

Interstate Chemicals Clearinghouse

Alternatives Assessment Guide

Version 1.0



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Disclaimer:

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Acronyms

AA	Acute Aquatic toxicity
AA	Alternatives Assessment
AOEC	Association of Occupational and Environmental Clinic asthmagens
AT	Acute toxicity
C	Carcinogenicity
CA	Chronic Aquatic toxicity
CLP	EU Classification and Labeling Programme
CMR	Carcinogenic, mutagenic or reproductive toxic chemical
D	Developmental toxicity
DMC	Domestic Material Consumption
DMI	Direct Material Input
DSL	Canadian Domestic Substances List
PBiT	Persistent, Bioaccumulative and inherently Toxic chemicals
E	Endocrine activity
ECOTOX	EPA Ecotoxicity database
ED-Cat. 1	EU Endocrine Disruptor Screening list-Category 1
EPA - C	EPA Integrated Risk Information System chemicals
EPA PBT	EPA Persistent Bioaccumulative and Toxic chemicals
EPA TRI	EPA Toxics Release Inventory chemicals
ESIS	European chemical Substances Information System
EU	European Union
EU PBT	EU Persistent Bioaccumulative and Toxic chemicals
F	Flammability
G&L	List of neurodevelopmental toxicants identified by Grandjean & Landrigan
GHS	Global Harmonisation System of Classifying and Labeling Chemicals
GHS – J	Japanese Global Harmonisation System database
GHS – K	Korean Global Harmonisation System database
GHS – NZ	New Zealand Global Harmonisation System database
Guide	IC2 Alternatives Assessment Guide
H	High level of concern
IARC	International Agency for Research on Cancer
IrE	Irritation-Eye
IrS	Irritation-Skin
IUCLID	OECD International Uniform Chemical Information Database ²
L	Low level of concern
M	Moderate level of concern
M/G	Mutagenicity/genotoxicity
MFA	Material Flow Accounting
N	Neurotoxicity
NTP	National Toxicology Program

NWMP	EPA National Waste Minimization Program priority chemicals
OE	Other Environmental hazard toxicity
OECD	Organisation for Economic Cooperation and Development
OEHHA	California EPA, Office of Environmental Human Hazard Assessment
OHAaT	NTP Reproductive toxic chemicals
OR P3	Oregon Persistent Priority Pollutant chemicals
OSPAR EDs	Oslo-Paris Commission Endocrine Disruptor chemicals
OSPAR PBT	Oslo-Paris Commission Persistent, Bioaccumulative and Toxic chemicals
PBiT	Persistent, Bioaccumulative and inherently Toxic chemicals
PBT	Persistent, Bioaccumulative and Toxic chemicals
PBT Profiler	EPA PBT modeling database
POPs	Stockholm Persistent Organic Pollutant chemicals
Prop 65	California Proposition 65
QSAR	Qualitative Structure Activity Relationships
R	Reproductive toxicity
RAs	Risk Assessments
REACH	Registration, Evaluation and Authorisation of Chemicals, EU Legislation
Repeat	Repeat dose study
RoC	NTP Report on Carcinogens
RTECS	Registry of Toxic Effects of Chemical Substances database
Rx	Reactivity
SFA	Substance Flow Analysis
SIDS	OECD Screening Information Data Set
Single	Single dose study
SLCA	Social life cycle assessment
SMM	Sustainable Materials Management
SnR	Sensitization-Respiratory
SnS	Sensitization-Skin
ST	Systemic toxicity
SVHC	EU Substance of Very High Concern
Team	Technical Alternatives Assessment Guide Team
TEDX	The Endocrine Disruptor Exchange
TOXNET	Toxicology Data Network Hazardous Substances Database
TMR	Total Material Requirement
vBiT	Domestic Substance List very bioaccumulative and inherently toxic chemicals
vH	Very high level of hazard concern
vL	Very low level of hazard concern
vPiT	DSL very persistent and inherently toxic chemicals
VwVwS	German Federal Environment Agency, Administrative Regulation on the Classification of Substances hazardous to water into Water Hazard Classes
WA PBT	Washington PBT chemicals
WHMIS	Workplace Hazardous Materials Information System chemicals

Overview

Purpose and Background

The [Interstate Chemicals Clearinghouse](#) (IC2), an association of state, local, and tribal governments along with supporting members from industry and the environmental community 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.

