a Material Health Assessment score compares to the score assigned to the chemical of concern.

ChemFORWARD

ChemFORWARD evaluates chemicals using human and environmental health and environmental fate hazard traits taken from the C2CC® Material Health Assessment and GHS. The method also provides a clear and transparent approach to assign an overall score to the chemical based on the availability and quality of hazard data.

The ChemFORWARD method is updated as needed to reflect changes in the Material Health Assessment methodology and is publicly available. ChemFORWARD's process includes an assessment verification by third-party experts to ensure assessment quality. For further details on the method, assessors should refer to the ChemFORWARD website.

EPA SCIL

As part of the Safer Choice Program, EPA also maintains EPA SCIL, a list of chemicals that meet the requirements for a less hazardous chemical set by the EPA Safer Choice Standard. Because some chemicals on the list can have more data gaps than others, it is important for the assessor to confirm that enough hazard traits are evaluated to enable comparison to the chemical of concern. In all other aspects, the hazard evaluation process used meets the criteria for a Level 2 evaluation.

EPA Safer Choice and SciveraLENS® GHS+

These methods are discussed in more detail in the Level 1 process. Under certain circumstances, these methods will meet the criteria for a Level 2 evaluation. For EPA Safer Choice, the assessor will need to confirm that the hazard traits used to evaluate the alternative meet the minimum hazard criteria established for the alternatives assessment. Some chemicals are evaluated for different hazard traits based on the function of the chemical (called the functional class). For SciveraLENS® GHS+, the assessor will need to

review the rationale for hazard trait score assignments used in the evaluations or pay to have the evaluations reviewed by a third party.

Stepwise Process

Level 2 should be performed for the chemical of concern and each alternative. Step 1 may be skipped if it was completed when identifying alternatives or during the initial screen against hazard lists.

1. Identify chemical information. Include Chemical Abstract System Registration (CAS) Numbers and any chemical synonyms. Note: CAS Numbers may not distinguish between bulk and nanomaterial substances with the same chemical composition and structure. Additional information will be needed to confirm the automated tool is screening the nanomaterial substance.
2. Select a hazard evaluation tool. Does the tool meet all the criteria for a Level 2 hazard evaluation?
   - If yes, follow the method described by the tool to complete the hazard evaluation. Note this may be as simple as searching for the chemical within a database.
   - If no, do not attempt to use this method. Look for a different method that meets the criteria.
3. Look at the final hazard evaluation for the alternative. Were there enough data to evaluate the alternative and were the data of sufficient quality, based on the requirements of the selected hazard evaluation tool?
   - If yes, record the final score produced by the hazard evaluation tool and move to Final Step: Comparing Hazard Scores.
   - If no, then the data gaps are likely severe enough that the alternative cannot be accurately compared to the chemical of concern. Remove the chemical from consideration in the AA unless additional information is found, or a more detailed evaluation is performed, such as a Level 3 evaluation.

Level 3: Comprehensive Hazard Evaluation

Level 3 expands on the methods used in Level 2 by examining additional hazard traits and filling in any data gaps with generated experimental or modeled data. A Level 3 assessment is also peer reviewed and validated.

Who should use this tool?

Level 3 is designed to be used by organizations with more resources and expertise that want the highest possible level of confidence that their alternative poses minimal threat to

human health and the environment. Level 3 may also be used when the chemical of concern is known to have hazard traits beyond those evaluated at Level 2.

What resources and knowledge are required to use this tool?

Level 3 assessments require a higher degree of technical expertise than Level 2. Specialists are needed to generate new data and to conduct an independent peer review of the final assessment.

What level of confidence does Level 3 provide?

While no assessment provides complete confidence, a Level 3 assessment is the most comprehensive review possible and is validated by peer reviewers. This process allows the chemical to have the highest degree of confidence possible in the assigned score.

Process

Assessors should identify a hazard evaluation method that meets the required criteria described in Level 2. Consult with hazard assessment experts to determine the correct way to incorporate new hazard trait evaluations into the final chemical score if needed. The process to incorporate additional hazard traits into the evaluation should be clearly documented in the final assessment.

If no single hazard evaluation method or tool can be modified to accommodate all the hazard criteria that will be used, multiple tools can be employed. However, assessors should clearly document what tools were used and how scores for individual hazard traits were used to determine an overall hazard score for each substance.

Level 3 should be performed for the chemical of concern and each alternative. Step 1 may be skipped if it was completed when identifying alternatives or during the initial screen against hazard lists.

1. Identify chemical information. Include Chemical Abstract System Registration (CAS) Numbers and any chemical synonyms. Note: CAS Numbers may not distinguish between bulk and nanomaterial substances with the same chemical composition and structure. Additional information will be needed to confirm the automated tool is screening the nanomaterial substance.
2. Select the hazard evaluation tool that will be used to evaluate alternatives and document any changes or additions made to include additional hazard criteria. Do the tool and all adjustments meet all the criteria for a Level 2 hazard evaluation?
    - If yes, proceed to the next question.

- If no, adjust the hazard evaluation tool so that it meets all the criteria described for a Level 2 evaluation. If the hazard evaluation tool cannot be adjusted to meet the criteria, do not attempt to use this method. Look for a different method that can meet the criteria.

3. What additional hazard traits will be included in the evaluation? How will data quality be evaluated? How will the additional hazard traits be included in the overall score? The assessor may need to consult the developer of the chosen method. Document the hazard traits and how they will be used as part of the selected method. Is the method clearly documented such that another assessor could successfully reproduce the results?
   - If yes, follow the method described by the tool to complete the hazard evaluation.
   - If no, do not attempt to use this method. Look for a different method that meets the criteria and can be expanded in a reproducible manner.
4. Look at the final hazard evaluation for the alternative. Were there enough data to evaluate the alternative and were the data of sufficient quality, based on the requirements of the selected hazard evaluation tool?
   - If yes, record the final score produced by the hazard evaluation tool and move to Final Step: Comparing Hazard Scores.
   - If no, then the alternative cannot be accurately compared to the chemical of concern. Remove the chemical from consideration in the AA unless additional information is found.

Final Step: Comparing Hazard Scores

After completing the hazard assessment, the assessor should compare alternatives to the chemical of concern to identify safer alternatives. Most of the hazard evaluation methodologies included in this module include a method to assign a final score to an alternative based on its hazard traits. Final scores can then be used to compare alternatives to the chemical of concern.

As an example, the GreenScreen® methodology assigns one of five benchmark scores based on the information identified in the hazard evaluation. These benchmark scores range from Benchmark-4, preferred options, to Benchmark-1, which are substances that should be avoided (

Table 3). For those alternatives where there is insufficient data to assign another score, the score Benchmark-U is assigned. The table also includes examples of alternatives that were identified as likely being Benchmark-1 during the initial screen against hazard lists. In this example, an assessor may conclude that any alternative that is assigned a score of Benchmark-4, Benchmark-3, or Benchmark-2 is safer than the chemical of concern.

Table 3: Example Final Hazard Scores for Alternatives and the Chemical of Concern.

Prefer-Benchmark-4
No alternatives identified
Use but still opportunity for improvement-Benchmark-3
Alternative a
Alternative b
Use but search for safer substitutes-Benchmark-2
Alternative c
Alternative d
Alternative e
Avoid-Benchmark-1
Alternative f
Alternative g
Chemical of Concern
Avoid-identified as likely Benchmark-1 during initial screen
Alternative h
Alternative i
Unspecified due to insufficient data-Benchmark-U
Alternative j
Alternative k

Depending on the needs of the alternatives assessment, alternatives can also be compared to each other to identify one or more preferred alternatives. For example, the two chemicals identified as Benchmark-3, (i.e., 'Use but still opportunity for improvement') could be selected as the preferred alternatives and would then be evaluated in other modules to determine whether any issues exist that would prevent them from being viable alternatives. Examples of characteristics that could preclude adoption of a preferred alternative include poor performance, lack of availability, issues associated with exposure, or unique impacts to at-risk communities. More information on determining AA needs is available in the chapter called 'Structuring the AA'.

If a hazard evaluation module is used to select only one or two preferred alternatives, then the assessor should document why other less hazardous alternatives are rejected. If no alternatives are identified as less hazardous, the review should identify what hazard traits would need to be improved to make alternatives safer options in the AA conclusions.

Process

1. Identify the hazard traits of the chemical of concern (this step may already have been done as part of the assessment scoping process or when identifying the minimum hazard criteria for the AA).
2. Establish the necessary criteria for an alternative to be considered acceptable. This could include specific hazard trait criteria or an overall score for the alternative that exceeds some threshold. A threshold for acceptability may have been established when decision criteria were identified. Document these criteria and the rationale for selecting them.
3. Compare each alternative to the chemical of concern. Are any alternatives not acceptable according to the established criteria?
   - If yes, designate the alternative as unfavorable and document the information used to reach the conclusion.
   - If no, continue the analysis.
4. Are there any acceptable alternatives according to the established criteria?
   - If yes, identify the alternatives as favorable and document the information used to reach the conclusion.
   - If no, stop the analysis. Further research is required to identify new alternatives that meet the criteria.
5. Decide whether alternatives should be compared to each other to identify preferred alternatives for further analysis. If yes, document which alternatives were identified as preferred and why.
6. Identify any acceptable/preferred alternatives that have hazard traits that should be evaluated further in the Exposure Assessment Module.

How have you addressed equity and environmental justice?

Environmental hazard traits, such as aquatic, terrestrial, or avian toxicity can have environmental justice impacts. For example, toxicity to wildlife and other natural resources can significantly impact economic, cultural, and religious practices of indigenous populations or other groups that rely on a specific ecosystem. If such environmental hazard concerns exist, they should be flagged and described.

Consider the hazard traits that were identified as connected to health outcomes that disproportionately impact EJ communities. Did an alternative demonstrate "high" concern for any of those hazard traits? Did a chemical used to create the alternative have any highly concerning hazard traits? If so, we recommend these alternatives are evaluated further using the Exposure Assessment Module.

For example, a safer alternative solvent used in a cleaning product could be classified as "high" for respiratory sensitization, which is not included in the minimum criteria for some hazard evaluations (Table 2). If adopted, this safer alternative could potentially exacerbate existing asthma, which is a common health concern in EJ communities. It will be important to understand the likelihood for exposure by inhalation given potential exposure pathways and considering physicochemical properties such as vapor pressure. Thus, further evaluation in the Exposure Assessment Module is warranted.

Appendix: Common Hazard Traits

Table 4: Common Hazard Traits Used in Hazard Assessments.

Hazard Trait	Definition
Carcinogenicity	Capable of increasing the incidence of malignant tumors, reducing their latency, or increasing their severity or multiplicity.[17]
Mutagenicity and Genotoxicity	**Mutagen**: Agents that induce permanent, transmissible changes in the amount, chemical properties, or structure of the genetic material. These changes may involve a single gene or gene segment, a block of genes, parts of chromosomes, or whole chromosomes. Mutagenicity differs from genotoxicity in that the change in the former case is transmissible to subsequent cell generations.[18] **Genotoxicity**: The more general germs genotoxic and genotoxicity apply to agents or processes which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non-physiological manner (temporarily) alter its replication. Genotoxicity test results are usually taken as indicators for mutagenic effects.[19]

[17] IARC. *Preamble to the IARC Monographs: A General Principles and Procedures: 2. Objective and scope*. 2006 [cited 2012 July 5]; Available from: http://monographs.iarc.fr/ENG/Preamble/currenta2objective0706.php.

[18] US EPA. *Design for the Environment Program AA Criteria for Hazard Evaluation*: 3. Terms. 2011 [cited 2012 July 1]. Available from: http://monographs.iarc.fr/ENG/Preamble/currenta2objective0706.php.

[19] GHS, Chapter 3.5: Germ Cell Mutagenicity. 2009 [cited 2012 July 1]. Available from: http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev03/English/00e_intro.pdf.

Hazard Trait	Definition
Reproductive toxicity	The occurrence of biologically adverse effects on the reproductive systems of females or males that may result from exposure to environmental agents. The toxicity may be expressed as alterations to the female or male reproductive organs, the related endocrine system, or pregnancy outcomes. The manifestation of such toxicity may include, but not be limited to, adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behavior, fertility, gestation, parturition, lactation, developmental toxicity, premature reproductive senescence, or modifications in other functions that are dependent on the integrity of the reproductive systems.[20]
Developmental toxicity (including Developmental Neurotoxicity)	Adverse effects in the developing organism that may result from exposure prior to conception in either parent, during prenatal development, or postnatal to the time of sexual maturation. Adverse developmental effects may be detected at any point in the lifespan of the organism. The major manifestations of developmental toxicity include: (1) death of the developing organism, (2) structural abnormality, (3) altered growth, and (4) functional deficiency.[21]
Endocrine Activity	A change in endocrine homeostasis caused by a chemical or other stressor from human activities such as the application of pesticides, the discharge of industrial chemicals to air, land, or water, or the use of synthetic chemicals in consumer products.[22]
Acute Mammalian Toxicity	Adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours.[23]

[20] US EPA, *Guidelines for Reproductive Toxicity Risk Assessment*. Federal Register, 1996. 61(212): p. 56274-56322. [cited 2012 June 30]. Available from: http://www.epa.gov/raf/publications/pdfs/REPRO51.PDF.

[21] US EPA, *Guidelines for Developmental Toxicity Risk Assessment*. Federal Register, 1991. 56(234): p. 63798-63826. [cited 2012 June 30]. Available from: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=23162#Download.

[22] US EPA. *Design for the Environment Program Alternatives Assessment Criteria for Hazard Evaluation*: 3. Terms. 2011 [cited 2012 July 1]. Available from: http://monographs.iarc.fr/ENG/Preamble/currenta2objective0706.php.

[23] GHS, *Chapter 3.1: Acute Toxicity*. 2009, United Nations. [cited 2012 June 30]. Available from: http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev03/English/00e_intro.pdf.

Hazard Trait	Definition
Systemic Toxicity & Organ Effects (including Immuno-toxicity); single dose	**Systemic toxicity**: Toxicity relating to the body as a whole or occurring at a site in the body remote from the point of contact with a substance.[24] **Single dose**: Total amount of a substance administered to, taken up, or absorbed by an organism, organ, or tissue in one application.[25] **Immunotoxicity**: Toxicity affecting integrated network of organs, glands, and tissues that has evolved to protect body from foreign substances, including bacteria, viruses, and other infection-causing parasites and pathogens.[26]
Systemic Toxicity & Organ Effects (including Immuno-toxicity); repeat dose	**Systemic toxicity**: Toxicity relating to the body as a whole or occurring at a site in the body remote from the point of contact with a substance.[27] **Repeat dose**: Total amount of a substance administered to, taken up, or absorbed by an organism, organ, or tissue in multiple applications.[28] **Immunotoxicity**: Toxicity affecting integrated network of organs, glands, and tissues that has evolved to protect body from foreign substances, including bacteria, viruses, and other infection-causing parasites and pathogens.[29]
Neurotoxicity	Adverse change in structure or function of central and/or peripheral nervous system following exposure to chemical, physical, or biological agent.[30] Neurotoxicity may be measured using a single instance of exposure or repeated exposure.

[24] Definition based upon definition for systemic found in the IUPAC Glossary of Terms Used in Toxicology, 2nd edition, available from the U.S. Department of health and Human Services at: http://sis.nlm.nih.gov/enviro/iupacglossary/glossarys.html, accessed 8/2012.

[25] Ibid.

[26] Ibid.

[27] Ibid.

[28] Ibid.

[29] Ibid.

[30] US EPA, *Guidelines for Neurotoxicity Risk Assessment.* Federal Register, 1998. 63(93): p. 26926-26954. [cited 2012 June 30]. Available from: http://www.epa.gov/raf/publications/pdfs/NEUROTOX.PDF.

Hazard Trait	Definition
Skin Sensitization	An allergic response following skin contact with the substance.[31]
Respiratory Sensitization	Hypersensitivity of the airways following inhalation of the substance.[32]
Skin Irritation or Corrosivity	**Skin irritation:** production of reversible damage to skin following application of test substance for up to 4 hours.[33] **Skin corrosion:** production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours.[34]
Eye Irritation or Corrosivity	**Eye irritation:** production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application.[35] **Eye corrosion:** production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application.[36]
Acute Aquatic Toxicity	The intrinsic property of a substance to be injurious to an organism in a short-term, aquatic exposure to that substance.[37]

[31] GHS, *Chapter 3.4: Respiratory or Skin Sensitization*. 2009, United Nations. [cited 2012 June 30]. Available from: http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev03/English/00e_intro.pdf.
[32] Ibid.

[33] GHS, Chapter 3.2: Skin Corrosion/Irritation. 2009, United Nations. [cited 2012 June 30]. Available from: http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev03/English/00e_intro.pdf.
[34] US EPA. *Design for the Environment Program AA Criteria for Hazard Evaluation*: 3. Terms. 2011 [cited 2012 July 1]. Available from: http://monographs.iarc.fr/ENG/Preamble/currenta2objective0706.php.
[35] GHS, *Chapter 3.3:Serious Eye Damage/Eye Irritation*. 2009, United Nations. [cited 2012 June 30]. Available from: http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev03/English/00e_intro.pdf.
[36] Ibid.
[37] GHS, *Chapter 4.1: Hazards to the Aquatic Environment*. 2009, United Nations. [cited 2012 June 30]. Available from: http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev03/English/00e_intro.pdf.

Hazard Trait	Definition
Chronic Aquatic Toxicity	The intrinsic property of a substance to cause adverse effects to aquatic organisms during longer term aquatic exposures which are determined in relation to the life cycle of the organism.[38]
Persistence	The length of time the chemical can exist in the environment before being transformed by natural processes.[39]
Bioaccumu-lation	The process in which a chemical substance is absorbed in an organism by all routes of exposure as occurs in the natural environment, e.g., dietary or ambient environment sources. Bioaccumulation is the net result of chemical uptake into the organism from respiration and the diet and chemical elimination from the organism including respiratory exchange, fecal egestion, metabolic biotransformation and growth dilution.[40]
Reactivity	A chemical that exhibits any of the following traits:[41] 1) Is normally unstable and readily undergoes violent change without detonating, 2) Reacts violently with water, 3) Forms potentially explosive mixtures with water, 4) When mixed with water, generates toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health and the environment, 5) Under acid or base conditions, can generate toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health and the environment, 6) Is capable of detonation or explosive reaction if subjected to strong initiating source or heated under confinement, 7) Is readily capable of detonation or explosive decomposition or reaction at standard temperature and pressure.
Flammability	Ability of a substance to be easily ignited and capable of burning with great rapidity.[42]

[38] Ibid.

[39] US EPA, *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances* 1999, p. 60194 – 60204. [cited 2012 June 30]. Available from: http://www.gpo.gov/fdsys/granule/FR-1999-11-04/99-28888/content-detail.html.

[40] Arnot, J. A. & F. A. Gobas, A review of bioconcentration factor and bioaccumulation factor assessments for organic chemicals in aquatic organisms. Environmental Reviews, 2006. 14: p. 257 – 297.

[41] Washington Dangerous Waste Regulations, WAC 173-303—090 (7) (a) (i)-(vii), available at: https://fortress.wa.gov/ecy/publications/publications/wac173303.pdf, accessed 8/2012.

[42] Based upon definition for flammable found in Webster's II New Riverside University Dictionary, The Riverside Publishing Company, 1988, Houghton Mifflin Company publishers.

Performance Evaluation Module

The Performance Evaluation module ensures that alternatives are technically favorable for the desired application and meet performance requirements. Without this assurance, companies may instead not remove the chemical of concern or may make a regrettable substitution by choosing an equally hazardous alternative that they know will work.

The module is based primarily on AA work by TURI at the University of Massachusetts at Lowell and guidance developed by the European Chemicals Agency (ECHA) for the REACH legislation. Applicable portions from the ECHA guidance can be found in the Appendix. The module provides three levels of performance evaluation as well as an initial step designed to help assessors identify what performance requirements alternatives should meet.

Table 5: Performance Evaluation Module Evaluation Levels.

Initial Step	*Select Performance Requirements:* Asks questions about the current function of the product or process function and the service it provides to determine baseline performance requirements.
Level 1	*Basic Performance Evaluation:* Uses a few, very basic questions about whether the alternative performs the required function in the product. This level uses qualitative information readily available from manufacturers and other sources to evaluate alternatives.
Level 2	*Extended Performance Evaluation:* Builds upon the information obtained in Level 1 to determine whether the alternative performs the required function in the product. It uses quantitative information of existing data reviewed by technical experts in the field to evaluate alternatives.
Level 3	*Detailed Performance Evaluation:* Expands upon the previous levels. It uses quantitative information to evaluate alternatives based upon results of specified tests reviewed and validated by technical experts.

Initial Step: Identify Performance Requirements

Before starting the technical performance evaluation, the assessor must first identify the relevant performance requirements they will use in their assessment. Performance requirements are those specific functions currently provided by the chemical of concern to a material, product, or process. To be adopted, an alternative must be able to provide similar functionality. Certain performance requirements may have been identified when decision criteria were chosen for the AA. More details on decision criteria are provided in the chapter on Structuring the AA.

To identify or refine performance requirements, we recommend considering what specific functions the chemical of concern provides at the chemical, material, product, process or

service levels. An alternative does not necessarily need to provide all these same functions to be a technically feasible alternative. Often, if the AA is not intended to identify alternatives for the manufacturers of a specific chemical or material, an alternative that provides the necessary product, process, or service function will be a viable substitute.

For example, per- and poly-fluoroalkyl substances have been used in compostable plates because they repel oil and water but don't prevent the breakdown during composting. This function works on the material level because it creates a compostable or otherwise disposable material that is also oil and water repellant. But it also provides a service to society, which is to have dishware holds food without leaking.

Identifying the performance requirements at all levels increases the likelihood of identifying viable substitutes. Looking again at compostable plates, an assessor will likely identify alternative chemicals that also repel oil and water that can be used added to compostable materials. However, an assessor might also identify reusable plates as a viable alternative. Reusable plates are incompatible with composting but are still oil and water repellant dishware, which means they still provide the same service function.

Finally, if the chemical of concern provides multiple functions, the assessor should consider whether all of those functions are necessary for all products, processes, or services under evaluation in the AA. Does the plate always need to be disposable in all applications included in the AA, or just in some applications? AA practitioners focused on identifying alternatives that are fit-for-purpose should consider this question. [43]

How have you addressed equity and environmental justice?

It is important to consider the essential function of the alternative in communities that may have been disproportionately impacted by chemical or product use. For example, consider the AA on solvent automotive paints conducted by the King County Hazardous Waste Management Program in Washington State.[44] Stakeholder engagement included talking to staff at automotive shops that use these paints. Employees helped assessors identify which performance requirements were essential for their needs as well as what tools and training would help alternatives to better replace the original products.

Process

[43] TURI and University of Massachusetts at Lowell, 2022. Guidance for Evaluating the Performance of Alternatives: Fit-for-Purpose Performance. Retrieved Dec 2023 from: https://www.sustainablechemistrycatalyst.org/alternatives-assessment

[44] Whittaker, S. and Brown, L, 2019. Waterborne vs. Solventborne Automotive Basecoats: An Alternatives Assessment. Local Hazardous Waste Management Program in King County. Publication Number LHWMP_0323

We strongly encourage assessors to engage with stakeholders that use or manufacture relevant products or processes to identify performance requirements. This includes but is not limited to businesses, employees, and consumers. When talking to consumers, it can be especially useful to talk to consumers that have diverse backgrounds, since for some products or processes uses and expected performance can be influenced by culture.

Questions in this section are designed to help the assessor answer three questions:

- What are the performance needs for the application, process, or product that contains the chemical of concern?
- Why is the chemical of concern used in this specific application?
- (If the AA practitioner is working with a specific business) At which of the following five levels does your business operate?

The answers to these questions will be used in the subsequent Performance Evaluation Module levels. All five questions do need to be answered to complete the Performance Evaluation.

- What are the performance requirements at the chemical level?
  - Does the chemical perform a specific function important for its performance? For example, if in a detergent one surfactant highly toxic to aquatic life is replaced with another that is less toxic, changes are made at the chemical level.
- What are the performance requirements at the material level?
  - Does the chemical perform a specific function important for the material performance? An example would be a plasticizer that is added to a hard plastic to make it more flexible, which may be needed for certain applications.
- What are the performance requirements at the product level?
  - Does the chemical perform a specific function important for its performance? For example, fire safety standards are required for some consumer products. Adding chemical flame retardants is one way to meet some of the fire standards in electronics. Using metal housings for electronics is an alternative way to meet these standards.
- What are the performance requirements at the process level?
  - Does the chemical perform a specific function important for its performance? An example would be use of a catalyst to improve the efficiency of a process.
- What are the performance requirements at the service level? What function does the product or process provide within a society?
  - What function within society does the product or process serve? For example, dry cleaning uses chemical treatments to clean clothes that should not undergo

traditional wet washing. Businesses can now purchase wet washing systems that are designed for fabrics that are typically dry cleaned.