In 2011, the IC2 sponsored creation of the IC2 Alternatives Assessment Guide (Guide) to:

- Be flexible enough to meet a wide range of user needs including small, medium, and large businesses, local, state, and federal governments, and other interested parties. Provide sufficient flexibility that assessors can define what comprises an alternatives assessment (AA), including which criteria to use and to what depth each criteria is evaluated.
- 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 AA.

The Guide is designed to meet [IC2 functions](#) and enable member states to standardize the AA process. It allows states with similar interests to share AA results conducted by one member state among the larger IC2 membership. Previous experience has shown that state 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 using different methodologies. Resources could have been saved if one state conducted an AA and shared the results among IC2 member states.

Eight IC2 member states, including California, Connecticut, Massachusetts, Michigan, Minnesota, New York, Oregon, and Washington, worked together on the Guide. Representatives from these states formed the Technical AA Guide Team (Team). IC2 requested technical support from the [United States Environmental Protection Agency \(EPA\) Design for the Environment \(DfE\) Program](#), which has extensive AA experience. In addition, Dr. Lauren Heine, Consulting Co-Director of [Clean Production Action](#), a non-governmental organization with extensive AA experience, was hired as a technical consultant. Team members have 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.

IC2 Alternatives Assessment Guide Development

In 2011, Ecology initiated the development process by providing a scoping document including potential components of an AA and solicited input from interested stakeholders. The Team started meeting regularly in August 2011. Draft modules were posted for public comment on the Washington State Department of Ecology [website](#). Comments were accepted on an ongoing basis. 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 provide opportunity for input into the process. Two webinars were held in August and November 2012 to update all interested stakeholders on progress and to accept comments and questions. The Team completed the draft Guide in March 2013. It was released for a 60-day public comment period and comments were received until May 2013.

The Guide is designed to meet the needs of a wide range of users, each with unique needs. As a result, the final product is complex and comprehensive. The Guide does not provide a single, specific framework for conducting an AA. Instead, it presents three potential frameworks. Up to seven modules, each evaluating a different aspect of potential alternatives, can be “plugged into” the chosen framework. Each module can be completed to different levels. Higher levels require greater expertise and resources, but afford the assessor greater confidence in their results. Assessors choose a framework, modules, and levels within modules to create an AA appropriate to the chemical, product, or process under assessment. The Guide provides some minimum expectations for an AA and will provide more on this topic later in this document.

If a state regulatory agency wished to establish minimum requirements for an AA, specific portions of the Guide could be selected as a model AA. It could decide which framework to use, the minimum number of modules to include, their order and appropriate levels, etc. If a small company with limited resources and expertise wished to conduct an AA, the assessor could select a basic framework and a minimum number of modules. A larger company with

more resources could chose components to optimize the AA process for the chemical, product, or process under review.

Some modules may be more complex than others. This added complexity is due to the emphasis the Team placed on each particular topic and the perceived importance the module has to the overall AA process. 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 suits 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 not all portions of the Guide may be used at any given time and no AA is expected to encompass all the modules and frameworks included.

The Golden Rule and Principles

Based on the goals and objectives of the Guide, the Team developed 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 option(s).
- **Transparency:** All assumptions, data sources, data quality, decisions, etc., should be documented and explained. For example, decision methods require establishing weighting criteria. The values selected for the relative weightings 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 remaining modules should be considered by the assessor if relevant to the particular chemical, product, or process under assessment.

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.

-
- **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 important trade-offs. Identify all opportunities for continuous improvement and set goals for meeting them, which may include a longer-term green chemistry design challenge.
 - **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 analytical requirements of the test method. As part of the data review, it's important to capture these uncertainties and factor them into the decision-making.

Identifying Chemicals of Concern

Identification of the chemicals of concern to be subjected to the AA process is outside the scope of this document and is assumed to occur before the AA process begins. Identification of chemicals of concern can be a long and involved process because of the technical and political issues associated with any decision. Chemicals of concern can be identified through:

- Legislative mandate.
- Regulation.
- Consumer concern.
- Business concerns including greening of product line and regulation avoidance.
- Corporate or government policies that address individual hazard properties of chemicals, such as carcinogenicity, mutagenicity or reproductive toxicity, or combinations of hazard properties, such as persistence with bioaccumulation potential and/or toxicity (PBT).
- Other.