If an assessor is conducting an AA to help a specific organization switch to a safer alternative, they may want to only consider certain performance requirements because of how their business operates. For example, a plasticizer manufacturer may only focus on chemical or material level functions, while an electronics manufacturer might only consider material and product level functions. The assessor should note any restrictions on what performance requirements were considered. We encourage all AA practitioners to consider the service level function, since all businesses ultimately provide some societal function.

Level 1: Basic Performance Evaluation

This level identifies favorable alternatives based on knowledge of their existing use, marketing information, and/or public reports. It focuses on readily available qualitative information. By considering the following questions, the assessor can make a reasonable evaluation of the alternative's technical feasibility.

Who should use this tool?

Assessors who have identified performance requirements that can be assessed using qualitative information. Those assessors conducting an AA for a specific company with more specific performance requirements may benefit from using a higher level in this module.

What resources and knowledge are required to use this tool?

Level 1 requires an assessor to have some understanding of the necessary performance requirements for alternatives. An assessor will also need some understanding of what authoritative bodies or expert sources might have information on the performance of various alternatives; these terms are defined in the process.

What level of confidence does Level 1 provide?

Level 1 can be used to determine whether an alternative meets the necessary performance requirements of a product or process. It may not address some performance requirements that are of interest to certain consumers or manufacturers. It is possible therefore someone looking to adopt an alternative may need to conduct additional performance tests to see how an alternative performs before adopting it.

Process

1. Has the alternative(s) already been identified as a favorable alternative with respect to one or more of the identified performance requirements?
   - Is the alternative being used (i.e., by others) for the same or similar function? For example, is a chemical being used as a flame retardant in other applications?
   - Is the alternative used in similar products available on the commercial market?
   - Is the alternative marketed in promotional materials as an option for providing the desired function for the specific application of interest?
   - Based upon answers to the above questions, does the alternative appear applicable to the product or process under evaluation?
     - If yes, identify the alternative as favorable. Evaluation complete.
     - If no, identify that the alternative is not technically favorable and document the information used to reach the conclusion. Continue the evaluation.
     - If unclear, continue the evaluation.

2. Has an authoritative body[45] demonstrated that the alternative functions adequately for both the process and product? Are there reports from an authoritative body that evaluates the alternative(s) for use in the specific or similar applications?
   - If yes, the alternative is identified as a potential alternative. Either exit the performance module or proceed to the next level of the assessment.
   - If no, continue the evaluation.

3. Is the proposed alternative(s) considered favorable but there are indications that it does not perform as well as the current chemical? For example, has the alternative been tested and found to insufficiently fulfill the necessary function?
   - If yes, can the process or product be modified to accommodate the alternative and improve its performance?
     - If yes, continue evaluation.
     - If no, is the difference in performance critical to the product?
       - If yes, eliminate the alternative as a favorable alternative and document the information used to reach the conclusion.
       - If no, continue the evaluation.
   - If no, continue the evaluation.

[45] An authoritative body is an organization independent of the manufacturer and not tied to industry funding in a way that could affect its independence. Authoritative bodies include state, federal and international government research organizations, independent research organizations conducting scientific studies, etc.

4. Has the proposed alternative(s) been identified by expert sources[46] as unfavorable, i.e., NOT a viable alternative based on performance?
    - If yes, how do the performance results compare to the desired function in the specific product or process?
        - Is the application of the alternative identical to the chemical of concern?
            - If yes the application is identical, the alternative is NOT technically feasible and document the information, including the expert sources that were consulted, used to reach the conclusion.
            - If no, the application is not identical, can the product or process be modified to accommodate the alternative?
                - If yes, identify the alternative as favorable. Evaluation complete.
                - If no, identify that the alternative is not technically favorable and document the information used to reach the conclusion. Evaluation complete.
    - If no, identify that the alternative is technically favorable and document the information used to reach the conclusion. Evaluation complete.
5. Optional. If desired consult with expert sources to compare technically favorable alternatives and identify those alternatives that are best in class. If none are identified, continue the AA with all acceptable alternatives.

Level 2: Extended Performance Evaluation

This level conducts a more in-depth investigation into the alternative's ability to satisfy performance criteria using both quantitative and qualitative information. It relies on technical experts for guidance on the likelihood of an alternative being technically favorable and adopted by companies. When available, specific performance tests can be used to evaluate technical performance.

Appropriate technical experts could include:

- Process engineers or scientists (chemists, materials scientists, etc.) employed by manufacturers currently using the chemical of concern or the alternative.
- Academic researchers who have published closely related scientific results associated with the performance criteria in question.

[46] Expert sources are individuals or organizations that have direct experience with the chemicals, materials, products or processes that are relevant to the performance evaluation. These sources can include researchers, purchasers, consumers, employees who have used the item in their work, manufacturers, and consultants. Examples of these types of expert are given in Level 2. The best expert sources to consult will depend on the performance requirement and the purpose of the assessment.

- End users of the products or processes using the chemicals of concern or the alternative, including employees who use the chemical, material, or product in their work.
- Marketing or sales staff familiar with customer requirements.
- Consultants with expertise in similar product development.

Before using information provided by a technical expert, use the following screening questions to ascertain whether technical experts may be biased. The conclusions from this screening should be documented in the AA report.

1. Are the technical experts independent and unbiased? For example, are they outside the management chain conducting the performance evaluation or otherwise free of influence by external factors that could bias the end results of the evaluation?
    - If yes, proceed with the recommendations of the technical experts.
    - If no, document your conclusion. Proceed to question 2.
2. Has the information provided been corroborated by any independent technical experts?
    - If no, include this information in your analysis of any data the expert provides.
    - If yes, proceed with the evaluation.

Who should use this tool?

Assessors who have identified performance requirements that cannot be assessed using only qualitative information or wish to use quantitative test data so that alternative performance can be numerically ranked. This level is also recommended for assessors who want to have performance findings reviewed by experts.

What resources and knowledge are required to use this tool?

Level 2 requires an assessor to have some understanding of the necessary performance requirements for alternatives. An assessor may want to identify and recruit independent experts to contribute to the evaluation.

What level of confidence does Level 2 provide?

Level 2 uses a mix of qualitative and quantitative information to determine whether an alternative meets necessary performance requirements. Since multiple technical experts are consulted, an assessor may have more confidence in the conclusions of the performance evaluation. However, the independence and veracity of the technical experts consulted is of critical importance to the assessment.

It is possible someone looking to adopt an alternative may still need to conduct additional performance tests to see how the alternative performs before adopting it.

Process

- Are specific tests available that would indicate the likelihood of the alternative satisfying the performance criteria for this application? Consider not only regulated performance criteria but also consumer acceptance and preference. Identify the appropriate tests. Testing may include laboratory testing, field tests, or industry standards (questionnaires, interviews, etc.).
  - If yes:
    - Have the tests been conducted and are the associated data readily available?
    - Has the alternative been sufficiently evaluated to identify it as a technically favorable alternative?
      - If yes, document the information and identify the alternative as technically favorable. Proceed with the evaluation.
      - If no, continue with the performance evaluation.
  - If no, can the technical feasibility be determined through other means? The ECHA Guidance (see Appendix) provides useful considerations on how to develop new feasibility tests. This guidance is intended to support applications for substance authorization under REACH. As such the terms used in this example and the audience are different from the ones we use in this module. We recommend that assessors considering this approach work closely with technical experts.
    - If yes, conduct the evaluation and determine if alternative is technically favorable. Document information used to reach the conclusion. Proceed with the evaluation.
    - If no, identify the alternative as potentially not technically viable. If it's possible to design quantitative feasibility tests, you can move to Level 3. Otherwise, proceed with the evaluation.
- Consult with technical experts to determine if using the alternative(s) would have a significantly adverse impact on any of the following:
  - The reliability of the product or process?
  - The quality and useful life of the final product?
  - Acceptance of the product by consumers?
  - The efficiency or throughput of the associated production process in a way that could be detrimental to the overall manufacturing process?
  - Function and performance of downstream processes?
  - Maintenance requirements including workforce training associated with manufacturing process?

  Remember to document which experts contributed information and what biases, if any, the experts might have.

- If the answer is yes to any of the above, document the findings. Are there known modifications that could mitigate these impacts?
  - If yes, evaluate the modifications against performance requirements. Document the conclusions of the tests and determine if any affect the technical performance of the product when the alternative is used. Note any modifications to the alternative and consider their impact in other evaluations, such as the exposure evaluation. Evaluation complete.
  - If no, consider whether the adverse impacts are sufficient to disqualify the alternative as technically favorable with respect to performance.
    - If yes, document the information used to reach the conclusion and label the alternative as not technically favorable. Evaluation complete.
    - If no, document the information used to reach the conclusion. Evaluation complete.
- If no, consider the alternative as a technically favorable based on performance. Document information used to reach the conclusion. Evaluation complete.

o Optional. If desired, use quantitative test data or consult with expert sources to compare technically favorable alternatives and identify those alternatives that are best in class. If none are identified, continue the AA with all acceptable alternatives.

Level 3: Comprehensive Performance Evaluation

At this level, the assessor would augment guidance from technical experts with experiments and/or tests to gain a deeper level of confidence with respect to the technical feasibility of the alternative. Quantitative testing must use the most current accepted analytical methods (e.g., ASTM D2240 using a Shore A durometer for hardness testing to ascertain a plasticizer's ability to achieve the desired level of rigidity for a plastic product) if available. Most commonly, this testing is conducted as a pilot scale test with a processing facility interested in adopting the alternative to confirm the technical feasibility of the alternative for the specific application.

Who should use this tool?

Assessors who require validated performance testing to evaluate alternative performance. Quantitative data is useful if the assessor intends to numerically rank alternative performance.

What resources and knowledge are required to use this tool?

Level 3 requires an assessor to identify or design performance tests that can be used to determine whether an alternative meets the necessary performance requirements. The assessor should consider carefully whether these tests are necessary to evaluate

performance, to avoid unnecessary elimination of viable alternatives from the assessment.[47]

What level of confidence does Level 3 provide?

Level 3 uses validated performance testing to evaluate alternative performance in consultation with technical experts. These tests can provide a high level of confidence that an alternative performs well under the parameters of the test. If a performance test is used that accurately reflects the performance needs of the product or process, then the assessor has a good degree of confidence that the alternative will meet the necessary performance requirements.

It is possible someone looking to adopt an alternative may still need to conduct additional performance tests to see how the alternative performs.

Process

Assessment of the alternative's performance feasibility is made using quantitative results in consultation with technical experts.

1. Has testing been performed using the specific standards/test procedures to indicate likelihood of satisfying the performance criteria within acceptable tolerances?
    - If no, perform the testing. Once the testing is complete, continue the evaluation.
    - If yes, does the alternative(s) pass the thresholds according to the test protocols?
        - If yes, the alternative is technically favorable. If the test was only done on material sample, proceed with product/process design/development using the alternative. Continue the evaluation.
        - If no, can the product or process design be modified to accommodate the alternative?
            - If yes, proceed with modifications and, if needed, product/process design/development and validation. Continue the evaluation.
            - If no, the alternative does not meet performance requirements. Document the information used to reach the conclusion. Evaluation complete.
2. Do test results support the assessment of the technical experts and indicate the product meets performance criteria?

[47] TURI and University of Massachusetts at Lowell, 2022. Guidance for Evaluating the Performance of Alternatives: Fit-for-Purpose Performance. Retrieved Dec 2023 from: https://www.sustainablechemistrycatalyst.org/alternatives-assessment

- If yes, proceed with product/process development using the alternative if the test was only done on material sample and validate the results. Identify the alternative as favorable. Evaluation complete.
- If no, can the process or product be modified to accommodate the alternative?
  - If yes, continue if needed with product/process development. Document information used to reach the conclusion and identify alternative as favorable. Evaluation complete.
  - If no, is the discrepancy sufficient to disqualify the alternative?
    - If no, continue if needed with product/process design/development. Document the information which led to this conclusion and identify alternative as favorable. Evaluation complete.
    - If yes, disqualify the alternative as technically favorable. Document the information used to reach the conclusion. Evaluation complete.

3. Optional. If desired, use test results to compare technically favorable alternatives and identify those alternatives that are best in class. If none are identified, continue the AA with all acceptable alternatives.

Appendix: Excerpt from ECHA Guidance[48]

3.6.1 Technical feasibility criteria

It may be possible to develop technical feasibility criteria. i.e. a list of technical requirements on function that must be fulfilled for an alternative to be technically feasible, (see Box 2 information below). A good understanding of the substance function is the basis for the development of these criteria. This list of criteria may include the tolerances of these requirements (i.e., an acceptable range) and may also include consideration of the constraints on functionality. For example, for replacing one substance with another the criteria may include a criterion on the minimum purity required or minimum physical or chemical properties that must be imparted to the end product. For the process changes needed to allow the use of an alternative, criteria may include the range of conditions that can be achieved with available technology and evaluation of whether these enable the alternative to be used for the desired function.

[48] European Chemical Agency, '*Guidance on the Preparation of an Application for Authorisation*', Version 1, January 2011, 141 pages.

Box 2. Technical Feasibility Criteria and Performance Analysis

The development of criteria for evaluating technical feasibility could include a series of steps, as set out below (a screen-printing ink cleaner is used as the example[49]):

1. Review the functional requirements of the use. For example, for a printing ink cleaner a minimal amount of residual ink on the screen after cleaning may be a specified requirement. A performance criterion may be that the screen must be cleaned until no visible ink residue remains on the screen surface.
2. Identify relevant performance characteristics that could be qualitatively or quantitatively evaluated. For example, these might include the ease of use (e.g., the physical effort required to clean the screens), the time required to accomplish the desired function (e.g., cleaning), the effectiveness of the alternative in achieving the function, or the effect of the alternative on the quality of the finished product (e.g., will use of the cleaner reduce the life of the screen).
3. Establish a performance scale for each of the performance measures to facilitate evaluation of the alternative/s. The scale should consider both subjective and objective characteristics. (For example, visual inspection could be used to assign a high, medium, or low level of cleanliness. A quantitative test, such as light transmission through cleaned screens, could be used to quantitatively measure the amount of residual ink left on a screen after cleaning). Some objective characteristics can be evaluated using standard product specifications, such as military specifications.

The technical criteria against which possible alternatives can be appraised for feasibility will depend on the Guidance on Authorisation Applications consideration of the function as well as other concerns such as customer requirements. The approach to technical feasibility set out here relies on setting a basis for technical feasibility that is determined by the functioning of the Annex XIV substance (the assumption here is that the Annex XIV substance performs the function adequately, otherwise the applicant would not be considering applying for continued use of the substance). However, this does not disregard the possibility that an alternative may out-perform the original substance in terms of technical functionality.

[49] Based on the EPA document: U.S. Environmental Protection Agency: Cleaner Technologies Substitutes Assessment - Office of Pollution Prevention and Toxics Washington, DC 20460 EPA Grant X821-543

Evaluation against technical criteria measures how well an alternative performs to meet the functional requirements of the use. Technical performance data can be collected for both current use and the alternative processes, and used as a basis for an evaluation. The effort required to perform a useful assessment of technical feasibility may vary depending on the thoroughness of the study and the specific nature of the process under consideration. In the first instance the evaluation would rely on the compiling of performance information from literature sources and from consultation rather than the design of an actual operating trial. The focus for the assessor will be on the:

- Design of accurate and reliable performance measures.
- Collection of required data from suppliers.
- Evaluation of relative performance of the alternative.

Cost and Availability Module

This module evaluates the cost and availability of potential alternatives in the AA process. Alternatives that appear feasible may either be cost prohibitive or not available in sufficient quantities to remain a favorable alternative. The basic evaluation looks at how alternatives are already used to determine cost and availability. Higher levels add questions about how currently externalized costs, such as social or health costs, or regulatory or market changes, would influence the cost or availability of an alternative.

This module provides a flexible framework that allows a wide range of assessors to determine if cost and availability considerations can add weight, positive or negative, to the selection of an alternative (**Error! Not a valid bookmark self-reference.**).

Table 6: Cost and Availability Module Evaluation Levels.

Level 1	*Basic Cost and Availability Evaluation:* This evaluation asks a few, very basic questions about whether the alternative is being used in cost competitive products. If yes, the alternative is considered feasible.
Level 2	*Basic Cost/Benefit and Availability Evaluation:* This evaluation builds upon the information obtained in Level 1 to determine whether the alternative could be available and cost effective if selected. It also includes some basic questions about the costs and benefits to society or the economy.
Level 3	*Extended Cost/Benefit and Availability Evaluation:* This evaluation expands upon the previous level to assess costs and benefits associated with product redesign to accommodate use of the alternative. The focus is on private costs and benefits. It also includes a more detailed evaluation of external costs and benefits.
Advanced (see Life Cycle Module Level 3)	*Full Cost/Benefit Analysis:* This level implements a full cost/benefit analysis and a more detailed life cycle costing evaluation as appropriate. It is the most complete and comprehensive evaluation of cost and available considerations.

Depending on the purpose of the AA, the assessor will likely need to establish boundaries for cost effectiveness and availability beyond what is described here. For example, an assessor conducting an AA as part of technical support to a specific company may need to identify alternatives that the company can access and use in a cost-effective manner, given their supply chains, resources that can be used to reformulate, external costs etc. An assessor that is more broadly identifying alternatives that are available within the market, however, will likely define availability by what any product manufacturers or users currently use. This assessor may also want to define cost-effectiveness by looking beyond the price of an alternative to society-wide costs and benefits of switching.

At all levels, the assessor must also take care to make sure that a cost comparison does not eliminate non-chemical alternatives, which may be difficult to identify as cost effective.

Alternative products or processes may require higher initial costs to switch but can be cheaper over the lifetime of the alternative due to decreased energy or waste disposal costs.

Moreso than the performance or inherent hazards, the cost and availability of an alternative are prone to changing as companies innovate or markets change. Therefore, it is important to state clearly what assumptions were made during the evaluation of cost and availability and how these assumptions impact the AA. Regardless of what level is used, all assumptions must be identified, explained, and justified.

How have you addressed equity and environmental justice?

When answering prompts in this module, be mindful of what costs or benefits are missing in the level of assessment used. Consideration of such costs (particularly those related to health or access) or cost over a lifetime may change how potential alternatives compare to each other and the chemical of concern. In some cases, a life cycle costing assessment may be useful. For example, consider a transformative process change like substituting anti-fouling boat paint with the creation of a boat washing industry. The alternative – while potentially more expensive on a per unit basis– may create opportunities for local small businesses, including jobs and local economic benefit.

If a full life cycle costing assessment is warranted and data and resources permit, employ that level of assessment in this guide and refer to the Stakeholder Involvement Module to guide effective engagement with potentially impacted communities.

If performing a full life cycle costing assessment is not feasible due to data and resource constraints, address, at minimum, whether changes in direct costs will significantly affect alternative accessibility. If yes, are there actions that would increase accessibility? Highlight options that would increase equitable access to alternatives in the AA conclusions.

Level 1: Basic Cost and Availability Evaluation

This evaluation asks a few, basic questions about whether the alternative is already being used for the application of interest or could be easily used in a cost-effective manner. The level is intended to help assessors generally identify what alternatives are already available in the market.

Who should use this level?

This level requires only limited knowledge and expertise by the AA assessor. The assessor determines if the alternative is currently being used in cost-effective products. Because the

assessor is only asking about the general availability and cost effectiveness of the alternatives, it is well-suited for AAs that identify alternatives that are already used in a similar product or process as the chemical of concern. This level is therefore more suitable for alternatives that are already in the market, as opposed to products that are still under development.

What resources and knowledge are required to use this level?

This level typically relies on publicly available information such as marketing information. An assessor can also speak with suppliers, product users and manufacturers to get more information on specific alternatives. Some of this information may have been collected when the assessor was first identifying alternatives.

What degree of confidence does this level provide?

A Level 1 evaluation will often be sufficient to determine whether alternatives are available to replace the chemical of concern in a product. Because this level only asks the assessor to consider the current cost or availability of alternatives, it only provides a snapshot of the current market for an alternative. Additionally, this level may not provide enough information to decide if an alternative would be available and cost effective for a specific company's product or process.

This level also does not consider the impact of any externalized costs on cost effectiveness, either from using the chemical of concern or using an alternative. Externalized costs can include things like the cost of disposing of hazardous materials during product manufacturing but also the health costs associated with exposure to a hazardous chemical. Externalized costs could also include the costs associated with climate change, if substitution were to significantly change the transport, energy, or water needs of the product or process. These costs are explored at higher levels.

Process

Level 1 uses readily accessible information to confirm that the alternative is either already used in products or could be used in a cost-effective manner based on information from expert sources. These expert sources could include:

- Product manufacturers.
- Retailers or distributors who sell relevant products.
- End users of the products or processes, including individuals, small businesses, or purchasers working for large organizations.
- Economists, especially those at academic or independent research institutions.
- Consultants with relevant expertise.

The best expert sources to consult will depend on the performance requirement and the purpose of the assessment.

The viability of the alternative is determined through responses to two simple questions:

1. Is the alternative currently used in the application of interest? Identify information sources used to reach the conclusion.
   - If yes, document information to reach the conclusion and identify alternative as favorable.
   - If no, continue to the next question.
2. Is the alternative currently offered for sale for the application of interest? Could the alternative be used in the application in a cost-effective way? Identify information sources used to reach the conclusion.
   - If yes, document information to reach the conclusion and identify alternative as favorable.
   - If no, document the information used to reach the conclusion. Identify the alternative as not favorable.

If the answer to either question is positive, the alternative is considered favorable for both cost and availability and the AA process continues. If all alternatives are identified as not favorable because they are not offered for sale or cannot be used for the application of interest in a cost-effective way, then the assessor is encouraged to look at a Level 2 Extended Cost and Availability Evaluation. This level asks basic questions about the impact of external costs on the cost-effectiveness of the chemical of concern and alternatives. A Level 2 evaluation may reveal differences in cost-effectiveness that cannot be identified by looking at what is currently available in the market.

Case Example

Deca-BDE in Televisions and Computers and Residential Upholstered Furniture, Washington Department of Ecology and Washington Department of Health

In 2008, the Washington Departments of Ecology and Health conducted an AA for Deca-BDE in electronic housings and residential upholstered furniture. For both types of applications, the assessment found that alternatives to Deca-BDE were already widely used. The AA found that the alternatives must be cost-effective, or manufacturers would not voluntarily be using them.[50]

[50] *pers. comm.,* Alex Stone, Washington Department of Ecology, January 14, 2013.

Level 2: Basic Cost/Benefit and Availability Evaluation

This level expands on Level 1 by considering the impact of external pressures on cost and availability. These externalities or other economic impacts can influence alternative availability or cost-effectiveness.

Externalities refer to costs or benefits directly or indirectly created by a product that may be paid for by those who have no control over product design or development. For example, products that become hazardous waste upon disposal incur costs to society for proper disposal. These costs can be paid by businesses or governments.

Human and environmental health externalities may be directly related to the toxic, eco-toxic, or physicochemical properties of a substance as well as, any other health and environmental impacts occurring in the affected supply chains. They can include differences in the potential costs associated with emissions from raw material extraction or processing and from the transport, storage, use, and disposal of chemical or materials. An assessor could also consider costs to human and environmental health due to climate change if the product or process is energy intensive or produces greenhouse gases.

Economic impacts are the net costs or savings to manufacturers, importers, downstream users, distributors and consumers in the supply chains for the chemical of concern and alternatives. Examples of economic impacts include 1) health care services required as a result of human health effects, and 2) reduced crop yield due to acidification. Macro-economic implications are also relevant such as economic growth, inflation, and taxes from the distribution of economic impacts and how relevant markets function.

Social impacts are the relevant impacts that may affect workers, consumers, and the public not covered under health, environmental, or economic impacts. Examples may include employment, working conditions, job satisfaction, education of workers, and social security. Other social impacts are discussed in the Social Impact Module.

Who should use this level?

This level is designed for assessors who want to determine whether alternative availability is likely to change and how that would impact its economic viability. As part of this evaluation, the assessor is also asked to decide if the wider adoption of an alternative would create any benefits or costs to society.

This level can be performed on its own or after a Level 1 analysis if the assessor concluded no alternatives were cost-effective and available based on current market information. The Level 2 evaluation can help the assessor identify alternatives where external pressures increase the cost-effectiveness.

What resources and knowledge are required to use this level?

Information sources include discussions with current and potential suppliers, simple internet searches, and readily available information on whether the potential alternatives are being used in competitive products on the market. An assessor can also talk to product users and manufacturers to get more information on specific alternatives.

It will also be necessary to talk to experts about external costs. Environmental and health economics experts can be consulted to identify potential costs or benefits of continuing to use the chemical of concern versus using alternatives. Stakeholders from impacted communities, especially EJ communities, at all stages of the product or service life cycle should also be consulted to ensure that all significant externalities have been documented. The Stakeholder Engagement chapter has more information on how to identify communities that may be impacted.

What degree of confidence does this level provide?

A Level 2 evaluation considers whether current or future uses of an alternative could be cost-effective compared to the chemical of concern. An assessor can use this level to identify alternatives that could be produced at both an amount and cost to compete with the chemical of concern were demand to increase. This level can increase confidence that viable emerging alternatives are not ignored.

The Level 2 evaluation will also provide some information on potential external costs or benefits that can help eliminate alternatives that will cost society. If an assessor needs a more detailed evaluation of external costs, they are encouraged to look at Level 3 of this module or the Advanced Cost/Benefit Analysis.

Some potential resources exist to help estimate the costs and benefits of externalities. We include a few examples but encourage assessors to seek out additional resources based on other external costs that may impact their evaluation.

- OSHA's Safety Pays Program includes a tool that assessors can use to estimate the cost of occupational injury or illness.
- OECD's project "Surveys on Willingness-to-Pay to Avoid Negative Chemicals-Related Health Impacts" can be used to understand how willing different societies are to pay money to avoid specific negative health outcomes associated with chemical use.

Process

The following questions guide this process:

1. Is the alternative being offered for sale for the application of interest? Identify what sources of information were used to reach the conclusion.
   - If yes, can the chemical of concern be replaced with alternative while maintaining cost effectiveness?
     - If yes, the alternative is favorable.
     - If no, continue the evaluation.
   - If no, if alternative production increases can price of the alternative chemical become cost effective?
     - If yes, the alternative is favorable.
     - If no, continue the evaluation.

2. Is the alternative currently being used for the application of interest? Identify what sources of information were used to reach the conclusion.
   - If yes, is the alternative being used in cost effective products or process when compared to those using the chemical of concern?
     - If yes, the alternative is favorable.
     - If no, continue the evaluation.
   - If no, is the price difference prohibitive?
     - If yes, document the reasoning used to reach the conclusion. Flag the alternative as potentially non-favorable and continue the evaluation.
     - If no, continue the evaluation.

3. Can the alternative be produced in sufficient quantity to meet increasing demand if the alternative is used in place of the chemical of concern?

   - If yes, can the chemical of concern be replaced with alternative while maintaining cost effectiveness?
     - If yes, document the information to reach the conclusion and identify alternative as favorable.
     - If no, document information used to reach the conclusion. Continue the evaluation.
   - If no, if alternative production increases can price of the alternative chemical become cost effective?
     - If yes, document information to reach the conclusion and identify alternative as favorable.
     - If no, document the information used to reach the conclusion. Continue the evaluation.

4. Consider the known external costs associated with the chemical of concern.
    - Based on what is known about the alternative, is there information to suggest that the alternative will change costs to society compared to the chemical of concern? Some examples of questions include:
        - Does using the alternative reduce the likelihood of negative health outcomes compared to the chemical of concern?
        - Does the alternative require significantly more or less energy during the manufacturing or transportation process?
        - Does the alternative require fewer input chemicals or materials that are damaging to the environment?
        - Is the cost of safely disposing or reusing the alternative significantly different?
        - Would adopting the alternative require widespread retraining or other substantial new costs throughout an industry?
    - If the answer is yes, document the conclusions, including any mitigating factors that might change costs, such as government assistance programs.
    - Based on what is known about the alternative, is there information to suggest that the alternative will add or remove benefits to society compared to the chemical of concern? This could include the creation of a new industry or widespread sustainability improvements. Document the conclusions.
    - Compare costs and benefits. Do the benefits outweigh the costs such that switching to the alternative would have a significant negative impact on society?
        - If yes, document the information used to reach the conclusion. Identify the alternative as favorable for this round of evaluation.
        - If no, identify the alternative as non-favorable for this round of evaluation.

Case Examples

Deca-BDE in Plastic Pallets, Pure Strategies, Inc.

In 2011, Pure Strategies, Inc., conducted an AA on the flame retardant Deca-BDE in plastic pallets for the Maine Department of Environmental Protection. In examining the costs of potential alternatives, the assessment identified costs involved in evaluating alternatives and the ultimate cost of pallets using alternatives in the marketplace. The assessment identified two alternative flame retardants on the market, but recognized that development and testing would be necessary to create a flame retardant and polymer mixture with the necessary performance criteria. Aside from the costs of development and testing, the assessment identified the key cost parameter as the recurrent costs of production of the flame retardant and polymer compound. The production of such a compound using either alternative was found to be less costly or comparable to Deca-BDE.

Five Chemicals Study AA Study, Toxics Use Reduction Institute
In 2006, at the direction of the Massachusetts' Legislature, TURI at the University of Massachusetts-Lowell assessed alternatives for five chemicals: lead and lead compounds, formaldehyde, perchloroethylene, hexavalent chromium, and di(2-ethylhexyl)phthalate. An evaluation of cost and availability was an integral part of the assessment. The legislature directed TURI to assess potential effects on the employment level and the economic competitiveness of the Commonwealth associated with adopting alternative chemicals or technologies. The final report includes several factors that could influence the overall benefit of switching to alternatives.

Level 3: Extended Cost/Benefit and Availability Evaluation

This level builds upon the previous levels and includes questions about the impact of redesigning the product or process. In addition, a final mitigation review is added to determine if there are any other possible steps to eliminate potential cost or availability limitations identified for alternatives. Level 3 also asks for more information about external costs associated with the process or the manufacture of a specific product.

In addition to readily evaluating information on the chemical cost and availability, this level determines if there are changes that can be made to the material used to reduce limitations related to cost and availability of the alternative. By altering the material to better incorporate the alternative (s), does the combined costs and availability of all components change to make the alternative(s) more favorable? For example, an alternative may not be cost effective because its use would require the addition of a much larger amount; however, if the product was changed, the amount of chemical added would be equal to or less than the original chemical now making it cost effective.

Who should use this level?

This level is best suited to assessors who can evaluate whether changes in the product or process being assessed will result in changes to the availability or cost comparability of an alternative. Level 3 is also useful for those who want to evaluate both internal and external costs and benefits in greater detail than in the previous levels.

What resources and knowledge are required to use this level?

The approach will depend on the level of knowledge and expertise of the individuals assessing the chemical, product, or process. The initial step to determine cost and availability can be done using readily available sources and evaluation of material changes as shown in the previous two levels. In addition, it is necessary to work with technical experts to evaluate the complete product to determine if changes can be made that will increase the viability of the alternative.

Like Level 2, it is also necessary to talk to experts about external costs. Environmental and health economics experts can be consulted to identify potential costs or benefits of continuing to use the chemical of concern versus using alternatives. Consult stakeholders from impacted communities, especially EJ communities, at all stages of the product or service life cycle to ensure that all significant externalities have been documented. The Stakeholder Engagement chapter has more information on how to identify communities that may be impacted.

What degree of confidence does this level provide?

This level provides the greatest amount of information on potential trade-offs without committing to a full life cycle cost assessment. It is designed to help assessors identify and discuss potential impacts or benefits to communities and businesses in a way that reinforces evaluations in other modules.

This level also helps assessors identify alternatives that may become readily available and cost-effective in the future or if products or processes are redesigned, which will help the assessor avoid eliminating potentially viable alternatives.

Process

Some potential resources exist to help estimate the costs and benefits of externalities. We include a few examples but encourage assessors to seek out additional resources based on other external costs that may impact their evaluation.

- OSHA's Safety Pays Program includes a tool that assessors can use to estimate the cost of occupational injury or illness.
- OECD's projects "Surveys on Willingness-to-Pay to Avoid Negative Chemicals-Related Health Impacts" and "Socio-economic Analysis of Chemicals by Allowing a better quantification and monetisation of Morbidity and Environmental impacts" can be used to understand the social, environmental, and health costs associated with continued hazardous chemical use.
- OECD's 2018 book on Cost-Benefit Analysis (CBA) and the Environment explores developments in CBA that can be used to evaluate climate and environmental health impacts. This book includes strategies to address the social costs of carbon emissions.
- The Climate Impact Lab's Climate Impact Lab Tracker is a high-level climate tracker that quantifies and projects the impacts of climate change historically and over the next ~75 years. It shows temperature impacts, mortality costs, and energy costs both in the U.S. and around the world. The maps are high level and would likely only be useful if considering impacts globally at the country level, or within the US at the state level.

How have you addressed equity and environmental justice?

When answering these prompts, be mindful of who benefits and who pays when an alternative is adopted.

For a level 3 evaluation, we recommend the following questions be included in your evaluation:

- To what extent does the alternative offer benefits to EJ communities in terms of local economic development or opportunities?
- To what extent will the alternative cost EJ communities in terms of negative impacts, such as costs due to negative health outcomes or climate change impacts?

During this assessment process, the following questions should be asked and answered:

1. Is the alternative being offered for sale for the application of interest? Identify what sources of information were used to reach the conclusion.
   - If yes, can the chemical of concern be replaced with the alternative while maintaining cost effectiveness?
     - If yes, document the information used to reach the conclusion and identify the alternative as favorable.
     - If no, document the information used to reach the conclusion. Continue the evaluation.
   - If no, if alternative production increases can price of the alternative chemical become cost effective?
     - If yes, document the information used to reach the conclusion and identify the alternative as favorable.
     - If no, document the information used to reach the conclusion. Continue the evaluation.
2. Is the alternative currently being used for the application of interest? Identify what sources of information were used to reach the conclusion.
   - If yes, is the alternative being used in cost effective products or process when compared to those using the chemical of concern?
     - If yes, document information to reach the conclusion and identify the alternative as favorable.
     - If no, document information used to reach the conclusion. Continue the evaluation.
   - If no, is the price difference prohibitive?
     - If yes, document the reasoning used to reach the conclusion. Identify the alternative as non-favorable for this round of evaluation.

- If no, continue the evaluation.

3. Can the alternative be produced in sufficient quantity to meet the demand if the alternative is used in place of the chemical of concern?
   - If yes, can the chemical of concern be replaced with the alternative while maintaining cost effectiveness?
     - If yes, document the information used to reach the conclusion and identify the alternative as favorable.
     - If no, document the information used to reach the conclusion. Continue the evaluation.
   - If no, if alternative production increases can price of the alternative chemical become cost effective?
     - If yes, document the information used to reach the conclusion and identify the alternative as favorable.
     - If no, document the information used to reach the conclusion. Continue the evaluation.

4. Can changes be made to the overall material, product, or process design to make the alternative cost-effective? Identify what sources of information were used to reach the conclusion.
   - If yes, document the conclusion and identify the alternative as favorable.
   - If no, document the conclusion. Continue the evaluation.

5. Are there other steps that can be taken to make the alternative cost effective or that make the re-designed product or process desirable from a market perspective? For example, although the re-designed product containing the alternative may be less cost effective, does it open new markets and avenues for expansion?
   - If yes, document the information used to reach the conclusion and identify the alternative as favorable.
   - If no, document the reasoning used to reach the conclusion. Identify the alternative as potentially non-favorable and continue the evaluation.

6. Are there substantive differences in the cost of the alternative, i.e., the inputs and outputs and associated impacts, during extraction, manufacture, use, disposal, etc., of the product? Information for this review should be based on an evaluation of detailed technical information available or test data completed by experts. The reasoning for inclusion or exclusion of specific inputs or outputs must be explained in the final AA report.
   - If yes, the cost will be considered as a factor impacting the viability of switching to the alternative. Document the information used to reach the conclusion, identify the alternative as potentially warranting more review for LCA. Continue the evaluation.

- If no, note that life cycle costs are not a limiting factor and document the information used to reach the conclusion. Continue the evaluation process.

7. Can any negative cost and availability impacts be mitigated to eliminate or minimize the impact? Mitigation may include but is not limited to purchasing contracts, purchasing liability insurance, recycling programs, product stewardship, use minimization, etc. Information for this review will be based on an analysis of readily available technical information accessible to the assessor.
   - If yes, note that the specific cost component is not a limiting factor and document the information used to reach the conclusion. Continue the evaluation process until all negative cost and availability impacts have been evaluated to determine if mitigation is possible.
   - If no, document the information used to reach the conclusion and bin the alternative as potentially warranting more review for this life cycle cost and continue until all identified cost have been evaluated.

Advanced: Full Cost/Benefit Analysis Evaluation

The full cost to society for manufacture, transport, use, and disposal of a particular product is considered in the Life Cycle Analysis Module. Life cycle considerations applied to economics are sometimes called Life Cycle Costing (LCC). LCC is a method designed to assess traditional costs and benefits associated with a product and includes consideration of "externalities" from the entirety of a chemical, material, product, or process life cycle.

This level results in the most complete and detailed evaluation of cost and availability information using traditional CBA and LCC techniques. More information on LCC techniques can be found in the Life Cycle Module.

Exposure Assessment Module

The Exposure Assessment Module is used after the Hazard Assessment Module to evaluate risk, which is the combination of the inherent hazards of a substance and how one encounters it. The exposure module may also be to identify new exposure scenarios or to understand the potential risk to communities that use the products frequently or live near manufacturing, use, and disposal sites.

Exposure should not be used to select alternatives without also considering hazard. By prioritizing alternatives with the lowest hazard, the assessor can be more confident that risk is reduced even if exposure increases later. An alternative with a low hazard but a higher exposure can be made safer if methods to reduce its exposure are implemented.

Not all alternatives will result in the same exposure scenarios. Exposure assessment can also support the selection of alternatives when the inherent hazards are similar but the functional use of one alternative would result in increased risk due to the quality and/or quantity of the resulting exposure.

In this module, qualitative or quantitative information from throughout the chemical or product life cycle are used to understand potential exposure. This assessment can also help assessors identify new or changing exposure routes or exposure pathways and evaluate whether they are significant enough to make an alternative unfavorable.

How have you addressed equity and environmental justice?

EJ communities are disproportionately exposed to toxic chemicals across their lifecycle of manufacturing, use and disposal. These disproportionate exposures may occur via several mechanisms including but not limited to residence in fence line neighborhoods, practicing subsistence living, or employment in industries that are significant users of toxic chemicals, often in underregulated or informal sectors, such as construction, janitorial, cleaning, beauty, or automotive repair.

Use the Exposure Assessment Module to evaluate alternatives with an EJ lens to safeguard against new, cumulative, or different burdens. Important considerations are highlighted in Assessing Exposure Impacts to EJ Communities.

This module consists of three levels and an Advanced Approach (

Table 7). Level 2 has been augmented to coincide with the comparative exposure approach identified in the National Academy of Sciences *A Framework to Guide Selection of Chemical Alternatives*, released in October 2014.

Table 7: Exposure Assessment Module Evaluation Levels.

Level 1	*Basic Exposure Evaluation:* This level asks a set of questions designed to identify exposure routes and pathways for the chemical of concern and the alternative. The goal is to identify red flags that indicate an alternative should not be recommended.
Level 2	*Comparative Exposure Evaluation:* This level utilizes a qualitative assessment of readily available data to identify whether material differences exist between the chemical of concern and potential alternative(s).
Level 3	*Detailed Exposure Evaluation:* This level builds on previous levels and requires detailed scientific studies as the basis for decisions. If these studies are not available then they are conducted and the data are used to determine the importance of exposure in the AA process.
Advanced	*Full Exposure Assessment:* This level requires a complete and detailed exposure assessment as defined in the Risk Assessment Process by the National Academy of Sciences.

It is important to state clearly what assumptions were made during the exposure assessment and how these assumptions impact the AA. Regardless of what level is used, all decisions or assumptions should be identified in the AA report.

Introduction

The Exposure Assessment Module provides a flexible framework that allows assessors to determine if exposure considerations can add weight, positive or negative, to the selection of an alternative.

According to Centers for Disease Control and Prevention, a hierarchy of exposure controls has been used to protect workers. The same approach applies to protecting consumers and the environment from exposure to hazardous chemicals. The concepts behind the hierarchy of exposure controls can be summarized as follows:

1. Elimination
2. Substitution
3. Engineering Controls
4. Administrative Controls
5. Personal Protective Equipment (PPE)

The control methods at the top of the list are considered more effective and protective than those at the bottom. Elimination and substitution are most effective at reducing risk by reducing hazards. They can best be applied when the product or process is still open to design and/or development and may be the most inexpensive and simplest to implement from the exposure perspective.

Engineering controls can reduce risk by putting a barrier between the user and the hazard. While engineering controls may be effective, they can and do fail, at which time risk will increase. Administrative controls and PPE are frequently used in the work environment. They may be easier to implement in the short term but less protective over time since they require individuals to take constant, consistent action to minimize exposure.

A similar control hierarchy can be defined for consumers and consumer products. Elimination represents the removal of toxic chemicals from products; substitution represents the use of presumably inherently safer alternatives in consumer products. Engineering controls refer to design solutions, such as packaging that prevents exposure during product use. Administrative controls on a consumer product could include appropriate directions and/or warnings for proper use such with ventilation. PPE may be recommended for use with certain products.

As with the occupational hierarchy, the most effective mechanisms for controlling consumer exposure to toxic chemicals in consumer products are the elimination of hazardous chemicals and/or their substitution with safer alternatives. Manufacturers cannot prevent consumers from tampering with engineering controls or ensure directions are followed or recommended PPE used.

Applying Life Cycle Thinking to Exposure Evaluation

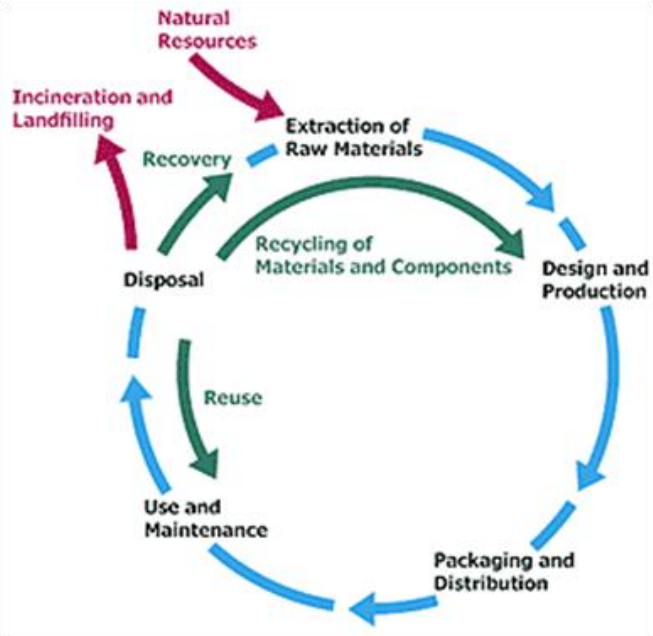
When evaluating the exposure potential of alternatives, it is important to use life cycle thinking to ensure that no significant exposure pathways are missed. LCT asks assessors to go beyond production site and manufacturing processes and consider the environmental, social and economic impacts of a product over its entire life cycle (

The main goal of LCT is to support LCA and reduce the impact of product emissions and resource use. But LCT can also be used by assessors to methodically evaluate the exposure pathways associated with an alternative product or process from cradle-to-grave or cradle-to-cradle. LCT is especially useful to help assessors identify any gaps in expertise in the product or process life cycle, so that assessors can take steps to engage with relevant stakeholders or researchers that can address those knowledge gaps.

Figure 9).

The main goal of LCT is to support LCA and reduce the impact of product emissions and resource use. But LCT can also be used by assessors to methodically evaluate the exposure pathways associated with an alternative product or process from cradle-to-grave or cradle-to-cradle. LCT is especially useful to help assessors identify any gaps in expertise in the product or process life cycle, so that assessors can take steps to engage with relevant stakeholders or researchers that can address those knowledge gaps.

Figure 9: Life Cycle Thinking.[51]



Assessing Exposure Impacts to EJ Communities

How have you addressed equity and environmental justice?

EJ communities are exposed to higher numbers of hazardous chemicals because of their location, employment, and/or cultural practices. Many EJ communities that are most impacted by chemical substitution are fenceline communities adjacent to chemical and product manufacturing, use, and disposal sites. Because many companies will make or use both the chemical of concern and potential alternatives, it is crucial for assessors to consider potential exposure scenarios within these communities.

Alternatives should not lead to increases in exposure or more hazardous exposures at these life cycle stages and any that may lead to reduced exposures should be prioritized.

Although exposure data for many alternatives may be difficult to obtain, we strongly recommend assessors address the impact to EJ communities to the extent possible. Assessors can incorporate several considerations into the different Exposure Assessment levels, such as:

- When considering how exposure potential is likely to change if an alternative is adopted, use a wide array of information sources. In addition to those items listed in

[51] United Nations Environmental Programme, *Life Cycle Management: A Business Guide to Sustainability*, 2007, 52 pages.

the Resources section, assessors should use knowledge of materials management and product stewardship for the application/use under evaluation when possible.

- In the Hazard Module, the assessment may have identified alternatives that are safer than the chemical of concern but still have certain hazard traits that were categorized as high or very high. When evaluating exposure, prioritize evaluating any exposure pathways that are connected to those traits. For example, if a safer alternative was categorized as having high chronic aquatic toxicity, it is important to confirm there are no significant exposure pathways in which the alternative concentrates in surface water. See an additional example in the Box: Asthmagens.
- Question whether the alternative is expected to significantly increase disproportionate exposures among EJ communities. Pay particular attention to fenceline communities, who already face increased exposures to chemicals due to emissions from manufacturing and disposal sites. Quantitative data are often lacking on alternatives, so a qualitative or semi-quantitative approach is sufficient, data permitting.
- Ask whether the alternative is likely to increase exposures for EJ communities who have the highest exposures to the chemical of concern. In many cases, this community will comprise manufacturing, disposal, and sanitation workers, who are exposed at work, sometimes without proper PPE, and often also exposed at home if they live near a manufacturing or disposal site.
- If disproportionate exposures are expected to persist with alternatives, are there additional provisions that should be flagged for the implementation stage, such as needs for continued oversight, environmental monitoring, and/or community/worker engagement to ensure EJ communities are protected?

As always, assessors should document any methods used and the rationale behind any decisions. To be transparent, we recommend this documentation include acknowledging likely exposure pathways where there was not enough data to evaluate the alternative.

Box: Exposure Evaluation of Potential Asthmagens.

Consider the example from the Hazard Assessment Module of an alternative that was evaluated as "high" for respiratory sensitization, which may exacerbate asthma, a disease that is significantly elevated within EJ communities. During the exposure assessment, assessors should pay attention to exposure pathways that indicate the alternative may be inhaled more than the chemical of concern. The assessor should ask:

- Is inhalation an expected route of exposure given reasonably foreseeable conditions of use of the alternative?
- Is the alternative classified as a VOC or is its vapor pressure indicative of concern for inhalation?

A "yes" answer to either of the above may be a reason to either list the alternative as unfavorable. The alternative could also be listed as a less favorable alternative that should only be used if no better alternatives are identified. If the alternative is still considered safer, the assessor could recommend protective measures such as industrial exposure controls that can reduce exposure.

Level 1: Basic Exposure Evaluation

Level 1 asks basic questions about possible differences in exposure that might indicate some alternatives should be eliminated or de-prioritized. This level can also be used to decide whether a comparative exposure evaluation would be helpful to the assessment.

If the preliminary questions in this level indicate no further exposure assessment is necessary, the assessor should continue to evaluate this decision throughout the AA process to guarantee that no other subsequent decisions in other modules affect this assumption.

Who should use this level?

Assessors are encouraged to use this level if they have identified less hazardous alternatives and want to confirm there are no significant differences in exposure between those alternatives and the chemical of concern. This level is also useful for assessors who want to determine if an in-depth comparative exposure evaluation would be useful.

What resources and knowledge are required to use this level?

This level asks qualitative questions to identify possible exposure scenarios. The assessor can primarily rely on publicly available information about exposure and discussions with exposure experts and stakeholders to complete the assessment. Physical chemical properties can also be used to identify potential red flags. It is important to include

stakeholders involved in all steps of the product or process life cycle to ensure any red flags are identified.

What degree of confidence does this level provide?

This level evaluates whether an alternative is expected to have a high exposure potential. It does not provide a quantitative analysis and does not consider how changes to an alternative might impact exposure. When considering alternatives that have comparable hazards to the chemical of concern, a more in-depth analysis may be needed.

Process

Before beginning this process for the alternatives, the assessor should attempt to characterize the exposures associated with the chemical of concern, to establish a basis for comparison. The same questions can be used.

1. PRELIMINARY QUESTION: Have you assessed the alternative for hazard?
    - If no, go to Hazard Module and conduct a Hazard Assessment before returning to this module.
    - If yes, has the alternative been fully assessed and been defined as inherently benign for all hazard criteria (such as GreenScreen Benchmark 3 or 4)?
        - If yes, further exposure assessment is not necessary. Document the information used to reach the conclusion. Exposure assessment complete.
        - If no, continue the evaluation.
2. *Qualitatively*, what are the exposure pathways created during manufacture, transportation, and/or storage, use, end-of-life, recycling, etc.? How might people or other species be exposed to the alternative(s) or the chemical of concern?

Take a systematic approach to reviewing exposure concerns during all product life stages (see the Appendix for suggestions). At minimum, consider the questions in As an example, consider a chemical added to a plastic toy intended for very small children, who often mouth at products. If the chemical has an aqueous solubility is greater than 20,000 mg/L, it is soluble in saliva and could be ingested by a child during the use phase. The Appendix includes other links between exposure pathways and exposure routes that should be considered.

3. For a given alternative, did the analysis identify any completed exposure pathway that was not also identified for the chemical of concern?
    - If yes, identify the scenario as a red flag and proceed with the evaluation. The child's toy would likely be given a red flag for chemical ingestion during the use

phase if the chemical of concern did not also present a similar completed exposure pathway.
    - If no, document the information used to reach the conclusion. Continue the evaluation.

4. Is there evidence that any of these completed exposure pathways would lead to significantly elevated exposure to an EJ Community or disadvantaged and/or vulnerable population? To the extent possible, use the considerations in Assessing Exposure Impacts to EJ Communities to answer this question.
    - If yes, note the exposure route as a potential red flag. Document the information used to reach the conclusion.
    - If no information was available, document what sources were used to reach that conclusion. Continue the evaluation.
    - If no, document information used to reach the conclusion. Continue the evaluation.

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Table 8: Qualitative Questions to Identify Exposure Pathways.

Life-Cycle Stage	Qualitative Inquiry
Manufacture	• Are workers prone to exposure (inhalation, ingestion, dermal, physical/chemical risk, etc.) during manufacture? • Does the manufacturing process lead to environmental exposure (leaching into air, water, soil)? If yes, what is the likely fate in the environment?
Transportation/Storage	• Is there risk of exposure from combustion, corrosivity, etc.?
Use	• Do the intended or foreseeable uses suggest an exposure pathway? • Is alternative prone to leaching, disassociation, degradation or other means of escape from product into the user or either indoor or outdoor environments?
End-of-Life	• Does disposal/reclamation/recycling create risk of environmental exposure from leaching into air, water, soil? • Does disposal/reclamation/recycling create risk of exposure to workers from inhalation, ingestion, dermal, physical/chemical risk, etc.?
	• Do any physical or chemical properties, such as persistence or solubility, suggest likely exposure pathways?

Possible exposure pathways could include:

- A substance used in a shower cleaning solution and is designed to be washed down the drain. Because the substance has been characterized as very persistent and very mobile, it is likely to remain in water and could reach both aquatic species and get into drinking water to expose people.
- A substance with a low vapor pressure used as a construction sealant. The substance is likely to disperse to the surrounding environment.

5. Next, for each potential exposure pathway, identify relevant exposure routes for people and/or environmental receptors for the chemical of concern and the alternative(s). (See Box on next page)
    - Is there evidence that the alternative follows any of these routes? It may be useful to consider certain physical chemical properties to see whether they indicate relevant exposure route (see box for details).

- If yes, note the completed exposure pathway and relevant exposure route. Document the information used to reach the conclusion. Continue the evaluation.
- If no, document information used to reach the conclusion. Continue the evaluation.

Box: Exposure Routes.

The EPA defines an exposure route as "a point of contact/entry of a stressor from the environment into an ecological receptor."[52] There are three ways chemicals can enter the body upon contact:

- Ingestion: Swallowing anything (e.g. food, beverages, or particulate matter) that contains the chemical of concern.
- Inhalation: Breathing in dust, gases, mists, or air that contains the chemical of concern.
- Dermal absorption: The chemical of concern is absorbed, on its own or mixed into a carrier substance, through the skin or mucus membranes.

Likely exposure routes can be identified through monitoring data or known fate and transport hazard endpoints identified in the hazard module. They can also be identified by reviewing product design information and physical chemical information for a substance. Examples include:

- A substance with a nanoscale particle size, such as an unbound, unagglomerated nanomaterial, is more likely to be inhaled, ingested, and absorbed through the skin.
- A chemical that has a vapor pressure less than 10^{-4} mmHg is more likely to be inhaled.
- A substance that has an aqueous solubility greater than 3000 mg/L but less than 20,000 mg/L is more likely to absorb through the skin, while a substance that has a solubility greater than 20,000 mg/L is likely to be ingested through water.[53]

Note: if the substance being evaluated is a nanomaterial, then physical chemical properties measured for the bulk material may no longer be applicable. If exposure information cannot be determined, note this lack of information as a red flag.

[52] EPA. 1997. Ecological risk assessment guidance for superfund: Process for designing and conducting ecological risk assessments - Interim final [EPA Report]. (EPA/540/R-97/006).

[53] European Commission, 2020. Assessment of presence of CMR substances in certain categories of consumer articles that could be subject of Article 68(2) of REACH. Accessed Nov 2023. Available from: https://op.europa.eu/s/y6cI

As an example, consider a chemical added to a plastic toy intended for very small children, who often mouth at products. If the chemical has an aqueous solubility is greater than 20,000 mg/L, it is soluble in saliva and could be ingested by a child during the use phase. The Appendix includes other links between exposure pathways and exposure routes that should be considered.

6. For a given alternative, did the analysis identify any completed exposure pathway that was not also identified for the chemical of concern?
    - If yes, identify the scenario as a red flag and proceed with the evaluation. The child's toy would likely be given a red flag for chemical ingestion during the use phase if the chemical of concern did not also present a similar completed exposure pathway.
    - If no, document the information used to reach the conclusion. Continue the evaluation.

7. Is there evidence that any of these completed exposure pathways would lead to significantly elevated exposure to an EJ Community or disadvantaged and/or vulnerable population? To the extent possible, use the considerations in Assessing Exposure Impacts to EJ Communities to answer this question.
    - If yes, note the exposure route as a potential red flag. Document the information used to reach the conclusion.
    - If no information was available, document what sources were used to reach that conclusion. Continue the evaluation.
    - If no, document information used to reach the conclusion. Continue the evaluation.

8. Has the alternative been found in bio- or environmental monitoring studies?
    - If yes, note it as a red flag. An alternative found in monitoring studies does not necessarily pose a risk without additional evaluation, such as a hazard assessment or more in-depth exposure evaluation. For this simplified initial evaluation, presence in monitoring studies is assumed to be a concern.
    - If no, document the information used to reach the conclusion. Continue the evaluation.

9. Compare how the chemical of concern and alternative(s) are used to provide a good or service.
    - Are they used in similar ways?[54] For example, are the manufacturing criteria for the chemical of concern and alternative(s) similar for any of the following characteristics? Only evaluate pertinent criteria.

[54] More information on manufacturing criteria is available in the Performance Evaluation Module.

- Do they perform the same function in the product or process?
- Are they used in the same relative amounts?
- Are they used in the same manner? For example, are they both blended into the product matrix as opposed to being chemically attached?

10. Are there substantial differences in how the chemical of concern and alternative(s) are used? Do the difference indicate a greater likelihood that workers will be more exposed or there will be more releases to the environment from the alternative?

    - If yes, identify the manufacturing criteria of concern as a red flag and proceed with evaluation.
    - If no, document the information used to reach the conclusion. Continue the evaluation.

11. CONCLUSION: Did you identify any red flags for this alternative?

- If no, your exposure assessment is complete. Document any information not already included in responses to previous questions and indicate an exposure assessment did not identify any areas of concern.
- If yes, document any additional information not already included in responses to previous questions. Based on the red flag or flags identified, decide whether a more detailed exposure assessment is warranted or whether the alternative should be eliminated from further consideration. Document the decision.

Level 2: Comparative Exposure Evaluation

Level 2 builds upon information in the previous level and asks additional specific questions related to exposure. It uses more information about physical chemical properties and other criteria to qualitatively assess the potential exposure impacts of replacing a chemical of concern with an alternative.

Who should use this level?

Assessors are encouraged to use this level if they have identified alternatives with similar hazard concerns and want to determine if there are significant differences in exposure. This level is also useful for assessors who want to determine if a quantitative comparative exposure evaluation would be useful.

What resources and knowledge are required to use this level?

This level asks qualitative questions about exposure that rely on knowledge about physiochemical properties and potential exposure pathways. Some of these questions build on work done in Level 1. The assessor can primarily rely on publicly available information

about exposure and discussions with exposure experts and stakeholders to complete the assessment.

What degree of confidence does this level provide?

This level evaluates whether major differences in exposure exist for an alternative. It does not provide a quantitative analysis of exposure. For alternatives that have any reduced hazard potential compared to the chemical of concern, this qualitative exposure evaluation should be sufficient. For alternatives with equivalent hazard concern to the chemical of concern, a quantitative exposure evaluation will likely be required.

Process

The process starts by identifying known and likely exposure pathways and then combining with exposure routes. If needed, completed exposure pathways are then used along with information from biomonitoring studies, manufacturing practices, and the hazard evaluation to determine whether exposure is more likely to occur if the alternative is used.

1. Identify possible exposure pathways created during the alternative's life cycle. How might people or other species be exposed to the alternative(s) or the chemical of concern? Have any exposure data been reported during the manufacture, transportation, and/or storage of the alternative or the product, use of the product or end-of-life?

   Are there other exposure pathways that are created during manufacture, transportation, and/or storage, use, end-of-life, recycling, etc. that have not been reported on?

Take a systematic approach to reviewing exposure concerns during all product life stages and make sure that all stages listed have been considered in the assessment. As an example, consider a chemical added to a plastic toy intended for very small children, who often mouth at products. If the chemical has an aqueous solubility is greater than 20,000 mg/L, it is soluble in saliva and could be ingested by a child during the use phase. The Appendix includes other links between exposure pathways and exposure routes that should be considered.

12. For a given alternative, did the analysis identify any completed exposure pathway that was not also identified for the chemical of concern?

    - If yes, identify the scenario as a red flag and proceed with the evaluation. The child's toy would likely be given a red flag for chemical ingestion during the use phase if the chemical of concern did not also present a similar completed exposure pathway.

- If no, document the information used to reach the conclusion. Continue the evaluation.

13. Is there evidence that any of these completed exposure pathways would lead to significantly elevated exposure to an EJ Community or disadvantaged and/or vulnerable population? To the extent possible, use the considerations in Assessing Exposure Impacts to EJ Communities to answer this question.
    - If yes, note the exposure route as a potential red flag. Document the information used to reach the conclusion.
    - If no information was available, document what sources were used to reach that conclusion. Continue the evaluation.
    - If no, document information used to reach the conclusion. Continue the evaluation.

in Level 1 and the Appendix may be used as starting points. Document any potential exposure pathways that are identified.

Compare physicochemical properties between the chemical of concern and alternative. A list of properties to consider is found in

2. Table 9. Other properties can be found in Greggs et al. (2018) “Qualitative Approach to Comparative Exposure in Alternatives Assessment”.

   Note: if the substance being evaluated is a nanomaterial, then physical chemical properties measured for the bulk material may no longer be applicable.

Table 9: Recommended Physicochemical Properties.

Property	Reason	Guidelines (NAS, 2014)
Volatility/ vapor pressure	Volatility and vapor pressure influence how likely the chemical is to be found in the air or how likely it is to enter the body	$<10^{-8}$ mmHg; considered likely to found in the air. $< 10^{-4}$ mmHg; considered to be more likely to enter the body.
Molecular weight and size	Generally, as molecular weight and size increase, bioavailability decreases (leading to a lower toxicity potential)	>1,000 amu is less likely to be bioavailable
Solubility in water	Generally, a chemical that is highly soluble in water will have more bioavailability and toxicity. In addition, water soluble chemicals are more likely to be found water bodies and precipitation.	<1 ppb generally have lower water solubility
Log of the water-octanol coefficient [55]	An indicator of potential for bioaccumulation, as well as bioavailability.	Higher log of the water-octanol coefficient values indicate greater bioaccumulation potential. Generally use the thresholds: <5 for mammals <4 for aquatic species
Boiling point	The boiling point helps to determine if the chemical will be a liquid or gas at a certain temperature.	<25 C will be a gas at room temperature

[55] Log of the octanol water partition coefficient which evaluates a chemicals tendency to dissolve either in water or organic solvents. Called 'Phase Partitioning' in the NAS Framework.

Property	Reason	Guidelines (NAS, 2014)
Melting point	The melting point will determine if the chemical will be a solid or liquid at a certain temperature.	<25 C will be a liquid at room temperature
Density or specific gravity	Has implications for where the chemical might partition when with other liquids or gases	
pH	A measure of free hydrogen. Has implication for water solubility and potential damage to cells.	For certain products, a pH of >2 and <11.5 is safest for eyes and skin (Safer Choice 2015)
Corrosivity	Associated with the ability to gradually destroy materials by chemical reaction.	GHS criteria are used to determine level of concern. Typically, the more extreme the pH (either high or low), the more likelihood of corrosivity issues whether it be to the eye, skin, respiratory system, etc. Typical pH values used are approximately below 3 and above 10. Review GHS criteria for more details.
Environmental Partitioning	A measure of how easily molecules or salts will break apart in under certain conditions (primarily in solution)	The higher the dissociation constant, the more likely the molecules or salts will break apart.

Property	Reason	Guidelines (NAS, 2014)
Use characteristics (binding properties) or synergistic effects	Other properties that can help determine the state of the chemical in the environment and biological compartments or interactions with other chemicals found in the environment.	The acid dissociation constant is used to help identify availability of chemicals to bind to one another. Acid dissociation constants of concern typically range between < 3 (acid) and > 11 (bases). Synergistic effects identify how other chemicals may impact availability of the chemical of concern. For example, dimethyl sulfoxide easily enters skin. Chemicals dissolved in the solvent can be more biologically available than chemicals dissolved in other solvents.

Are the chemical properties for the chemical of concern and alternative materially similar? Or do material differences exist? (For any of the characteristics in

- Table 9, only evaluate pertinent criteria for the alternatives). Document your conclusions for

3. For each potential exposure pathway identified in step 1, determine what exposure routes for people and/or environmental receptors if any are relevant. Use the physical chemical property data identified in step 2. For each alternative and the chemical of concern, document any completed exposure pathways identified based on the identified exposure pathways and likely exposure routes. If there are adequate data indicating the alternative does not create likely exposures, further evaluation is not required.

4. Did the analysis identify any completed exposure pathway for the alternative that was not also identified for the chemical of concern?
    - If yes, did the life cycle evaluation indicate any completed exposure pathways where the alternative presents a materially greater exposure concern? If yes, identify the pathway as a concern and proceed with the evaluation.
    - If no, are there adequate data to support that the alternative does not pose an exposure concern?
        - If yes, document the information used to reach the conclusion. Evaluation complete.
        - If no, identify the exposure pathway as a data gap that may affect the alternative's viability as a safer alternative. Proceed with the evaluation.

5. Is there evidence that any of these completed exposure pathways would lead to significantly elevated exposure to an EJ Community, disadvantaged and/or vulnerable population, or other sensitive species or population? To the extent possible, use the considerations in Assessing Exposure Impacts to EJ Communities to answer this question.
    - If yes, did the life cycle evaluation indicate any completed exposure pathways where the alternative presents a materially greater exposure concern? If yes, identify the pathway as a concern and proceed with the evaluation.
    - If no information was available, document what sources were used to reach that conclusion. Continue the evaluation.
    - If no, document information used to reach the conclusion. Continue the evaluation.

6. Compare the manufacturing criteria for the chemical of concern and alternative. Are there substantial differences in how the chemical of concern and alternative(s) are used? For example, are the manufacturing criteria for the chemical of concern and

alternative(s) similar for any of the following characteristics? Only evaluate pertinent criteria. [56]

- Do they perform the same function in the product?
- Are they used in the same relative amounts or is the alternative used in lesser amounts?
- Are they used in the same manner? For example, are they both blended into the product matrix as opposed to being chemically attached?

Do the differences indicate a greater likelihood that workers will be more exposed or there will be more releases to the environment from the alternative?

- If yes, identify the manufacturing criteria of concern and proceed with evaluation.
- If no, are there adequate data to support that the alternative does not pose an exposure concern for any of the identified manufacturing criteria?
  - If yes, document the information used to reach the conclusion.
  - If no, identify the manufacturing criteria with a data gap that may affect the alternative's viability as a safer alternative. Proceed with the evaluation.

7. Consider the persistence, bioaccumulative, mobile and toxic properties of the alternative identified in the Hazard Module.

- Did the hazard evaluation find evidence that the alternative is very persistent and very mobile?
  - If yes, the alternative should be flagged as potentially concerning. Very persistent and very mobile chemicals can potentially contaminate water and spread globally.
  - If no, document the information used to reach the conclusion. Continue the evaluation.

- Did the hazard evaluation find evidence that the alternative is very high or high for other human health or environmental hazards that have an impact on an EJ Community or disadvantaged and/or vulnerable population? See Assessing Exposure Impacts to EJ Communities for an example.
  - If yes, did the comparative exposure evaluation indicate that there are significant exposure pathways that are relevant for one or more of those hazards?
    - If yes, the alternative should be flagged as potentially concerning, since there is evidence switching to the alternative may increase or shift health burdens within an EJ community.
    - If no, document the information used to reach the conclusion. Continue the evaluation.

[56] More information on manufacturing criteria is available in the Performance Evaluation Module.

- If no, document the information used to reach the conclusion. Continue the evaluation.

8. Consider the presence of the alternative in monitoring studies:
   - Has the alternative been found in bio- or environmental monitoring studies?
     - If yes, mark the alternative as potentially worse unless a higher degree of evaluation is performed. An alternative found in monitoring studies does not necessarily pose a risk without additional evaluation. This could include hazard or exposure assessments.
     - If no, has it been looked for in bio- and environmental monitoring studies and not found?
       - If yes, identify the alternative as favorable and proceed with evaluation.
       - If no, identify exposure as a potential data gap that may affect the alternative's viability as a safer alternative. Continue the evaluation.

9. CONCLUSION: Did you find material differences between the chemical of concern and this alternative that indicate that people or the environment are more likely to be exposed to the alternative?
   - If no, your exposure assessment complete. Document any information not already included in responses to previous questions and indicate a comparative exposure assessment did not identify any areas of concern.
   - If yes, document any additional information not already included in responses to previous questions and indicate the alternative is not suitable without a more detailed exposure assessment.

Many examples exist that demonstrate the importance of asking these questions. The following two examples show the data collected and how exposure can be compared.

Example 1: Replacement of one plasticizer in a specific type of plastic with another, safer plasticizer.

The new plasticizer is from the same chemical family, used in the same amounts, and functions and is released in the same manner. Are there any reasons why any of the above issues would be substantially different for the new plasticizer compared with the previous?

In the table below, 'Positive' means the alternative is preferred over the chemical of concern and therefore its use is a positive. The more 'positives', the more preferred the alternative is compared to the chemical of concern. 'Negative means the alternative has greater concerns in this area. 'Equal' means there is no apparent difference between the two chemicals for the exposure concern under evaluation. 'No data' indicates no determination could be made.

If an alternative has numerous checks in the 'No data' column, the uncertainty increases around use of the alternative as a positive change. The assessor may decide not to use an alternative that has numerous entries in the 'No data' column.

Table 10: Qualitative Exposure Comparison of Two Plasticizers.

Comparison	**Materially Better**	**Materially Worse**	**Materially Similar**	**No Data**
Compare exposure pathways: Do they differ? No, the alternative is used in approximately the same amount and in the same manner, i.e. it is an additive in the plastic matrix. The exposure pathways are identical and it is unlike that the alternative would have a substantive difference in exposure.			=	
Compare exposure routes: Are the physicochemical properties substantively different between the two plasticizers? No, both chemicals have similar structures and physicochemical properties. No substantive difference could be identified.			=	
Compare the manufacturing criteria: The alternative is an equivalent replacement for the chemical of concern. It is used in a similar manufacturing process at roughly the same concentration.			=	
Consider the presence of the alternative in monitoring studies: The alternative has not been found in monitoring studies. In addition, it is believed to be rapidly degraded and is unlikely to bioaccumulate.	+			
Consider the persistence, bioaccumulative, mobile, and toxic properties of the alternative: The alternative is not expected to either persist, mobile, or bioaccumulative and based upon the hazard assessment is less toxic than the chemical of concern.	+			

Comparison	Materially Better	Materially Worse	Materially Similar	No Data
Therefore, the alternative is not expected to be a PBT.				

Summary: Based upon the above review, exposure is not expected to be a factor in the assessment of the alternative. The chemical is used in roughly the same amounts and in a similar chemical process to the chemical of concern. The alternative is not expected to be a PBT. Therefore, any exposure concerns would be less or equivalent to the chemical of concern.

Example 2: Replacement of a halogenated flame retardant with another, safer flame retardant.

The new flame retardant is used in the same amounts, in the same manner (additive), the product experiences the same life cycle (i.e., manufacture, use, end-of-life, etc.) and is released in the same manner. Are there any reasons why any of the above issues would be substantially different for the new flame retardant compared with the previous?

The following example compares resorcinol bis-diphenyl phosphate (RDP) which contains 5% triphenyl phosphate (TPP) as a potential replacement for the toxic flame retardant Deca-BDE) and antimony trioxide mixture. Antimony trioxide is used with Deca-BDE as a synergist and improves the effectiveness of the flame retardant. The information in this table was copied from the National Academy of Science's publication, *A Framework to Guide Selection of Chemical Alternatives*. Section 12: Case Studies of the report includes Case Study 1: Chemical Substitution of a Restricted Substance (Deca-BDE) (pages 189-211) which provided the details for the following example.

Table 11: Qualitative Exposure Comparison of Two Flame Retardants.

Notes	Property	Positive	Minus	Equal	Not enough data
Compare physicochemical properties between the chemical of concern and alternative.					

Deca-BDE is a solid at room temperature. RDP is a liquid at room temperature. However, after it has been blended into a polymer, it has the properties of a solid. Flammability and explosive potential: Deca-BDE is not flammable. RDP and TPP are flammable, but at high temperature. None of the three chemicals are explosive. RDP is readily absorbed by the body, but also readily metabolized and excreted. TPP is absorbed and metabolized by the liver to DPP. DPP can be found in breast milk.	Physical state			=	
	Log of the water-octanol coefficient	+			
	Water Solubility	+			
	Flammability		-		
	Explosivity			=	
Consider other inherent chemical properties of the alternative relevant to exposure.					
Vapor pressure: Deca-BDE has a lower vapor pressure than RDP and TPP, indicating that RDP might be slightly more likely to be in the air and inhaled. RDP and TPP are more likely to be metabolized more easily.	Vapor Pressure		-		
Compare exposure routes between the chemical of concern and alternative:					
	Ingestion			=	
	Inhalation			=	
	Dermal			=	
Compare the manufacturing criteria for the chemical of concern and alternative.					
“Because the manufacturing process for the enclosure part, the product-use pattern, and end-of life hardware disposal are expected to be the same for [Deca-	Manufacturing process			=	

BDE] and its alternatives, the completed exposure pathways will be considered the same for alternative for [Deca-BDE] …"					
Consider the alternative's presence in the product. Qualitatively, what are the completed exposure pathways that occur during manufacture, transportation, and/or storage, use, end-of-life, etc.?					
"Consumer exposure to [Deca-BDE] is possible given that it can be released from common home products and become a component in house dust. It is also possible that workers exposed to [Deca-BDE] may inadvertently carry particles containing the chemical home with them. This may lead to exposure to family members through household dust or direct contact, as has been proven with other hazardous chemicals such as pesticides and lead…"	Dust (Air – inhalation and ingestion)				X
	Breast milk (infants - ingestion)			=	
	Drinking Water			=	
Compare the release mechanisms for the chemical of concern and the potential alternative. Are the release mechanisms similar during the different life cycle phases?					
"Environmental releases of [Deca-BDE] can occur during each stage of a product's life cycle, including chemical manufacturing, product manufacturing, product storage and use, and end-of-life handling". This is expected to be true for alternatives, as well."				=	
Compare the fate, transport, and partitioning in environmental media for the chemical of concern and alternative.					
RDP is expected to partition to the soil and sediment. It is expected to be immobile in soil. Deca-BDE has	Sediment			=	
	Soil			=	

a similar fate, transport and partitioning profile.)	Water			=	
Consider the persistence, bioaccumulative, and toxic properties of the alternative.					
RDP bioaccumulation will depend on whether it breaks into monomer units in the environment and TPP has moderate potential for bioaccumulation. RDP is moderately persistent, while TPP has low persistence. RDP and TPP are both highly toxic to aquatic organisms. Deca-BDE has high persistence, and also high bioaccumulation, it is a human developmental toxicant.	persistent	+			
	bioaccumulative	+			
	toxic	+			
Consider the presence of the alternative in monitoring studies: Has the alternative been found in bio- or environmental monitoring studies?					
Deca-BDE has been found in the environment, surface water. Detected in surface water, blood. No biomonitoring data available on RDP. TPP has been found in drinking water, house dust and breast milk, adipose tissue, plasma.					X

Conclusion: Based upon this review, RDP with TPP as a 5% component (hereafter referred to as 'RDP/TPP') '… meet the requirement *of being safer than those based on the original Deca-BDE/antimony trioxide* [mixture].'

Level 3: Detailed Exposure Evaluation

Level 3 builds upon the previous levels and requires higher quality information before a particular issue is resolved. It uses detailed quantitative information to assess the potential exposure impacts of replacing a chemical of concern with a safer alternative.

Who should use this level?

Assessors are encouraged to use this module if they want detailed exposure information to evaluate alternatives. This level is also useful for assessors that can consider design changes to the alternative product or process that could change exposure potential.

What resources and knowledge are required to use this level?

This level asks for quantitative information about exposure. If important data is lacking, validated studies are conducted to fill in any data gaps.

What degree of confidence does this level provide?

This level evaluates whether significant differences in exposure are expected for an alternative compared to the chemical of concern. It also asks assessors to consider whether product or process redesigns can change the exposure potential of the alternative. It is not a full exposure assessment.

Process

1. Consider the presence of the alternative in monitoring studies:
    - Has the alternative been found in bio- or environmental monitoring studies?
        - If yes, what levels are found, how broadly is it found in humans and the environment, has it been found in sensitive populations or do known hazards exist (See Level 2 of Hazard Module)? Based upon this information, is the alternative an exposure concern?
            - If yes, how do levels compare to toxicity thresholds for hazard endpoints in chemical assessment? How do they compare to ambient levels? How do they compare to levels with known adverse effects, particularly for sensitive populations? Are any of these issues a concern?
                - If yes, eliminate from consideration those alternatives with a higher likelihood for exposure via relevant pathways and known physical properties relative to their toxicity, particularly to sensitive populations. Document information used to reach the conclusion and proceed to question #8.

        - If no, document information used to reach the conclusion. Continue the evaluation.
    - If no, document information used to reach the conclusion. Continue the evaluation.

  - If no, has it been looked for in bio- and environmental monitoring studies and not found?
    - If yes, identify the alternative as favorable and proceed with the evaluation.
    - If no, identify exposure as a serious data gap that may affect the alternative's viability as a safer alternative. Proceed with the evaluation.

2. Consider the alternative's presence in the product. What data are available to evaluate exposure during manufacture, transportation, and/or storage, use of the product or end-of-life?
   - Have emissions from worker, user, or environmental exposures been reported or measured during manufacture, transportation, and/or storage, use or end-of-life of the alternative?
     - If yes, do these levels pose a potential threat?
       - If yes, document the information used to reach the conclusion and proceed to question #8.
       - If no, continue the evaluation.
     - If no, are there adequate data to support that the alternative does not pose an exposure concern?
       - If yes, document the information used and identify that exposure is not a concern for the alternative being evaluated.
       - If no, identify exposure as a serious data gap that may affect the alternative's viability as a safer alternative. Proceed to question #8.

3. Consider the quantity of the alternative involved.
   - What quantity is used during product manufacture, in the product as it is used, released after use or at end-of-life, etc.? Do differences in quantity affect exposure at any of those stages?
     - If yes, does the increase in quantity used pose a potential exposure threat?
       - If yes, document the information used to reach the conclusion and continue with the evaluation.
       - If no, continue the evaluation.
     - If no, are there adequate data to support the determination that the quantity used does not pose an exposure concern for any of the identified pathways?
       - If yes, document the information used and identify that exposure is not a concern for the alternative being evaluated.

- If no, identify exposure as a serious data gap that may affect the alternative's viability as a safer alternative. Proceed to question #8.

4. Consider the persistence, bioaccumulative, mobile and toxic properties of the alternative.
   - Did the hazard evaluation find evidence that the alternative is very persistent and very mobile?
     - If yes, the alternative should be flagged as potentially concerning. Very persistent and very mobile chemicals can potentially contaminate drinking water and spread globally. Proceed to question #8.
     - If no, document the information used to reach the conclusion. Continue the evaluation.

   - Did the hazard evaluation find evidence that the alternative is very high or high for other human or environmental health hazards that have an impact on EJ communities? See Assessing Exposure Impacts to EJ Communities for an example.
     - If yes, did the comparative exposure evaluation indicate that there are completed exposure pathways that are relevant for one or more of those hazards?
       - If yes, the alternative should be flagged as potentially concerning, since there is evidence switching to the alternative may increase or shift health burdens within an EJ community.
       - If no, document the information used to reach the conclusion. Continue the evaluation.
     - If no, document the information used to reach the conclusion. Continue the evaluation.

5. Identify possible exposure pathways created during the alternative's life cycle. How might people or other species be exposed to the alternative(s) or the chemical of concern? Have any exposure data been reported during the manufacture, transportation, and/or storage of the alternative or the product, use of the product or end-of-life?

   Are there other exposure pathways that are created during manufacture, transportation, and/or storage, use, end-of-life, recycling, etc. that have not been reported on?

Take a systematic approach to reviewing exposure concerns during all product life stages and make sure that all stages listed have been considered in the assessment. As an example, consider a chemical added to a plastic toy intended for very small children, who often mouth at products. If the chemical has an aqueous solubility is greater than 20,000 mg/L, it is soluble in saliva and could be ingested by a child during the use phase. The Appendix

includes other links between exposure pathways and exposure routes that should be considered.

14. For a given alternative, did the analysis identify any completed exposure pathway that was not also identified for the chemical of concern?

    - If yes, identify the scenario as a red flag and proceed with the evaluation. The child's toy would likely be given a red flag for chemical ingestion during the use phase if the chemical of concern did not also present a similar completed exposure pathway.
    - If no, document the information used to reach the conclusion. Continue the evaluation.

15. Is there evidence that any of these completed exposure pathways would lead to significantly elevated exposure to an EJ Community or disadvantaged and/or vulnerable population? To the extent possible, use the considerations in Assessing Exposure Impacts to EJ Communities to answer this question.
    - If yes, note the exposure route as a potential red flag. Document the information used to reach the conclusion.
    - If no information was available, document what sources were used to reach that conclusion. Continue the evaluation.
    - If no, document information used to reach the conclusion. Continue the evaluation.

in Level 1 and the Appendix may be used as starting points. Document any potential exposure pathways that are identified.

6. Consider other inherent chemical properties of the alternative that are relevant to exposure. (Note: if the substance being evaluated is a nanomaterial, then physical chemical properties measured for the bulk material may no longer be applicable.)
   - Does the alternative have properties that contribute to exposure? For example, is it very water soluble, does it volatilize readily into the air, etc.?
     - If yes, document the information used to reach the conclusion and proceed to the next question.
     - If no, document the information used to reach the conclusion. Continue the evaluation.

   - Is the alternative more likely to volatilize or leach from a product or from the manufacturing process? For example, is the alternative more volatile or soluble, are particle sizes and/or shapes, etc., a factor? Consider physical properties relevant to exposure.
     - If yes, document the information used to reach the conclusion and proceed to question #7.

- If no, document the information used to reach the conclusion. Continue the evaluation.

7. Consider exposure scenarios based on substance amounts, possible exposure pathways and exposure routes (refer to Appendix[57]),.
   - Have potential exposure scenarios been estimated for all possible pathways including manufacture, transportation, and/or storage, release, use and end-of-life components?
     - If yes, do these exposure scenarios indicate a serious concern?
       - If yes, document the information used to reach the conclusion and proceed to question #8.
       - If no, document the information used to reach the conclusion. Continue the evaluation.
     - If no, conduct exposure scenarios. Once scenarios are complete, return to question #7.
   - Have potential exposure scenarios for populations that may have a greater sensitivity to the alternative (people living in EJ communities, developing fetus, young children, those with specific medical conditions, the elderly, etc.) been identified?
     - If yes, do these exposure scenarios indicate a serious concern?
       - If yes, document the information used to reach the conclusion and proceed to question #8.
       - If no, document the information used to reach the conclusion. Continue the evaluation.
     - If no, conduct exposure scenarios. Once scenarios are complete, return to question #7.
   - Have potential exposure scenarios been conducted for organisms in the environment that are important for healthy ecosystems (aquatic and terrestrial)?
     - If yes, do these exposure scenarios indicate a serious concern?
       - If yes, document the information used to reach the conclusion and proceed to question #8.
       - If no, document the information used to reach the conclusion. Continue the evaluation.
     - If no, conduct exposure scenarios. Once scenarios are complete, return to question #7.
8. Consider redesign options using the alternative.

[57] See Appendix: Examples of Exposure Pathways and Chemical Properties that May Enhance Exposure

- Can the product be redesigned to reduce exposure during manufacture, transportation, and/or storage, use and end-of-life? If so, does redesign affect the type or extent of exposure or the quantity of the alternative used?
    - If yes, does it allow for elimination, substitution, or reduction in use or do changes in quantity affect exposure?
        - If yes, document the information used to reach the conclusion. Continue the evaluation.
        - If no, document the information used to reach the conclusion and proceed to question #9.
    - If no, proceed to question #9.

9. Consider mitigation of potential problems.
    - Have steps been taken during the design and manufacture to eliminate the need for the alternative, allow for the substitution of a less hazardous alternative, reduce the possibility of exposure, etc.? For example, is the alternative bound in the product in such a way that prevents dissociation, leaching or volatilization?
        - If yes, document the mitigation activities and identify the alternative as favorable based upon the exposure evaluation. Evaluation complete.
        - If no, document the information used to reach the conclusion and bin alternative as unfavorable. Evaluation complete.

Advanced: Full Exposure Assessment

This level conducts a full exposure assessment as required within the risk assessment process defined by the National Academy of Sciences. Only qualified and experienced risk assessors familiar with the Risk Assessment process can conduct this type of assessment. For more information on the process involved, see Resources below.

Resources

Risk Assessment in the Federal Government: Managing the Process, Committee on the Institutional Means for Assessment of Risks to Public health, Commission on Life Sciences, National Research Council, 1983, The National Academy Press, 191 pages.

A Framework to guide Selection of Chemical Alternatives, National Resource Council of the National Academy of Sciences, 2014, 280 pages.

AirTox Screen: An EPA tool that includes census tract-based displays for cancer risks, emissions data and other AirToxScreen data on a map. Users can "zoom" into areas and see summary level information (including specific chemicals contributing to risks). The tool is based on the National Emissions Inventory, chemical transport modeling with Community Multiscale Air Quality modeling system, and air quality dispersion modeling.

TRI Toxics Tracker: A chemical-based mapping tool from EPA that allows users to view data over the last 10 years related to chemical releases, waste managed, waste transfers, and pollution prevention. The tool can also overlay demographic data such as age, education, percent low income, English ability, and percent People of Color. TRI data include those lists of chemicals that industry is required to report under Comprehensive Environmental Response, Compensation, and Liability Act and the Emergency Planning and Community Right-to-Know Act.

Environmental Justice Dashboard: A county level mapping tool from the Centers for Disease Control that can be used to explore data on environmental exposures, community characteristics, and health burdens. While it does not have specific health or exposure data, it does allow for overlay mapping of facilities that may contribute to disproportionate exposures such as landfills and superfund sites.

Appendix: Examples of Exposure Pathways and Chemical Properties that May Enhance Exposure

For each level in this module, here are some examples of pathways of exposure to consider. This list is not meant to be exhaustive but to give an indication of what exposure pathways

might be considered. There may be additional pathways that are unique to the chemical, product, or process being evaluated.

1. Inhalation
   A. Indoor and Outdoor
      - Emissions to air during manufacture, transport, storage, use and disposal
      - Volatilization
      - Particulates
2. Discharge to water during manufacture, use, and storage.
3. Leaching or disassociating or degradation from the product into:
   A. Water (groundwater or surface water)
   B. Food (including wildlife that could become a food source)
   C. Mouth (e.g., food containers or children's toys)
   D. Indoor dust
4. Dermal
   A. Products intended for use on skin.
      - Products that have the potential to be in contact with skin.
      - Water used for washing/cleaning.
5. Injection
   A. Products for use in medical treatment.
   B. Products for cosmetic use (e.g., tattoos).
6. Presence in the environment and in living organisms.
   A. Biomonitoring
   B. Environmental monitoring
7. Inherent properties of the chemical including:
   A. Persistence
   B. Bioaccumulation potential
   C. Volatility
   D. Particle size and shape
   E. Bioavailability

Materials Management Module

The Materials Management Module helps assessors consider how different alternatives can impact natural resource use and the generation of both hazardous and non-hazardous waste. It can be used to compare products containing materials derived from very different sources. This module may not discriminate at the chemical substitution level.

The Materials Management Module may also help assessors to achieve sustainable materials management. Products can be made more sustainable through redesigns that enable material recovery and/or benign release into the environment. This module emphasizes alternatives that further the concept of "Cradle to Cradle"[58] design through materials management.

How have you addressed equity and environmental justice?

Material extraction, disposal, and reuse can significantly impact the health of workers and communities located nearby sites. As an example, mining activities often negatively impact local environments and any communities that live or work near them.[59,60] Prioritizing "Cradle-to-cradle" design and choosing alternatives with minimal negative impacts during material extraction, that are designed to be reused, can help address historic and current environmental injustices.

Given the global nature of many supply chains, the extraction and disposal of different materials used to make a chemical, material, or product may occur at many geographically disparate locations. For an assessor who cannot meaningfully engage with impacted communities around the globe, the Materials Management Module provides a lens to consider what impact alternative materials may have on specific EJ communities.

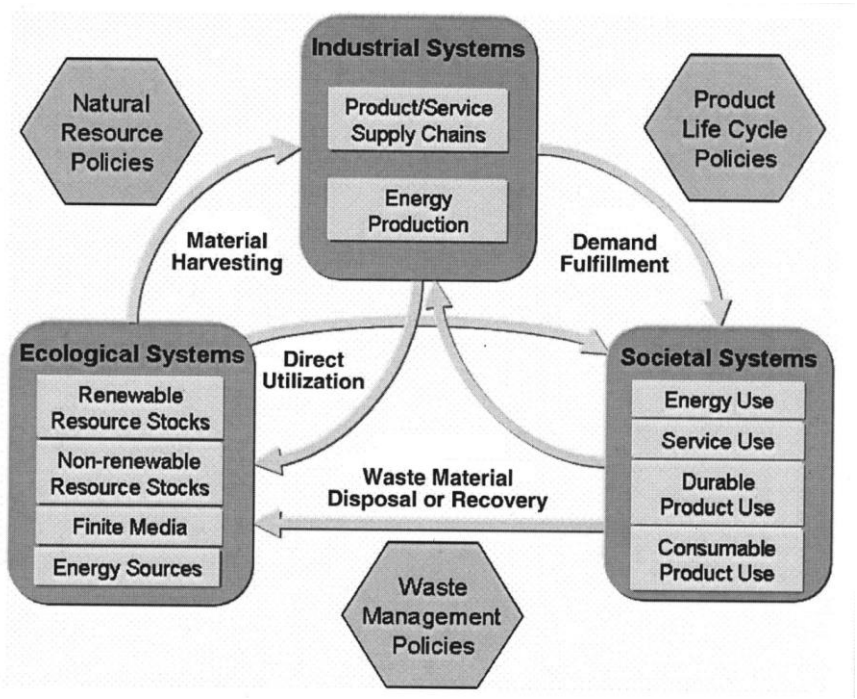
Materials management is a process that is directly connected to industrial, ecological, and societal systems. Figure 10 demonstrates how materials flow among the three systems and how decisions in each can affect materials management.

[58] Braungart, Michael & William McDonough, *Cradle to Cradle: Remaking the Way We Make Things*, 2002.

[59] Lèbre, É., et al. (2020). The social and environmental complexities of extracting energy transition metals. *Nature Communications,* vol. 11, pg. 4823. https://doi.org/10.1038/s41467-020-18661-9

[60] United Nations Sustainable Development Solutions Network. (2016). Mapping Mining to the Sustainable Development Goals: An Atlas. https://www.undp.org/sites/g/files/zskgke326/files/publications/Mapping_Mining_SDGs_An_Atlas_Executive_Summary_FINAL.pdf

Figure 10: Mapping of Material Flows.[61]



The Organisation for Economic Cooperation and Development (OECD) defines Sustainable Materials Management (SMM) as: "*… an approach to promote sustainable materials use, integrating actions targeted at reducing negative environmental impacts and preserving natural capital throughout the life cycle of materials, taking into account economic efficiency and social equity.*"

Historically, governments have managed the impact of materials on the environment by managing waste. While successful, research shows that waste management is not the most efficient or effective process for controlling material flows in industrial and economic systems. SMM shifts the focus of governments, industry, and consumers from individual material, product, or process attributes to the entire system of material flows and associated life cycle impacts.

OECD policy principles for SMM states that SMM preserves natural resources that are needed to support life.[62] Natural resources include abiotic and biotic resources. Abiotic resources are non-living resources such as water, air, oil, coal, minerals, etc. Biotic sources

[61] Fiksel, J. (2006), A Framework for Sustainable Materials Management, *Journal of Materials (JOM)*, August 2006, pp.15- 22, accessed 12/2013.

[62] OECD, Policy Principles for Sustainable Materials Management, April 2011, 55 pages.

are living resources such as trees, fish, animals, etc. To achieve SMM, the OECD recommends preserving natural capital and designing and managing materials, products, and processes for safety and sustainability from a life cycle perspective.[63]

The EPA developed an extensive SMM program, which focuses on:

1. Knowing and reducing the life cycle impacts across the supply chain.
2. Using less material inputs (reduce, reuse, recycle).
3. Using less toxic and more renewable materials.
4. Considering whether services can replace products.

The Materials Management Module builds upon the work of EPA and OECD to incorporate the goals of SMM into the AA process. It includes steps to inventory, assess, and optimize products to improve the impacts associated with the use of raw materials and generated wastes.

The goals of the Materials Management Module are based on the goals for SMM including:

1. Using sustainable raw materials that are:
   A. Less resource intensive materials. Some raw materials require fewer natural resources to produce or can be generated in a manner that uses fewer natural resources.

   B. Sustainably renewable or recyclable materials. Renewable materials are not always managed sustainably. For example, trees are renewable resources. SMM requires some degree of stewardship and monitoring to ensure material extraction or reclamation meets SMM goals. An example of this stewardship is the Forest Stewardship Council.

2. Using fewer materials in products or using materials that have benign impacts in place of materials with negative impacts across the life cycle. Substituting products with services (i.e., leasing models) can also reduce material consumption.

3. Designing for recovery: Design products to facilitate material recovery for reuse or recycling. Reuse or recycling could include designing products to assimilate into the environment in benign ways such as cleaning products that biodegrade rapidly and completely when sent down the drain.

The Materials Management Module incorporates these concepts into two Levels and an Advanced Option (Table 12):

Table 12: Materials Management Module Evaluation Levels.

[63] IBID, p. 23.

Level 1	*Basic Materials Management Evaluation:* This level identifies raw materials used and wastes generated by the baseline product and compares them to those identified for the alternative(s). The level also asks assessors to consider opportunities to mitigate impacts.
Level 2	*Extended Materials Management Evaluation:* This level quantifies raw materials and wastes for the baseline product and compare them to those for the alternative(s). Impacts of material generation and waste are evaluated to prioritize mitigation efforts.
Advanced (See LCM, Level 3)	*Advanced Materials Management Evaluation:* Uses Material Flow Analysis or best practices 1) from the ISO14040 guidelines with a focus on material inputs and outputs and 2) for product optimization from "Cradle to Cradle" design.

Level 1: Basic Materials Management Evaluation

The objectives of Level 1 for the product containing the chemical of concern and potential alternative product designs are to inventory the raw materials used and the wastes generated after use. Level 1 also considers opportunities to mitigate impacts to achieve sustainable materials management.

1. Identify the natural resources and raw materials used in association with the baseline product and alternative product design(s).
   - Does the alternative use more renewable raw materials?
     - If yes, document information used to reach the conclusion and identify alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with resource use for the alternative along with the information used to reach these conclusions. Continue the evaluation.
   - Does the alternative use fewer raw materials?
     - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with resource use for the alternative along with the information used to reach these conclusions. Continue the evaluation.
   - Does the alternative use more recycled materials?
     - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with resource use for the alternative along with the information used to reach these conclusions. Continue the evaluation.

2. Identify the wastes generated in association with the baseline product and alternative product design(s).
   - Does the alternative generate less waste?
     - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.
   - Does the alternative generate fewer wastes that are expected to have negative impacts?
     - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.
   - Is the alternative product more recyclable or benignly degradable than the baseline product?
     - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.
3. Based on the responses to questions 1 and 2:
   - Are any alternatives more favorable from the perspective of sustainable materials management?
     - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.
4. Can impacts from raw materials use be mitigated in a way that supports the principles of SMM? If yes, identify what benefits might result from:
   - Using fewer raw materials or raw materials that have fewer negative impacts.
   - Using raw materials that are renewable or recyclable.
   - Using renewable or recycled raw materials that can be demonstrated to be managed in a more sustainable way (e.g., certified wood products).
   - Generating raw materials from greener rather than more polluting processes. For example, there are numerous ways to generate ethanol including as a by-product of other reactions.

Would benefits likely result from any of the strategies being implemented?

- If yes, document information used to reach the conclusion and identify benefits. Continue the evaluation.
- If no, document the positives and negatives associated with the baseline product and alternative along with the information used to reach these conclusions. Continue the evaluation.

5. Can impacts from waste generation be mitigated in a way that supports the principles of SMM? If yes, identify what benefits might result from:
   - Identify strategies for how the baseline product or the alternative product(s) could be altered to enhance recovery and reuse/recycling of materials. Describe any business models or product stewardship initiatives that could support materials recovery.
   - If the product is disposed to the environment after use (for example, shampoos or cleaning products), evaluate the degradability (or biodegradability) of the chemicals in the baseline product and in the alternative product(s). Identify any strategies for product reformulation that would enhance the degradability of the product after it is released into the environment.
   - Would benefits likely result from any of the strategies being implemented?
     - If yes, document information used to reach the conclusion and identify benefits. Assessment complete.
     - If no, document the positives and negatives associated with the baseline product and alternative along with the information used to reach these conclusions. Assessment complete.

Level 2: Extended Materials Management Evaluation

Level 2 quantifies the raw materials used and the wastes generated, and the impacts associated with those raw materials and wastes, for the baseline product and alternative product design(s) to identify those alternatives that improve SMM. Level 2 also helps assessors to consider and evaluate opportunities to mitigate negative impacts to achieve sustainable materials management.

1. Quantify the raw materials used in association with the baseline product and the alternative product design(s).
   - Does the alternative use fewer raw materials?
     - If yes, quantify and document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.

- Does the alternative use fewer raw materials with associated negative impacts?
  - If yes, quantify and document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
  - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.
- Does the alternative use more renewable raw materials? If so, are the renewable raw materials managed sustainably?
  - If yes, quantify and document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
  - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.
- Does the alternative use recycled materials? If so, are the recycled materials managed sustainably?
  - If yes, quantify and document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
  - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.

2. Quantify the wastes generated in association with the baseline product and alternative product design(s). Quantify the wastes generated through extraction of raw materials, generation of feedstock, manufacturing, and at the end of product life.
   - Does the alternative generate less waste?
     - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.
   - Does the alternative generate less waste with expected negative impacts?
     - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.
   - Is the alternative product more recyclable or degradable than the baseline product?

- If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
- If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.

3. Assess whether an alternative is more favorable prior to mitigation:
   - Is an alternative more favorable from the perspective of sustainable materials management?
     - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.

4. Assess how the quantity of raw materials used and/or the associated impacts from the raw materials might be mitigated.
   - Can fewer natural resources be used to generate the same raw materials through more efficient or effective technologies?
     - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.

   - Can fewer natural resources with negative impacts be used to generate the same raw materials through more efficient or effective technologies? Could the raw materials be generated via a greener rather than a polluting process? For example, there are numerous ways to generate ethanol including as a by-product of other reactions.
     - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.

   - If the raw material is renewable, is it known to be managed in a sustainable way? If not, could it be?
     - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
     - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.

- If the raw material is recyclable, is it recycled in a sustainable way? If not, could it be? For example, recycled materials from certain sources could contain toxic chemicals or there could be known hazards associated with some recycling processes.
    - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
    - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.

5. Assess how the reuse/recycling could be improved to mitigate impacts.
    - Could the product or the alternative product(s) be designed to facilitate recovery and reuse/recycling of materials after use? If yes, is the use of the resulting reused/recycled material expected to provide overall benefits?
        - If yes to all, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
        - If no to any, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.

    - If the alternative product goes into the environment after use (for example, shampoos or cleaning products), could more of it be formulated to degrade rapidly so that it does not harm organisms in the environment?
        - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue the evaluation.
        - If no, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Identify the concerns associated with the alternative and identify it as unfavorable with regards to SMM considerations.

6. Assess whether an alternative is more favorable after mitigation:
    - Is an alternative more favorable from the perspective of sustainable materials management?
        - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Assessment complete.
        - If no to any, document the positive and negative impacts associated with the alternative along with the information used to reach these conclusions. Continue the evaluation.

Advanced Materials Management Evaluation

As an advanced inventory option, perform a full Material Flow Analysis (MFA) or a full Life cycle Assessment focused on material inputs and outputs and associated impacts (See Level 3 of Life cycle Module). While LCA and MFA share many characteristics, there are some differences.[64]

Designing or redesigning products for material recovery and/or benign release into the environment can lead to systemic solutions. As an advanced option for impact mitigation, the "Cradle to Cradle" or an equivalent approach can be used to support product optimization. More information is available in the Appendix.

Appendix: Material Flow Analysis

Different material flow analysis methods have different foci. Some focus on large geographic areas, such as national boundaries and have mainly been used for accounting studies. The European Topic Centre on Sustainable Consumption and Production developed definitions of three such different material flow analysis methods:

Total Material Requirement (TMR) is a measure of all of the material input required by a national economy. This is calculated from a life-cycle perspective, so TMR includes not only the direct use of resources, but also indirect material flows associated with domestic extraction and those associated with the production of imported goods (the so called "hidden flows").

In economic terms, TMR is a measure of the physical basis of a national economy. In environmental terms, it is a proxy for potential environmental pressures associated with the resource extractions. Since all these material inputs will sooner or later be transformed to material outputs (i.e., emissions, waste) TMR also constitutes a proxy for potential future environmental pressures, on a life cycle-wide basis, to the domestic as well as foreign environment.

TMR = DMI + I + uDE + iF
DMI = Direct Material Inputs + imports (fossil fuels, minerals, biomass)
I = Indirect Imports
uDE = unused Domestic Extraction
iF = indirect Flows associated to imports

Direct Material Input (DMI) measures the input of materials, which are directly used in the economy; materials used in domestic extraction and physical imports. Unlike TMR, it does not include so-called "hidden flows." DMI is often used as a substitute for TMR

[64] Finnveden, Göran and Åsa Moberg, 2005, Environmental systems analysis tools – an overview, *Journal of Cleaner Production*, 13, 1165-1173.

because data on TMR is more difficult and time consuming to compile. A DMI based indicator could, theoretically, report an incorrect conclusion if a country is decreasing its domestic resource extraction while increasing imports of raw materials or vice versa. Even so, empirical analyses show that there is a correlation between DMI and TMR.

> DMI = domestic extraction (fossil fuels, minerals, biomass) + imports

Domestic Material Consumption (DMC) is the total of all materials used up by a country and is defined as all materials entering directly the national economy (used domestic extraction plus imports), minus the materials that are exported.

> DMC = DMI – exports

In economic terms, it is related to the consumption activities of the residents of a national economy. It is also the MFA indicator most closely related to the Gross Domestic Product. In environmental terms, DMC is a proxy for potential environmental pressures associated to the disposal of residual materials to the domestic environment.

In another approach to material substance flow analysis, the Wuppertal Institute developed the concept of Material Intensity per Unit Service or MIPS. According to the Wuppertal Institute:

> *MIPS is an elementary measure to estimate the environmental impacts caused by a product or service. The whole life cycle, from Cradle to Cradle, (extraction, production, use, waste/recycling) is considered. Material Intensity per Unit Service can be applied in all cases where the environmental implications of products, processes, and services need to be assessed and compared.*
>
> *A practical application of the Material Intensity per Unit Service Concept is called material intensity analysis. Material intensity analyses are conducted on the micro-level (focusing on specific products and services) as well as on the macro-level (focusing on national economies).*

Substance Flow Analysis is similar to material flow analysis, except that the analysis focuses on substances instead of materials.

In general, an MFA may be used to account for material flows and to compare alternative materials used in products. One of the main limitations of an MFA, however, is that it requires expertise in evaluation and implementation of the technology and is typically beyond the capability of most manufacturers.

Cradle to Cradle Products Innovation Institute: The Cradle to Cradle Products Innovation Institute was created to bring about a new industrial revolution that turns the making of things into a positive force for society, economy, and the planet. The Institute administers the publicly available Cradle to Cradle Certified^{CM} Product Standard, a

continuous improvement quality standard gifted to the Institute by William McDonough and Michael Braungart after eighteen years of development with the world's leading brands.

Cradle to Cradle: Remaking the Way We Make Things, written by William McDonough and Michael Braungart. The authors present a manifesto calling for a new industrial revolution, one that would render both traditional manufacturing and traditional environmentalism obsolete.

European Commission: International Reference Life Cycle Data System – Review Schemes for Life Cycle Assessment. This reference considers the environmental implications of the whole supply-chain of products, both goods and services, their use, and waste management, i.e., their entire life cycle from —cradle to grave.

Social Impact Module

The Social Impact Module helps the AA process to avoid shifting a burden from one community of people to another. It requires assessors to evaluate the impacts of an alternative upon the workers, communities, and societies involved in its extraction, manufacture, transport, use, and disposal.

Elements in the Social Impact Module may also be addressed in other modules. For example, workers are important stakeholders, and their concerns should be addressed during stakeholder engagement. Worker health and safety impacts are important components of hazard and exposure, which are addressed in those modules. Designing products using Cradle-to-Cradle thinking for circular economy, which is discussed in the Materials Management Module, can reduce the impact of material extraction and disposal on workers and communities living near sites.

This module draws attention to specific worker health and safety, and community and global societal issues, including environmental justice concerns. It emphasizes their importance in an AA and conducts an assessment beyond what might have been included in other modules.

How have you addressed equity and environmental justice?

This module can be leveraged to consider environmental justice more deeply by helping assessors to prioritize alternatives that benefit vulnerable and disadvantaged communities. Useful tools like EJScreen, Social Hotspots Database, and EJ Index are included in the resources and LCA tools to help assessors identify and examine social factors related to environmental justice that should be considered when evaluating social impacts. The environmental justice insets found throughout the guide, can also help ensure consideration of the social impacts of the AA through an environmental justice lens.

Tables 13, 14, and 15 list considerations for worker health and safety, communities, and global society across a typical product life cycle. As outlined in the Life Cycle Module, impacts across the full life cycle of the product should be considered as well as any mitigating impacts that can reduce or eliminate a concern.

Table 13: Worker Considerations Across the Product Life Cycle *(not exhaustive)*

Demographics	
• Sex	• Literacy
• Age	• Gender equality
• Culture	• Human rights
• Language or cultural issues	• Disability issues

Health	
• Physical or social impacts such as ergonomics, noise, culture, etc.	• Body burden of chemicals with unknown impacts
• Health care	• Life expectancy
• Sensitive populations such as pregnant women, children, the elderly, etc.	• Sanitary facilities including toilet, potable water, food storage, etc.
• Treatment with dignity and respect	• Non-abusive work conditions and hours
Environment	
• Generation of toxic wastes	• Use of hazardous chemicals
• Product recycling, extraction, and disposal	• Adequate training and hazard communication
Financial	
• Compensation: overtime, lost time and wages	• Pay equality • Part-time workers
• Number and quality of jobs	• Educational level of workers

Table 14: Community Considerations Across the Product Life Cycle *(not exhaustive)*

Demographics	
• Quality of life including historical, cultural or religious priorities, etc.	• Use of forced or child labor
Health	
• Quality of life including recreational activities	• Communities over-burdened by pollution
• Sale of products banned in other, regulated areas in unregulated markets	Generation of toxic wastes or use of hazardous chemicals
Environment	
• Disproportionate impacts on 'fenceline' communities	• Product recycling, extraction, and disposal
• Impacts upon local water, air, land, etc.	
Financial	
• Quality and type of jobs	• Corruption
• Crime	
Community	
• Establishment of partnerships with local, state, tribal and federal organizations	• Empowerment of communities to take action to improve their health and environment

• Product availability	• Discrimination, harassment, intimidation or retaliation

Table 15: Global Societal Considerations Across the Product Life Cycle *(not exhaustive)*

Demographics	
• Use of forced or child labor	
Health	
• Sale of products banned in other, regulated areas in unregulated markets	• Changes to quality of life
Environment	
• Product recycling, extraction, and disposal	• Body burden of chemicals with unknown impacts
Financial	
• Wealth of society	• Product availability
Global	
• Discrimination, harassment, intimidation or retaliation • Product availability	• Supports to harmful actions such as military action, genocide, etc.

The listed considerations may not cover all important issues but are examples of the types of concerns that might arise. Additional concerns should be addressed if important to the specific AA. Standards listed in the Resources section contains other issues that, although not included above, may also be important to a specific assessment.

This module establishes three levels of assessment, beginning with a limited, qualitative evaluation. If a deeper evaluation is needed, the assessor can complete a social life cycle assessment as outlined in the Life Cycle Module (

Table 16).

Table 16: Social Impact Module Evaluation Levels.

Level 1	*Basic Social Impact Evaluation:* Emphasizes impacts on a local level and includes a qualitative evaluation of social impacts using readily available information.
Level 2	*Extended Social Impact Evaluation:* Requires a more detailed review of social impacts within the supply chain and an expanded evaluation of global impacts.
Level 3	*Detailed Social Impact Evaluation:* Includes a detailed review of all social impacts including local, supply chain, and global concerns.
Advanced (see LCM, Level 3)	*Full Social Life cycle Assessment Evaluation:* Conducts a full social life cycle assessment (SLCA) related to the alternative.

This module draws from the UNEP *Guidelines for Social Life cycle Assessment of Products*, and other appropriate literature (see Resources). It provides a flexible framework that allows a wide range of assessors to determine what social impacts an alternative may create. Assessors working with businesses are encouraged to use this module to evaluate the social impact of the chemical of concern and potential alternatives within the business's chain of custody.

As with other modules, it is important to state clearly what assumptions were made during the social impact evaluation and how these assumptions impact the AA. Regardless of what level is used, all decisions or assumptions should be identified in the AA report.

Level 1: Basic Social Impact Evaluation

Level 1 identifies potential differences in social impacts to local workers, affected communities such as "fenceline" communities, and product users. It emphasizes whether alternatives create different impacts at any of the product life cycle stages to workers, communities surrounding manufacturing facilities, or to society at a local level. The local level is defined as area surrounding the factory or facility producing the product containing the chemical of concern. Assessors can also evaluate impacts to workers, the community and the global society from a broader perspective using a qualitative approach with whatever information is readily available.

1. Are there local worker health and safety issues that have not been addressed by other modules?
   - Using qualitative information, are there any concerns in Table 13 that affect local worker health and safety?
     - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
     - If no, document the information used to reach the conclusion and continue the AA.

2. Are there local community impacts that have not been addressed by other modules?
   - Using qualitative information readily available to the general population, are there any concerns in Table 14 that affect local worker health and safety?
     - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
     - If no, document the information used to reach the conclusion and continue the AA.

3. Are there local societal impacts that have not been addressed by other modules?
    - Using qualitative information readily available to the general population, are there any concerns in Table 15 that affect local worker health and safety?
        - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
        - If no, document the information used to reach the conclusion and continue the AA.

4. Are there any other local concerns that were not addressed in the preceding questions?
    - Using qualitative information readily available to the general population, are there any additional concerns not addressed?
        - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
        - If no, document the information used to reach the conclusion and continue the AA.

5. Are there any larger community concerns associated with this alternative?
    - Using qualitative information readily available to the general population, are there any concerns in Table 14 that affect larger community concerns?
        - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
        - If no, document the information used to reach the conclusion and continue the AA.

6. Are there any global societal concerns associated with this alternative?
    - Using qualitative information readily available to the general population, are there any concerns in Table 15 that affect global societal concerns?
        - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
        - If no, document the information used to reach the conclusion and continue the AA.

7. Can any steps be taken to mitigate negative impacts associated with the alternative?

- Can any worker health and safety, community or larger societal negative impacts be mitigated to eliminate or minimize the impacts?
- Would selection of a different alternative (chemical or non-chemical) reasonably satisfy the product/function needs while reducing impacts?
- Are there any other possibilities for mitigation?
    - If the answer is yes to any or all questions, note that the specific component is not a limiting factor and document the information used to reach the conclusion. Continue the evaluation process until all negative impacts have been evaluated to determine if mitigation is possible.
    - If the answer is no to all questions, document information used to reach the conclusion and flag the alternative as potentially needing further review in this module.
    - Continue evaluation process until all components have been evaluated.

Level 2: Extended Social Impact Evaluation

Level 2 identifies potential differences in social impacts to workers, affected communities and societies at both the local level and also along the supply chain producing the chemical or product components. It includes all of the assessments in Level 1. It also includes a more detailed evaluation of potential global concerns that requires some quantitative data. Level 2 uses a more quantitative approach built upon the assessment found in Level 1 to evaluate the possible global impacts.

The supply chain includes workers, communities, and societies that produce components that are a major portion of the chemical, product, or process at the local level. For example, a factory that builds airplanes generates local impacts for the workers, community, and society involved in assembling the plane. The factory also impacts businesses that supply parts for the plane. Assessors should consider both local and distant supply chains in Level 2.

1. Are there local or supply chain worker health and safety issues not addressed by other modules?
    - Using quantitative information, are there any concerns in Table 13 that affect local and supplier worker health and safety?
        - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
        - If no, document the information used to reach the conclusion and continue the AA.

2. Are there local worker or supply chain community impacts that have not been addressed by other modules?
    - Using quantitative information, are there any concerns in Table 14 that affect local and supplier communities?
        - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
        - If no, document the information used to reach the conclusion and continue the AA.

3. Are there local worker and supply chain societal impacts not addressed by other modules?
    - Using quantitative information, are there any concerns in Table 15 that affect local workers and supply chain global concerns?
        - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
        - If no, document the information used to reach the conclusion and continue the AA.

4. Are there any remaining local worker and community concerns not addressed in the previous questions?
    - Using quantitative information readily available to the general population, are there any additional concerns that have not been addressed?
        - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
        - If no, document the information used to reach the conclusion and continue the AA.

5. Are there any global worker, community or societal concerns associated with this alternative?
    - Using quantitative information, are there any concerns in Tables 12, 13, or 14 that affect the larger global society?
        - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.

- If no, document the information used to reach the conclusion and continue the AA.

6. Can any steps be taken to mitigate negative impacts associated with the alternative?
   - Can any local and supply chain worker health and safety, community or larger societal negative impacts be mitigated to eliminate or minimize the impacts?
   - Would selection of a different alternative (chemical or non-chemical) reasonably satisfy the product/function needs while reducing impacts?
   - Are there any other possibilities for mitigation?
     - If yes to any or all questions, note that the specific component is not a limiting factor and document the information used to reach the conclusion. Continue the evaluation process until all negative impacts have been evaluated to determine if mitigation is possible.
     - If no to all questions, document information used to reach the conclusion and flag the alternative as potentially requiring more review. Continue the evaluation process until all components have been evaluated.

Level 3: Detailed Social Impact Evaluation

Level 3 identifies potential differences in local, community, and global impacts to workers, affected communities, and societies. It evaluates all life cycle stages of the alternative at the local, supplier, and global levels using more quantitative data.

1. Are there local, supply chain, or global worker health and safety issues that have not been addressed by other modules?
   - Using quantitative information, are there any concerns in Table 13 that affect local, supplier, or larger societal worker health and safety?
     - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
     - If no, document the information used to reach the conclusion and continue the AA.

2. Are there local, supply chain, or global community impacts not addressed by other modules?
   - Using quantitative information, are there any concerns in Table 14 that affect local, supplier, or the larger community issues?
     - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns

that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
    - If no, document the information used to reach the conclusion and continue the AA.

3. Are there any local, supply chain, or global societal impacts not addressed by other modules?
    - Using quantitative information, are there any concerns in Table 15 that affect local, supplier, or the larger society?
        - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
        - If no, document the information used to reach the conclusion and continue the AA.

4. Are there any remaining local, supply chain, or larger societal concerns that have not addressed by the preceding questions?
    - Using quantitative information readily available to the general population, are there any additional concerns that have not been addressed?
        - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
        - If no, document the information used to reach the conclusion and continue the AA.

    - Using quantitative information readily available to the general population, are there any additional concerns that have not been addressed?
        - If yes, document the information used to reach the conclusions and how the concerns may impact the potential use of the alternative. Identify the concerns that may eliminate this alternative from consideration unless mitigation or control are feasible. Continue the AA.
        - If no, document the information used to reach the conclusion and continue the AA.

5. Can any steps be taken to mitigate negative impacts associated with the alternative?
    - Can any local and supply chain worker health and safety, community or global societal impacts be mitigated to eliminate or minimize the impacts?
    - Would selection of a different alternative (chemical or non-chemical) reasonably satisfy the product/function needs while reducing impacts?

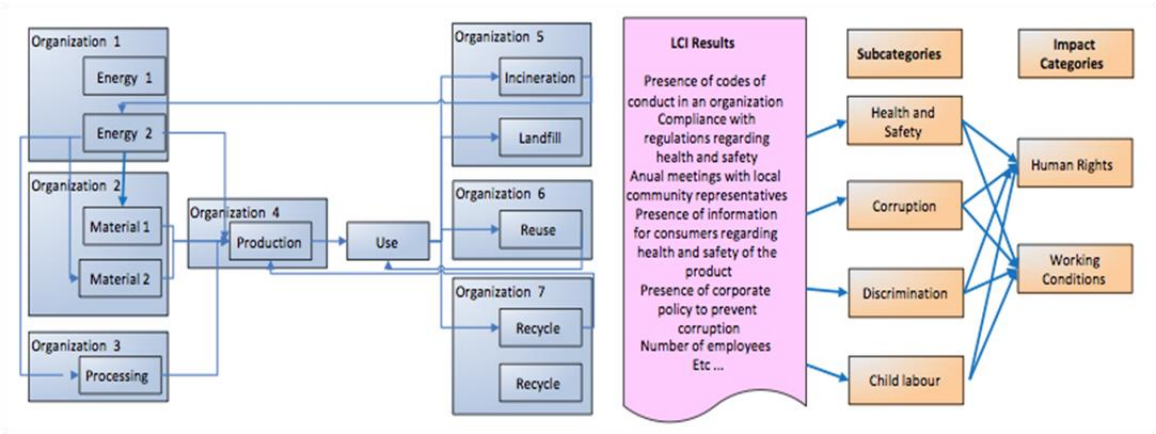
- Are there any other possibilities for mitigation?
  - If the answer is yes to any or all questions, note that the specific component is not a limiting factor and document the information used to reach the conclusion. Continue the evaluation process until all negative impacts have been evaluated to determine if mitigation is possible.
  - If no, document the information used to reach the conclusion and flag the alternative as potentially requiring more review. Continue the evaluation process until all components have been evaluated.

Advanced: Full Social Life Cycle Assessment Evaluation

The advanced option conducts a full SLCA evaluation. It builds upon the work in the previous three levels and conducts an SLCA related to the production of the chemical or product. UNEP describes an SLCA as 'a social impact (actual and potential impact) assessment technique that aims to assess the social and socio-economic aspects of products and their potential positive and negative impacts along their life cycle.'[65] Examples of social life cycle inventory and interrelationships are shown in

Figure 11.[66]

Figure 11: Examples of a Social Life Cycle Inventory and Interrelationships to Subcategories and Impact Categories.



[65] Guidelines for Social Life cycle Assessment of products and organizations, UNEP Life Cycle Initiative, 2020, p. 134. https://www.lifecycleinitiative.org/library/guidelines-for-social-life-cycle-assessment-of-products-and-organisations-2020/

[66] Towards a Life cycle Sustainability Assessment: Making Informed Choices on Products, UNEP, 2011, 86 pages, p. 23.

In 2022, the United Nations Life Cycle initiative published "Pilot projects on Guidelines for Social Life Cycle Assessment of Products and Organizations 2022" which contains nine examples of SLCA.[67] Further information can be found in the Life Cycle Module.

Resources

ISO 26000 - Social Responsibility: ISO 26000 provides guidance on how organizations can operate in a socially responsible way. Since there are no requirements, there is no certification for ISO 26000 unlike other well-known ISO standards. Instead, it defines social responsibility, helps organizations translate principles into effective actions, and shares best practices for global social responsibility. ISO 26000 is aimed at all types of organizations regardless of their activity, size, or location.

SA8000® Standard: The SA8000® standard is an auditable social certification standard. It is based on International Labour Organization conventions and national laws. The standard spans industry and corporate codes to create a common language for measuring social compliance. Those seeking to comply with SA8000® have adopted policies and procedures that protect the basic human rights of workers including avoiding child labor and forced and compulsory labor, discrimination, and protecting health and safety, freedom of association, right to collective bargaining, reasonable working hours, and remuneration.

Global Reporting Initiative: The mission of the Global Reporting Initiative is to make sustainability reporting standard practice for all organizations. The initiative's core product is the Sustainability Reporting Framework and corresponding Sustainability Reporting Guidelines. The G3.1 Guidelines are an update that launched in March 2011. They include expanded guidance for reporting on human rights, local community impacts, and gender.

The Social Hotspots Database: Aims to foster greater collaboration in improving social conditions worldwide by providing the data and the tools necessary for improved visibility of social hotspots in product supply chains. The fee-based service requires registration and is geared at working with companies.

[67] Pilot projects on Guidelines for Social Life Cycle Assessment of Products and Organizations 2022, Life Cycle Initiative and Social Life Cycle Alliance, 2022.

Life Cycle Module

The Life Cycle Module provides information about life cycle impacts associated with the baseline product and the alternatives. Assessors can use this information to:

- Further discriminate between safer alternatives by comparing life cycle tradeoffs.
- Identify opportunities to mitigate undesirable impacts.
- Avoid an alternative with undesirable life cycle impacts that cannot be mitigated.

The Life Cycle Module identifies potential social, economic, or environmental issues and then guides the assessor to either 1) address those impacts in other modules or 2) continue with the module to gather more information to assess and address outstanding impacts.

The Life Cycle Module is designed to address concerns not included in other modules and should be used after the Hazard, Performance Evaluation, Cost and Availability, and Exposure Assessment modules. Because life cycle impacts can be broad, many life cycle considerations are included in other modules, including the Cost and Availability Module, the Social Impact Module and the Materials Management Module. Assessors should complete of each of those three modules before using this one.

The Life Cycle Module evaluates life cycle impacts from products not individual chemicals. Evaluating life cycle impacts from the full product perspective provides a more detailed and comprehensive evaluation of the impacts of substitution. This is particularly true if a product is reformulated or substituted.

How have you addressed equity and environmental justice?

Environmental justice insets in other modules within this guide already incorporate many aspects of life cycle thinking that are relevant to environmental justice. Including EJ in the Life Cycle Module can help the assessor select non-chemical alternatives that support a circular economy and help to address burdens created by the chemical of concern.

Tools such as EJScreen, Social Hotspots Database, and EJ Index can help ensure that environmental justice concerns are included in life cycle considerations within the alternatives assessment, particularly if relevant place-based is available. The Urban Institute has compiled a particularly helpful database of Metadata for Environmental Justice Screening Tools that reviews many of the important nuances of several state and national level tools currently available, including the purpose of the tool, the corresponding legislation driving the tool, and the way that the tool defines environmental justice.

Life Cycle Thinking and Life Cycle Assessment

Life cycle stages range from the extraction of raw materials from natural resources to product design and production, to packaging and distribution, through use and maintenance and finally disposal and/or recovery (

The main goal of LCT is to support LCA and reduce the impact of product emissions and resource use. But LCT can also be used by assessors to methodically evaluate the exposure pathways associated with an alternative product or process from cradle-to-grave or cradle-to-cradle. LCT is especially useful to help assessors identify any gaps in expertise in the product or process life cycle, so that assessors can take steps to engage with relevant stakeholders or researchers that can address those knowledge gaps.

Figure 9).

LCT uses the approach and principles behind LCA to determine whether impacts associated with a given alternative are likely to be greater, lesser, or similar to those associated with product or process containing the chemical of concern. The basic tenets behind LCT are:

- To think about a chemical/product/process not as a single, static entity but as a dynamic continuum that starts with raw materials and ends with an end-of-life scenario.
- To avoid undesirable burden shifting from one stage in a product life cycle to another due to changes in product formulation or design.
- To look at product impacts from a cradle-to-grave or "Cradle-to-Cradle" perspective and identify potential environmental, economic, or social impacts for each life cycle phase.
- To foster choices that support innovation and benefits over the full life cycle.

Businesses are responsible for many choices about their products and processes, and LCT is an important tool for decision-making. Product design and development decisions impact not only how the product is made but also how it will be used and disposed of or remade into a new product. LCT can be used to modify manufacturing processes to improve energy or raw materials use and to reduce or eliminate the generation of hazardous substances. LCT contributes to sustainable production, consumption, and materials management by considering impacts across the entire life cycle of a product.

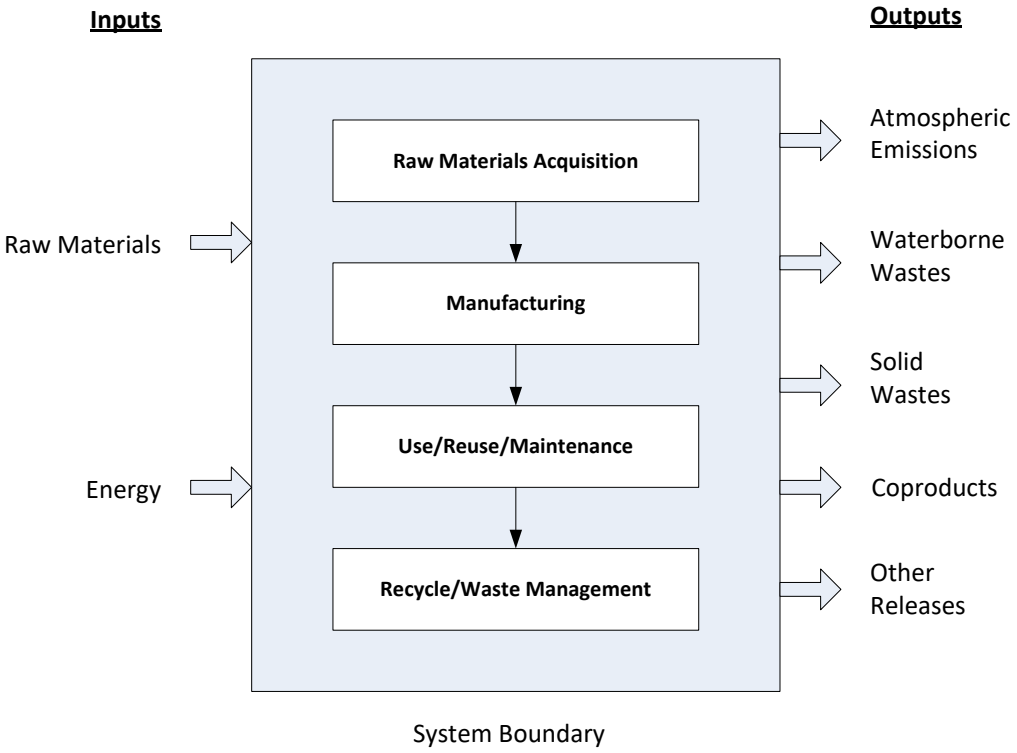
LCT may also include taking action to mitigate negative impacts. LCT can inform the design and decision-making processes and improve the positive impacts of products and services. It is a useful component of an AA because LCT helps assessors to further discriminate between alternatives identified as favorable using other modules.

While the approach to conducting an LCA has been standardized through the ISO 14040 series that provides a technically rigorous framework for carrying out LCAs, LCT has not yet been systematized. To apply LCT, it is helpful to borrow from LCA and define the "unit processes." In this module, the product containing the chemical of concern is called the baseline product, which defines the "functional unit" under consideration. The unit processes are the steps involved in the life cycle of the functional unit that can be quantified.

Assessing impacts across the life cycle means first considering all material and energy inputs and outputs (including chemicals, materials, water, energy, etc.) associated with each stage in the life cycle. This includes the extraction of raw materials to production, storage, and use of the product, to recycling, recovery, reuse, and/or disposal of wastes, as well as any transportation that is required.

In an LCA, spatially and temporally diverse processes from each stage in the life cycle are linked together to model the life cycle of a product. provides a schematic to account for material and energy inputs and outputs.

Figure 12: Life Cycle Assessment Stages and Inputs/Outputs.[68]



The impacts associated with the inputs and outputs of the processes at each life cycle stage are then measured and compared for the baseline product and the alternative(s). Example types of impact commonly used in LCA include:

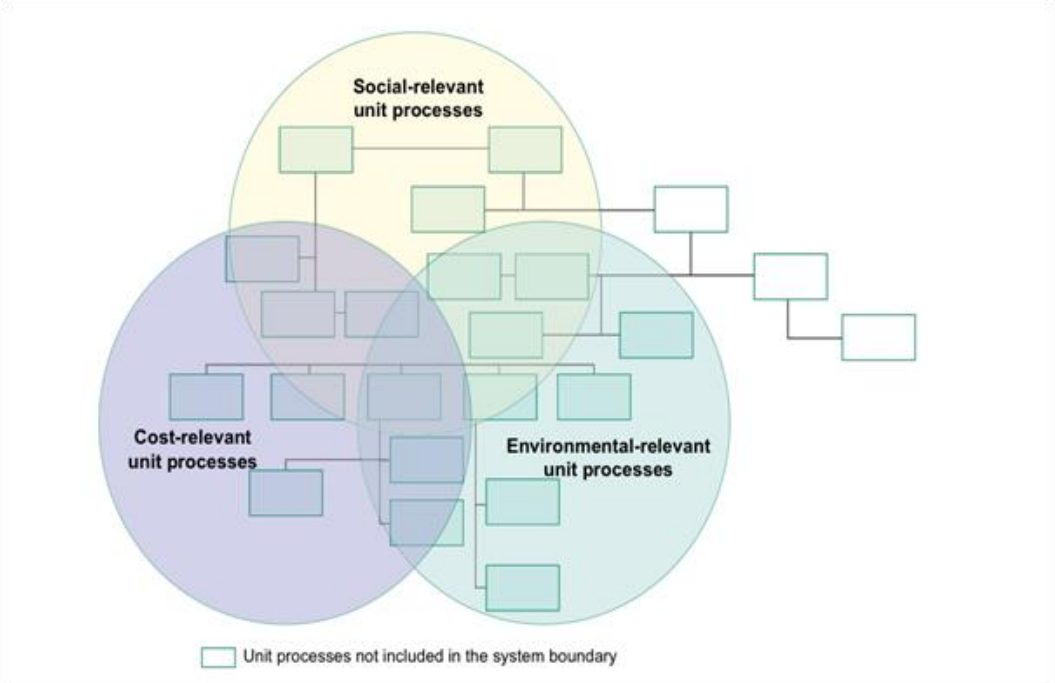
- Climate change
- Acidification
- Eutrophication
- Photochemical ozone creation
- Human toxicity of releases
- Ecotoxicity of releases
- Land use
- Resource depletion

LCT can be applied to environmental, economic, and socially relevant unit processes (See Figure 13). Because LCT addresses impacts in the product "system" there is unavoidable overlap between environmental, economic, and social impacts. For example, negative impacts on freshwater might create social impacts when access to fresh water is reduced, which in turn creates associated economic impacts when water treatment becomes necessary. The Life Cycle Assessment module will guide the assessor to determine if social,

[68] US EPA, *Life cycle Assessment: Inventory Guidelines and Principles*, February 1993, EPA/600/SR-92/245, Figure 1, page 2.

economic, and environmental impacts are likely to occur with the baseline product and/or the alternatives.

Figure 13: Environmentally, Socially, and Cost Relevant Unit Processes.[69]



Assessors do not need to evaluate every process at every life cycle stage for every alternative under consideration. For any set of alternatives, many of the unit processes will be the same. Only those processes that can be used to discriminate between alternatives should be evaluated. For example, a cleaning product may have multiple formulations that all use the same packaging. Therefore, packaging is not discriminating. Those impacts or processes where the life cycle differences are most discriminating are referred to as life cycle "hotspots."

In the evaluation, one safer alternative may stand out with clear and discriminating benefits at a life cycle stage. Another may be found to be a "deal-breaker", meaning that impacts identified at one of its life cycle stages cannot be mitigated and are judged to be very undesirable. Other alternatives may have life cycle impacts that can be mitigated by readily available technologies. For example, negative impacts from transportation may be addressed by changing the mode of transportation or by switching to a supplier or distributor who is geographically closer.

[69] United Nations Environmental Programme, *Towards a Life Cycle Sustainability Assessment*, Figure 14, page 35, accessed 2/2013.

Alternatives should be compared at the product level rather than at the chemical level for purposes of consistency. Measured LCT differences are typically relative and not absolute. It can be difficult to clearly define "significant differences." Differences between energy consumed or materials used for the production of two different chemicals may seem significant at the chemical level but may be negligible when the final products are compared. Consistently applying LCT at the product level helps provide some standardization.

Applying the Life Cycle Module

The Life Cycle Module uses several steps to identify life cycle differences that can discriminate between options (Table 17). The Initial Screen guides the assessor to first determine if discriminating life cycle differences are likely to exist between the baseline product and an alternative. With increasing levels, the assessor is asked to collect and use more detailed data to complete the evaluation.

If the Cost and Availability, Social Impact, or Materials Management modules have been completed, the Life Cycle Module can be used to refine identified potential social, economic, raw material, or waste related impacts.

Table 17: Life Cycle Module Evaluation Levels.

Initial Screen	*Initial Screen.* Identifies potential unit processes at each life cycle stage that can discriminate between the baseline product and the alternative(s). Determines whether a deeper analysis is needed and whether life cycle differences are social, economic or related to raw materials and wastes.
Level 1	*Basic Life Cycle Evaluation.* Assesses life cycle impacts based on readily available data and identifies what further information is needed to inform decision making. Identifies life cycle "hot spots" associated with the baseline product and the alternative to support mitigation efforts.
Level 2	*Extended Life Cycle Evaluation*. Conducts a more detailed LCT analysis that concentrates on those factors identified in the initial screen as discriminating. Determines extent to which impacts can be mitigated and the product design optimized for life cycle benefits.
Level 3	*Detailed Life Cycle Evaluation*. Conducts a life cycle evaluation of the chemical, product or process using standard ISO 14040 and SLCA, CBA and materials management evaluations. Supports more informed mitigation and optimization of products.

Initial Screen

The Initial Screen determines which life cycle attributes are important for evaluation by comparing the unit processes associated with each LCT stage for the baseline product and the alternatives. These preliminary steps are roughly analogous to the goal definition and scoping phase of a traditional LCA.[70] Differences between products and processes at each life cycle stage may be societal, economic, or environmental. The Initial Screen will guide assessors to:

1. Use the Social Impact Module to address social impacts.
2. Use the Cost and Availability Module to address economic impacts.
3. Use the Materials Management Module to address impacts associated with the supply of raw materials and the generation of wastes.

For environmental impacts not considered by the other modules, the Initial Screen will help define the boundaries of the system that can then be assessed using higher levels of the Life Cycle Module.

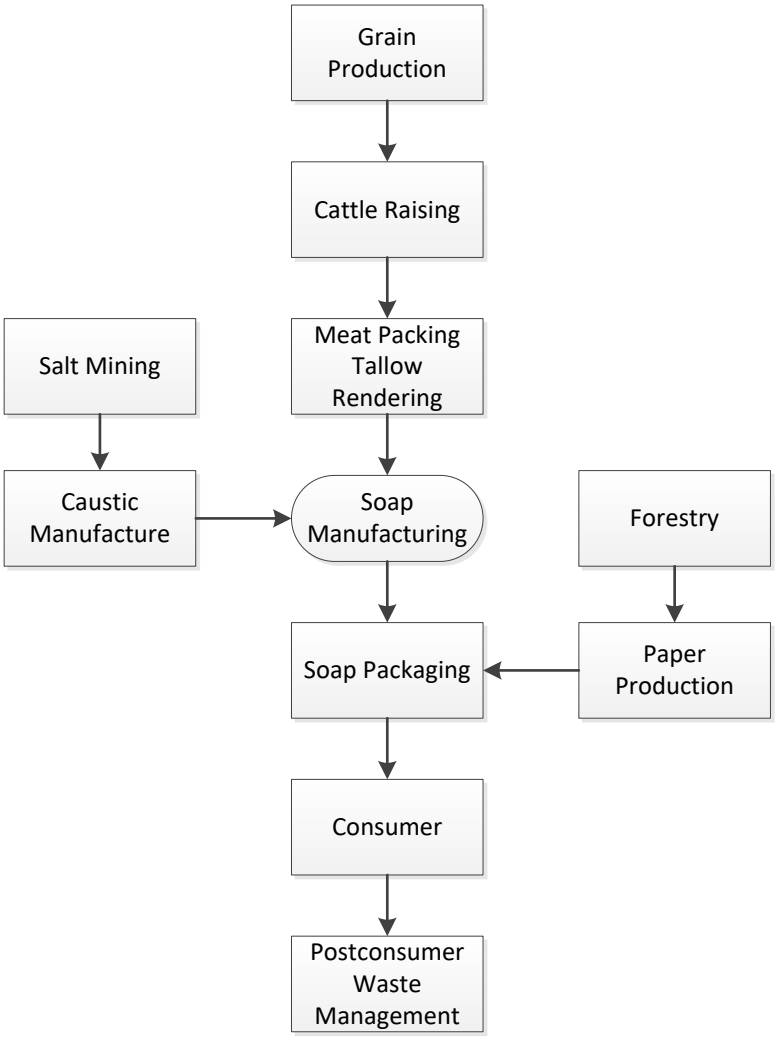
While LCA scoring review may be quantitative, it is based on many assumptions about how products are used and the boundaries of the unit processes. These assumptions can have a profound effect on the outcome of the analysis. In many cases, supply chain transparency is limited and will make it difficult for the assessor to have good knowledge of all life cycle segments. Therefore, the first steps are to identify and document what is known and not known about the product life cycle.

The Initial Screen begins by developing a diagram of the major processes that take place in each of the product's life cycle stages (i.e., a "process flow" diagram). The first iteration of this diagram can be quite simple, showing the major flows of materials and energy throughout the life cycle of the product, the major sources of each material, the production processes, use(s), and end-of-life disposition. An example is provided in

[70] US Environmental Protection Agency, Life Cycle Assessment: Principles and Practices aka Life Cycle 101, accessed 2/2013.

Figure 14.

Figure 14: Flow Diagram of a Hypothetical Bar Soap System.[71]



The initial flow diagram is qualitatively assessed to establish the similarities and differences between the baseline product and the alternatives. For example, for the hypothetical bar soap system (

[71] For more information, see LCA 101, EPA, 2006, accessed 7/2013

Figure 14), a chemical may be substituted into the soap's fragrance but the other processes will remain unchanged. Therefore, there is no need to compare the baseline product and the alternatives for those processes that do not discriminate between the products. At the completion of these preliminary steps, the assessor can determine whether additional data and analysis are necessary to inform the AA.

The following questions are intended to assist in the scoping process.

1. How does the baseline product compare to the alternatives for material inputs and outputs and processes at each stage of the life cycle?
    - How does the baseline product compare to the alternatives with respect to the source of raw materials, production processes, manufacturing, transportation, use, and end-of-life management?
    - Are any differences expected to be discriminating at the product level? For example, small changes in chemical formulations may not be discriminating at the product level.
        - If no, then further LCA may not be necessary.
        - If yes, then further consideration should be given to possible differences in social, economic, or environmental impacts associated with those changes.

2. At which stages are the material inputs and outputs and/or process flows expected to be different between the baseline product and the alternatives?
    - Are there differences in the raw materials used to produce the alternative chemical, or to produce new materials that must be used in the product?
    - What processes, if any, will differ in the materials processing and manufacturing stages, due to the use of the alternative chemical?
    - Will the use of the alternative in the product result in additional or different chemical releases/exposures to humans or the environment?
    - Will the use of the alternative affect the generation of wastes and the way in which the product can be reused, recycled, or disposed?

3. What type of changes in the life cycle impacts, whether environmental, economic, or social might be associated with the differences noted above for the baseline product and the alternatives?
    - For each of the differences noted, are cost impacts expected?
        - If yes, address cost impacts using the Cost and Availability Module.
        - If no, continue with the LCA.
    - For each of the differences noted, are social impacts expected?
        - If yes, assess social impacts using the Social Impacts Module.
        - If no, continue with the LCA.

- For each difference(s) noted, is it likely to increase use of raw materials and waste generation?
  - If yes, assess impacts from the use of raw materials and waste generation using the Materials Management Module.
  - If no, continue with the LCA.
- For each of the differences noted, are increased environmental impacts expected? These impacts may include but are not limited to climate change, acidification, eutrophication, photochemical ozone creation, releases toxic to humans and the environment, land use, or resource depletion.
  - If yes, continue with the LCA.
  - If no, document the information used to reach the conclusion. Continue with the LCA.

4. What is the scope of the assessment?
   - Document the potential differences in impacts noted between the baseline product and the alternative(s) across the life cycle. This assessment may be limited to just those areas where there are differences. Differences that appear to be discriminating may be referred to as life cycle "hot spots."

5. What type of information is needed to conduct the analysis?
   - Adjust the level of detail of the analysis as feasible by aggregating processes, so that fewer individual pieces of data need to be collected.
   - Determine what data will need to be collected.

The preliminary steps of the LCT process are complete.

Level 1: Basic Life Cycle Evaluation

Level 1 assesses potential impacts associated with differences in unit processes across the life cycle. Only those unit processes and impacts identified as discriminating in the Initial Screen are used. Readily available information is used to evaluate the life cycle impacts and determine if that information is sufficient or if additional data and analysis are needed for one or more-impacts. Additional data is gathered only where needed for decision making.

1. Determine what data can be obtained directly from facilities or suppliers (i.e., primary data), or from existing studies or databases (i.e., secondary data) for the impacts associated with the process flow differences.

2. Are there substantial differences in the quantity and quality of data gathered for the baseline product as compared to the alternatives for the impacts of interest?
   - If no, continue with the Level 1 assessment.

- If yes, is there is sufficient information to compare the baseline product to the alternative for the impacts of interest?
  - If yes, continue with the Level 1 assessment.
  - If no, move to Level 2 for that particular impact.

3. Is there sufficient information to compare the baseline product to the alternatives for each of the discriminating life cycle impacts (aka "hot spots")? Sufficient information may be available for some but not all of the hot spots.
   - If yes, document the metrics used and summarize the differences between the products for each of the hot spots for which there is sufficient information. Continue with Level 1.
   - If no, proceed to Level 2 for additional data gathering and analysis for each of the hot spots for which there is insufficient information.

4. For each product for which hot spot differences have been sufficiently assessed, can any of the negative impacts be mitigated to reduce the differences?
   - If yes, note what changes in the product or processes would need to be made in order to mitigate the negative impacts. Reassess the differences after mitigation.
   - If no, use the information to inform decision making and document decisions. Evaluation complete.

Level 2: Extended Life Cycle Evaluation

Level 2 scopes and conducts a more detailed and quantitative data gathering and analysis including a partial LCA informed ISO 14040 guidelines. A Level 2 assessment is based upon detailed technical information and data available through published LCAs, life cycle inventory databases, or primary data obtained from the supply chain. Depending upon the level of technical information involved, assessors may need to seek out additional expertise.

The following information for both the potential alternatives and the baseline product should be collected.

- The detailed life cycle inventory data (i.e., inputs, outputs, and energy use) for all unit processes identified as discriminating for the product and the alternatives.
- All impact assessments results associated with the life cycle inventory.
- A summary of all interpretations of life cycle inventory and impact assessment data.

Completing Level 2 should result in sufficient information to compare the baseline product and the alternatives and complete the analysis. Data gaps that cannot be reasonably filled may also be identified. Where data gaps occur, they should be documented and the uncertainty should be addressed in the interpretation of results.

Assessors can use Level 2 to better quantify those life cycle impacts that determine whether a potential alternative is an improvement. They can also use Level 2 to guide mitigation strategies.

1. Based on the life cycle inventory and the life cycle impact assessment, are there discriminating differences between the baseline product and the alternatives?
   - If yes, summarize the metrics used and document the interpretation of results. Continue the evaluation.
   - If no, summarize the metrics used and document the interpretation of results. Continue the evaluation.
2. Do the discriminating results suggest one alternative may be more or less preferred over another?
   - If yes, document the rationale. Continue the evaluation.
   - If no, document the information used to reach the conclusion. Continue the evaluation.
3. For each hot spot associated with the baseline product and/or the alternatives, can the negative impacts be mitigated?
   - If yes, note what changes in the product or processes would need to be made in order to mitigate the negative impacts. Reassess the differences using the Life Cycle Module after mitigation.
   - If no, use the information to inform decision making and document decisions. Evaluation complete.

Level 3: Detailed Life Cycle Evaluation

Level 3 consists of a full life cycle assessment that meets ISO 14040 requirements and includes a social life cycle assessment, materials flow analysis, cost benefit analysis, and other pertinent considerations. More information on these techniques is found in the Appendix.

Appendix

Life Cycle Assessment

ISO defines LCA as the "compilation and evaluation of the inputs, outputs, and the potential environmental impacts of a product system throughout its life cycle" (ISO 14040: 1997). The goal of LCA is to quantify all physical exchanges with the environment, whether they are inputs like natural resource or land use, or energy, or outputs such as emissions to air, water, and soil (

Figure 15).

Figure 15: Life Cycle Impact Assessment.

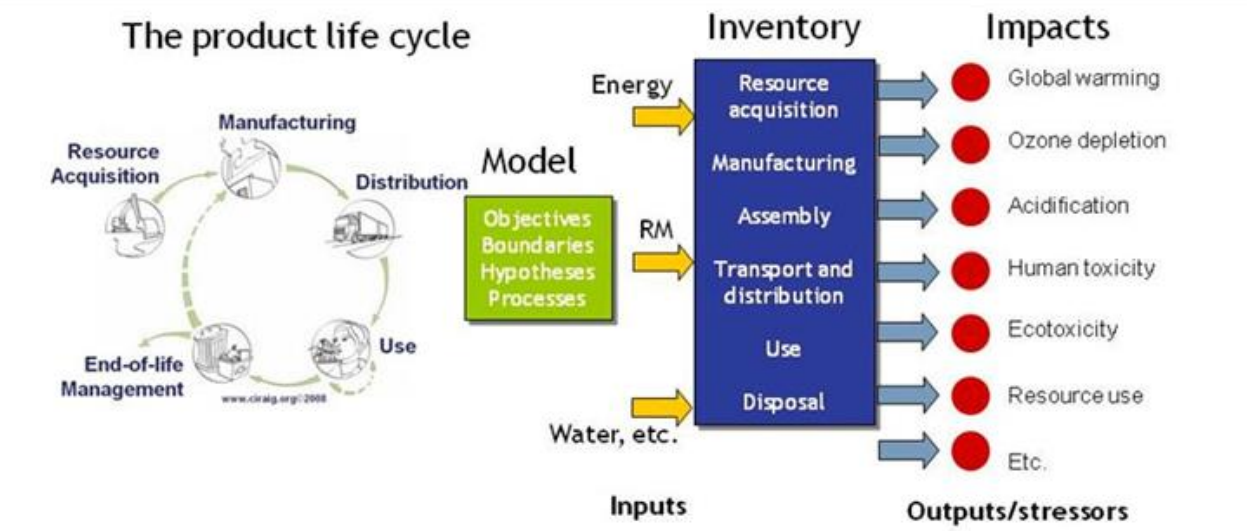


Figure 1. Life Cycle Impact Assessment translates the inventory of emissions from a product's life cycle into an environmental profile of the product representing its potential contributions to a wide range of environmental impacts

LCA is the preeminent framework for understanding the Cradle-to-Cradle environmental impacts of products, processes, services, policies, and decisions. The LCA framework provides a structure for capturing ancillary (indirect) and supply chain effects in addition to the direct effects of immediate interest. LCAs of many different systems have shown that the largest impacts often occur in ancillary and supply chain processes.

The LCA methodology has been formalized (ISO 14040 series) and improved over several decades in Europe and the United States. Regulated by the ISO 14040 series standards, LCA consists of four distinct phases:

1. Define goal and scope and determine methodological framework.
2. Inventory of all the inputs and outputs related to the product system.
3. Assess the potential impacts associated with these inputs and outputs.
4. Interpret the inventory data and impact assessment results as they relate to the goal and scope of the study.

While the ISO 14040/44 standards provide the general framework for LCA, it gives the practitioner a range of choices that can affect the results and conclusions.

Comprehensive guidance is required to support consistent and robust results derived from LCAs. The International Reference Life cycle Data System Handbook: General Guide for Life cycle Assessment aims to improve the consistency of data generation from LCAs. UNEP's work to promote LCA is spearheaded by UNEP and the Society of Environmental Toxicology and Chemistry's Life Cycle Initiative and a guide to performing LCA.

Government environmental entities or non-governmental organizations including academic institutions have also created specific guidelines for performing LCA. While some guidelines are general and provide overviews of the LCA framework, others are highly specific to elements of an LCA. Practitioners can use existing guidelines to complement their understanding and improve their general background needed for specific evaluations related to alternatives analysis.

After constructing a process flow and system boundary, LCA tools will help analyze the direct and indirect effects of the system by creating a life cycle inventory and then linking it to human health and environmental damage categories. Due to time and cost constraints, less involved variants have been created. For example, the boundaries of a system can be limited to certain life cycle stages or to certain impact categories. Alternatively, an analysis can be performed using only generic secondary data or proxy information. Such simplifications can affect the accuracy and applicability of LCA results but nevertheless allow for the identification and assessment of potential impacts.

Material Flow Analysis

An MFA examines the movements of materials through, for example, an industry sector and its supply chain, or a given region. MFAs are used to identify key environmental issues related to the resource efficiency of systems and develop strategies to improve them. They are a very good first step when modeling a product life cycle.

Life Cycle Costing

Similar to LCA, LCC is a technique that accounts for all the costs across the lifetime of a product, including manufacturing, transport, and use through disposal. This information is valuable in understanding the total cost of an investment or ownership. For example, while upfront costs may be greater for a given product, the overall lifetime cost may be lower for an alternative due to lower operating or disposal costs. Similar approaches exist to estimate social impacts and benefits associated with a product's life cycle.

Cost Benefit Analysis

CBA, also often referred to as cost-benefit assessment or benefit-cost analysis, allows alternatives to be compared, primarily in monetary terms, by calculating the ratio or sum of the favorable outcomes of an alternative and the associated opportunity cost.

An AA using CBA must incorporate a life cycle perspective, assessing the effects of manufacturing upstream, production, and downstream effects, including end-of-life impacts (e.g., disposal or reuse). Only costs that vary between alternatives in either magnitude or timing must be included in the AA. A CBA must always include a base-case or "no action" scenario, which incorporates inevitable future changes in conditions that do not

depend on alternative selection. The analysis should cover a specified time frame with stated start and end dates. For each alternative, costs and benefits that occur at different points within the time frame should be discounted to account for the differing time-cost of money.

Most commonly, CBA results are reported in terms of the net benefits, subtracting the costs from the benefits when both are in terms of Net Present Value or annualized value. Net present value is determined by assigning monetary values to benefits and costs, discounting future benefits and costs appropriately, and subtracting the total discounted costs from the total discounted benefits. Alternatives with a positive net present value are preferred while a negative net present value indicates an option that should be generally avoided.

CBA puts all costs and benefits into standard units (usually dollars) so that they can be compared directly. In reality however, it is unlikely that it will be possible to monetize all impacts (e.g., social and wider economic impacts). Also, it might be difficult and sometimes impossible to estimate environmental impacts based on the current body of knowledge. Furthermore, some costs or benefits do not have a market value. However, market-based methods, describing straightforward commercial and financial gains and losses, such as lost productivity (e.g., crop production), costs for the replication of services (e.g., water purification), or additional costs to recreation and leisure, could be used in this context.

CBA is among the methodologies that, when consistently and completely implemented, can be used to evaluate alternatives. The following information on CBA is based on guidance created by the California Environmental Protection Agency to support their Green Chemistry Legislation.

Some challenges to the valuation process in CBA include:

- Identifying relevant costs and benefits, including changes to future economic activity, consumer behavior, or technology due to the base case scenario and each alternative.
- Placing costs and benefits accurately in time.
- Defining the time frame to capture all costs and benefits without diluting the effects over time.
- Selecting an appropriate discount rate, especially for intergenerational effects.
- Avoiding double counting of costs and benefits.
- Finding applicable valuation estimates for environmental costs and benefits.
- Selecting the best valuation for benefits when the effects vary across the population.
- Identifying and describing sources of uncertainty and sensitivity.

The reader should refer to the case studies, as well as other publically available documents, to find guidance in addressing these challenges.

This guide suggests using a CBA-type approach, which involves recognizing that not all impacts can be quantified or monetized. As such, the analysis should involve quantifying and monetizing impacts as far as is practicable (and appropriate) and combining the monetized results with qualitative and/or quantitative descriptions of all non-monetized impacts.

The iterative approach to the CBA means that a first "initial" CBA could be undertaken applying immediately available information. This is likely to be made up of predominately qualitative information.

The following are references for conducting a full cost benefit analysis.

- *Guidelines for Preparing Economic Analyses*, EPA, 2010. This guidance was updated in 2016.
- *Towards a Life Cycle Sustainability Assessment*, United Nations Environment Programme, *2011*.
- Zerbe, R.O. and Dively, D.D. 1994. *Benefit Cost Analysis in Theory and Practice*.
- Mishan, EJ and Quah, Euston. 2007. *Cost Benefit Analysis* (5th ed.).
- Prato, Tony. 1998. *Natural Resource and Environmental Economics, Chapter 11: Benefit-Cost Analysis of Resource Investments*, pp. 265-299.
- *Cost-Benefit Analysis Support for California EPA's Green Chemistry Initiative*, California Environmental Protection Agency, Department of Toxic Substances Control, 2012.

Social Life Cycle Assessment

An SLCA is described in the UNEP guidelines for Social Life Cycle Assessment of Products as 'a social impact (and potential impact) assessment technique that aims to assess the social and socio-economic aspects of products and their potential positive and negative impacts along their life cycle'. A social life cycle inventory is a compilation of a list of possible social interventions caused by the potential alternative.

SLCA concerns can be complicated. Examples of social life cycle inventory are shown in

Figure 11.

LCA Tools

Climate Impact Lab: **Climate Impact Lab Tracker** is a high-level climate tracker that quantifies and projects the impacts of climate change historically and over the next ~75 years. It shows temperature impacts, mortality costs, and energy costs both in the U.S. and

around the world. The maps are high level and would likely only be useful if considering impacts globally at the country level, or within the US at the state level.

***DTSC Life Cycle Overview*:** Life cycle Assessment Support for California's Green Chemistry Initiative was written in support of California's Green Chemistry Legislation.

European Environment Agency: Life cycle Assessment: A Guide to Approaches, Experiences, and Information Sources is a general overview of what LCA is and what can be evaluated with the framework. It provides a discussion of the methodological background for performing LCAs and has a list of informational sources including newsletters, journals, books, reports, conference proceedings, databases, standards, and software for LCA practitioners.

European Commission: International Reference Life cycle Data System Handbook: General Guide for Life cycle Assessment is heavily focused on the methodological aspects of life cycle inventory and Life Cycle Impact Assessment. The target audience is described as experts in the public and private sector dealing with environmental decision support related to products, resources, and waste management. It was developed by the Joint Research Council and Institute for Environment and Sustainability and is an overarching guidance for detailed LCA.

Environmental Impacts of Products: Analysis of the life cycle environmental impacts related to the final consumption of the EU-25 focuses on the European Commission's development of an input-output model for product evaluation. The product categories are not specific to chemicals but capture the broad range of items used throughout an economy. It was developed by the Joint Research Council, European Science and Technology Observatory, and Institute for Prospective Technological Studies.

EPA: Life cycle Assessment: Principles and Practice was an educational tool for those who want to learn the basics of LCA. It discusses the basic stages of LCA including goal and scope definition, life cycle inventories, life cycle impact assessments, and improvement analysis.

EJScreen is a mapping tool that may help users identify areas with potential environmental quality Impacts related to 13 EJ indexes. The mappable indices and indicators include PM2.5, ozone, diesel PM, air toxics cancer risk, air toxics respiratory hazard index, toxic releases to air, traffic proximity, heart disease, asthma, cancer, and more.

ATDSR: EJ Index is a census tract-based mapping tool that ranks the cumulative impacts of environmental injustice on health based on 36 environmental, social, and health factors (many overlapping with EJScreen factors), grouped into 3 overarching modules and 10 different domains. The tool could be used to measure progress towards EJ and health equity goals or to identify potential social impact hotspots.

European Union (EU) - Calcas: Coordination Action for Innovation in Life cycle Analysis for Sustainability: D20 Blue Paper on Life cycle Sustainability Analysis. This paper discusses changes that could be incorporated into the LCA standardized by ISO to better address sustainability assessments. Particular attention is given to assessing complex systems with extended and durable effects on the whole of society, broadening the scope of analysis and deepening available model. The paper was developed for the European Union by LCA researchers at l'Energiae l'Ambiente , Leiden University, and the Swedish Environmental Research Institute.

GHG Protocol: Product Life cycle Accounting and Reporting Standard developed greenhouse gas accounting and reporting standards for businesses, governments, NGOs, and academic institutions. It focuses on LCA methodology providing basic information for new LCA practitioners that focuses on greenhouse gas assessment. It was developed by the World Business Council for Sustainable Development and the World Resources Institute.

ReCiPe Impact Assessment Guidelines: ReCiPe 2008: A life cycle impact assessment method which comprises harmonized category indicators at the midpoint and the endpoint level is an extensive discussion of the different life cycle impact assessments metrics and their evaluation. It is an excellent resource for those trying to bridge life cycle inventories with life cycle impact assessments. This document provides step-by-step instructions for performing a life cycle impact assessment using a life cycle inventory, including environmental and human health damage characterization factors that can be implemented. It was developed by life cycle impact assessment researchers in the Netherlands including PRé Consultants, University of Leiden, Radboud University Nijmegen, and Bilthoven.

UNEP: Life cycle Approaches: The Road from Analysis to Practice presents the general background for LCA and life cycle management principles. It discusses the key steps in performing each analysis but does not provide step-by-step instructions for executing an LCA. The document was developed by the UNEP and the Society of Environmental Toxicology and Chemistry.

Evaluation of Environmental Impacts in Life cycle Assessment provides a qualitative overview of the life cycle impact assessment framework for those interested in understanding the importance of performing the assessment. It does not provide step-by-step instructions for performing a life cycle impact assessment. It was developed by the UNEP Division of Technology, Industry and Economics, Product and Consumption.

The Urban Institute: Metadata for Environmental Justice Screening Tools is an AirTable compilation that summarizes environmental justice tools in the United States, including 29 state-specific tools. The summaries describe indicators and data sources used, if and how

race and ethnicity are included, and how the tools quantify and prioritize burdens among potential environmental justice communities. It also includes links to each tool.

Standards and Specifications

ISO 14040:2006 Environmental management – LCA – Principles and Framework
ISO 14044:2006 Environmental management – LCA – Requirements and Guidelines
ISO 14045: 2012 Environmental management—Eco-efficiency assessment of product systems – Principles, requirements and guidelines
ISO/TR 14047:2012 Environmental management – LCA – Illustrative examples on how to apply ISO 14044 to impact assessment situations
ISO/TR 14048:2002 Environmental management—LCA—Data documentation format
ISO/TR 14049:2012 Environmental management – LCA – Illustrative examples on how to Apply ISO 14044 to Goal and Scope Definition and Inventory Analysis
ISO 14063: 2020 Environmental management – Environmental Communication – Guidelines and examples
PAS2050:2008 Specification for the Assessment of the Life cycle Greenhouse Gas Emissions of Goods and Services

LCA Resources and Networks

- European Platform on LCA
- UNEP / SETAC Life cycle Initiative
- Danish LCA Centre
- German Network on Life Cycle Inventory Data
- Australian Life cycle Assessment Society and National LCA database
- American Center for LCA
- NREL US Life Cycle Inventory database
- Japan Environmental Management Association for Industry and National LCA database
- Thai National Metals and Materials Technology Centre and National LCA database

Glossary

Alternatives assessment (AA): a process for identifying and comparing potential chemical and non-chemical alternatives that can be used as substitutes to replace chemicals or technologies of high concern. The AA Guide addresses these issues from a product perspective although other uses are possible.

Authoritative body: An organization independent of the manufacturer and not tied to industry funding or engaged in any advocacy activities in a way that could affect its independence. Authoritative bodies include state, federal, and international government research organizations, independent research organizations, etc.

Bioaccumulation: Progressive increase in the amount of a substance in an organism or part of an organism which occurs because the rate of intake exceeds the organism's ability to remove the substance from the body. (IUPAC)[72]

Biomonitoring: Continuous or repeated measurement of any naturally occurring or synthetic chemical, including potentially toxic substances or their metabolites or biochemical effects in tissues, secreta, excreta, expired air or any combination of these in order to evaluate occupational or environmental exposure and health risk by comparison with appropriate reference values based on knowledge of the probable relationship between ambient exposure and resultant adverse health effects. (IUPAC)

Carcinogenic, Mutagenic, and Reproductive toxicant (CMR): A label applied to a substance that presents one or more of the three hazard traits described. Carcinogenic substances can cause or increase the likelihood of certain cancers. Mutagenic chemicals can cause genetic mutations; many mutagenic substances, but not all, are also carcinogenic. Reproductively toxic substances are able to damage the reproductive process.

Decision Method: The way in which decisions can be reached in a specific framework. In the frameworks identified in the Guide, there are many ways in which a decision can be reached. These frameworks encompass different decision-making methods and are an important component in any AA.

Disadvantaged and/or vulnerable population: a group of people defined by a specific demographic or characteristic that have been overburdened and disproportionately impacted by exposure to toxic chemicals and/or have greater susceptibility to adverse

[72] IUPAC: Taken from IUPAC *Glossary of Terms Used in Toxicology*, 2nd Edition – IUPAC Recommendations 2007, prepared for publication by John H. Duffus, Monica Nordberg & Douglas M. Templeton, accessed 2/2013.

health effects from exposure to toxic chemicals given the accumulation of an array of risk factors associated with being underserved and marginalized populations.

End of life: The point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs first.[73]

Environmental justice: the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation and enforcement of environmental laws, regulations, and policies.[74]

Environmental justice community: a group of individuals that are geographically or culturally linked together. Members of these communities often are among one or more disadvantaged and/or vulnerable population. Frequently, EJ communities may self-identify as a community, sometimes for the purpose of political organization and action.

Environmental monitoring: Continuous or repeated measurement of agents in the environment to evaluate environmental exposure and possible damage by comparison with appropriate reference values based on knowledge of the probable relationship between ambient exposure and resultant adverse effects. (IUPAC)

Equity: the act of giving fair treatment to individuals. Equitable action occurs at multiple steps within the AA process when assessors address current barriers to individual action.

Exposure: Concentration, amount, or intensity of a particular physical, chemical, or environmental agent that reaches the target population, organism, organ, tissue, or cell, usually expressed in numerical terms of concentration, duration, and frequency (for chemical agents and micro-organisms) or intensity (for physical agents). (IUPAC)

Exposure assessment: Process of measuring or estimating concentration (or intensity), duration and frequency of exposures to an agent present in the environment or, if estimating hypothetical exposures, that might arise from the release of a substance, or radionuclide, into the environment. (IUPAC)

External Costs: A negative effect on a third party who is not part of a market transaction. For example, if a manufacturing facility emits waste into a river which poisons the fish in a nearby fishery, the fishery experiences an external cost to restock as a consequence of the manufacturing operations. Other examples of external costs are the effects of second-hand

[73] Division 4.5, Title 22, California Code of Regulations Chapter 55. Safer Consumer Products, Section 69501.1 (30), accessed 2/2103.

[74] US EPA. Learn About Environmental Justice. 2023 [cited 10 October 2023]. Available from: https://www.epa.gov/environmentaljustice/learn-about-environmental-justice

smoke on nonsmokers, increasing the incidence of respiratory distress, and a smokestack which deposits soot on someone's laundry, thereby incurring costs of relaundering.[75]

Externality: A cost or benefit that involves a third party who is not a part of a market transaction; "a direct effect on another's profit or welfare arising as an incidental by-product of some other person's or firm's legitimate activity" (Mishan, 1976). The term "externality" is a general term which can refer to either external benefits or external costs.[76]

Exposure pathways: The route a substance takes from its source (where it began) to its end point (where it ends), and how people can come into contact with (or get exposed to) it. An exposure pathway has five parts: (1) a source of contamination (such as an abandoned business or a naturally-occurring source); (2) an environmental media and transport mechanism (such as movement through groundwater); (3) a point of exposure (such as a private well); (4) a route of exposure (eating, drinking, breathing, or touching), and (5) a receptor population (people potentially or actually exposed). When all five parts are present, the exposure pathway is termed a completed exposure pathway.[77]

Exposure scenario or exposure profile: Set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment.[78]

Far field exposure: The result of human contact with chemicals in outdoor air, drinking water, and food as a result of general chemical use and release throughout its life cycle and subsequent fate and transport in the physical environment (air, water, soil, and sediment) and food web bioaccumulation.[79]

Framework: A step-wise process used to conduct an AA and evaluate alternatives. In combination with the decision method, the framework creates a clear AA structure. The

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[75] EPA DfE Program, *Cleaner Technologies Substitutes Assessment-A Methodology and Resource Guide*, Social Benefits/Cost Assessment, accessed 7/2013.

[76] IBID.

[77] Agency for Toxic Substances & Disease Registry (ATSDR), *Glossary of Terms*, accessed 2/2013.

[78] European Chemicals Agency (ECHA), *Guidance on information requirements and chemical safety assessment Chapter R.20: Table of terms and abbreviations,* accessed 1/2024.

[79] Definition from *Prioritizing Chemicals and Data Requirements for Screening-Level Exposure and Risk Assessment*, Jon A. Arnot, et al., Environ. Health Perspect., 2012 November, 120(11), 1565-1570, accessed 2/2013.

three frameworks used in the Guide are Sequential, Simultaneous and Hybrid, a combination of the previous two.

Functional use: The job (function) that a chemical performs in a formulation, material, or product. Function is related to chemical structure and physical and chemical properties. Examples of functional use classes for chemicals include surfactants, solvents, etc. From a life cycle perspective, the unit of comparison assures that the products being compared provide an equivalent level of function or service.

Functional substitution: The application of information on function to identify, evaluate, and select safer alternatives that achieve a particular result. Functional substitution considers chemical function alternatives, which include drop-in chemical replacements, to service function alternatives, which includes new ways of achieving the same functional goal in society.[80]

Hazard: Set of inherent properties of a substance, mixture of substances, or a process involving substances that, under production, usage, or disposal conditions, make it capable of causing adverse effects to organisms or the environment, depending on the degree of exposure; in other words, it is a source of danger. (IUPAC)

Hazard assessment: Evaluation of the hazards posed by a chemical, product, or process.

Inherently toxic: Chemicals toxic to human and non-human species as defined by the Canadian Environmental Protection Act of 1999. "A substance is toxic if it is entering or may enter the environment in a quantity or concentration, or under conditions that:

- Have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
- Constitute or may constitute a danger to the environment on which life depends; or
- Constitute or may constitute a danger in Canada to human life or health."[81]

Internalized Costs: The direct negative effects incurred by industry or consumers from their actions in the marketplace. Examples include a firm's cost of raw materials and labor, a firm's costs of complying with environmental regulations, or the cost to a consumer of purchasing a product.[82]

[80] Tickner et al. (2015). "Advancing Safer Alternatives Through Functional Substitution." *Environ. Sci. Technol.* 2015, 49, 2, 742–749. DOI: 10.1021/es503328m

[81] Environment Canada, Section 64, accessed 2/2013.

[82] EPA DfE Program, *Cleaner Technologies Substitutes Assessment-A Methodology and Resource Guide*, Social Benefits/Cost Assessment, accessed 7/2013.

Life Cycle Assessment (LCA): A technique (ISO 14040) to assess the environmental aspects and potential impacts associated with a product, process, or service, by:[83]

- Compiling an inventory of relevant energy and material inputs and environmental releases for studied life cycle phases.
- Evaluating the potential environmental and human health impacts associated with identified inputs and releases from processes within studied phases.
- Interpreting the results to help make an informed decision.

Life Cycle Thinking (LCT): Use of a holistic life cycle perspective to help manufacturers and policy makers identify possible improvements across the industrial system and through all the product's life cycle stages, including disposal, recycling and reuse. It also applies to improving industrial processes and activities. The key aim of thinking about products and processes using life cycle thinking is to avoid burden shifting. This means minimizing impacts at one stage of the life cycle, or in one geographic region, or in a particular impact category, while avoiding unrecognized increased impacts elsewhere.[84]

Mobility: The potential of the substance or the components of a mixture, if released to the environment, to move under natural forces to the groundwater or to a distance from the site of release.[85]

Nanomaterial: A material with any external dimension in the nanoscale or with an internal surface structure at the nanoscale, which is 1 to 100 nanometers.[86]

Near field exposure: Indoor, occupational, industrial, and direct exposure pathways from consumer use (e.g., application of personal care products).[87]

Persistence: Attribute of a substance that describes the length of time the substance remains in a particular environment before it is physically removed or chemically or biologically transformed. (IUPAC)

Persistent, bioaccumulative and toxic pollutants (PBTs): Long-lasting substances that can build up in the food chain to levels that are harmful to human or ecosystem health. These

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[83] Adapted from EPA LCA webpage, accessed 7/2013.

[84] Adapted from EPA Life cycle Perspective webpage, accessed 7/2013.

[85] European Chemicals Agency (ECHA). (2020). *Guidance on the compilation of safety data sheets Version 4.0,* accessed 1/2024.

[86] ISO. (2008). International Organization for Standardization. Technical specification ISO/TS 27687:2008(E): Nanotechnologies Terminology and definitions for nano-objects—Nanoparticle, nanofibre and nanoplate.

[87] Definition adapted from *Prioritizing Chemicals and Data Requirements for Screening-Level Exposure and Risk Assessment*, Jon A. Arnot, et al., Environ. Health Perspect., 2012 November, 120(11), 1565-1570, accessed 2/2013.

contaminants can be transported long distances and move readily from land to air and water.[88]

Product Flow Diagram: A diagram that identifies all the processes that contribute to the creation of a product; emphasizes processes that can contribute to hazards to worker health and safety or hazards in a final product.

Product Life cycle: The life cycle of a product system begins with the acquisition of raw materials and includes material processing and production, manufacture and assembly, transport, use, retirement, and disposal of residuals produced in each stage.

Repository: A collection of alternatives assessments made available to others beyond the entities who conducted the AA. Repositories may include government, business, non-profit or consultant-developed databases, websites, or software tools that provide information on potential alternatives.

Risk: The probability of harm a chemical may have upon human health and the environment. Risk is defined as a function of hazard and exposure.

Risk assessment: Identification and quantification of the risk resulting from a specific use or occurrence of a chemical or physical agent. The assessment considers possible harmful effects on individuals or populations exposed to the agent in the amount and manner proposed through all possible routes of exposure. (IUPAC)

Risk reduction process: A process based upon the definition of risk as a function of hazard and exposure. Low hazard chemicals are subjected to exposure evaluation to identify the chemicals that have the lowest possible chemical hazard and lowest exposure potential.

Safer chemical: Any chemical used as a replacement for a toxic chemical that, while still maintaining the functionality and performance required, has been identified both as posing a lower chemical hazard.

System Flow Diagram: A depiction of the inputs and outputs of a system and how they are connected.

Very bioaccumulative and toxic (vBT): A substance that exhibits high levels of bioaccumulation AND is toxic to human health or the environment.

Very persistent, very bioaccumulative (vPvB): A substance that exhibits high levels of both persistence AND bioaccumulation potential.

[88] EPA PBT Chemical Program, accessed 2/2013.

Very persistent and toxic (vPT): A substance that exhibits high levels of persistence AND is toxic to human health or the environment.