This is only a partial list of the possible ways to identify a chemical of concern. The exact process, however used, occurs prior to implementation of the Guide.

Responsible Parties

There is no fixed requirement regarding who should conduct the AA. The responsible entity may vary depending on the chemical, product, or process being evaluated. Ultimately, the manufacturer or importer is responsible for their products and the AA process to assess if the chemicals used have the lowest potential impact upon human health and the environment. Other parties may be interested in assessing a particular chemical, product, or process and subjecting it to the AA process. Interested parties could include:

- The manufacturer, processor, or importer
- A consortium
- An independent group
- An industry/government partnership
- A government entity
- Other

How to Implement the Guide

This section provides an overview of the eleven modules included in the Guide and identifies three possible frameworks that can be used. Each framework is described in greater detail in [Frameworks Module](#). Any framework may be used as long as the decision-making is transparent and well documented, and the hazard is emphasized. Regardless of which framework is used, the AA objectives must be met – to replace chemicals of concern used in products or processes with safer alternatives.

The Guide allows the results from the assessment modules to be combined in a flexible manner to meet the needs of a wide range of users, products, and processes. The actual selection of modules used, their arrangement, and how decisions are made are left to the assessor; however, minimum expectations and recommendations are included. As with all AAs, documentation, transparency of decisions made, and the evaluation results are fundamental to completion of a valid AA.

Recommended Implementation of the Guide

An AA consists of five distinct steps ([Figure 1](#)):

1. Identify Chemicals of Concern
2. Initial Evaluation
3. Scoping
4. Identification of Alternatives
5. Evaluate Alternatives

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, the chemical identification process is outside the scope of this document. The Guide assumes that the chemical, product, or process of concern has already been established.

2. Initial Evaluation

The Initial Evaluation Module asks the question ‘Is an AA necessary?’ and helps the assessor determine whether or not the chemical of concern is truly needed in the product or process. If it is possible to eliminate the chemical of concern without substitution and maintain the function of the product, an AA is not necessary. The assessor documents the information used to reach the conclusion and eliminates the chemical from the product. If, however, the Initial Evaluation indicates that an AA is necessary, the assessor proceeds to the next step.

3. Scoping

Once an AA is deemed necessary, the assessor identifies whether stakeholder involvement would improve the process and, if so, to what degree (level) stakeholders will be involved. The assessor also determines which of the three frameworks is appropriate for the chemical, product, or process under review.

Stakeholder Involvement Module:

The Stakeholder Involvement Module ensures that stakeholders are considered 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 optimized outcomes including greater buy-in and less opposition to change.

Frameworks Module:

The Frameworks Module guides practitioners in how to use the results from the other AA modules to identify the best alternatives to chemicals of concern in products or processes of concern that are feasible and meet the needs of the organization. Three distinct frameworks to decision-making are presented. The module explains how they can be used and the strengths and weaknesses of each method.

The assessor determines which of the three frameworks will be appropriate for the AA:

Sequential Framework:

In the Sequential Framework ([Figure 2](#)), the modules selected are evaluated in a linear order. Only those alternatives identified as most favorable continue on for evaluation.

The Sequential Framework identifies which modules are recommended for an adequate assessment, along with a proposed order for their implementation. More details are available in the [Frameworks](#) Module.

Simultaneous Framework:

In the Simultaneous framework ([Figure 3](#)), data are collected on all potential alternatives for each of the selected modules. Once the data are collected, the potential alternatives are compared simultaneously using one of three decision methodologies. More details are available in the Frameworks Module.

Hybrid Framework:

In the Hybrid Framework ([Figure 4](#)), both the Sequential and Simultaneous Frameworks are used. Potential alternatives are first screened through a limited number of modules

using the Sequential Framework. The remaining pool of alternatives is then compared using the Simultaneous Framework. More details are available in the Frameworks Module.

4. Identification of Alternatives

Once the AA has been scoped, the [Identification of Alternatives Module](#) helps the assessor identify the universe of potential alternatives to be considered during the AA process. Alternatives may include chemical substitutions, alternative materials, or product redesign eliminating the need for a chemical. At this point, the widest range of possible alternatives should be researched, including emerging technologies.

If there are many potential alternatives, an initial screen using lower levels of the [Hazard Module](#) and the [Performance Evaluation Module](#) can help screen out less favorable alternatives saving time and resources. Otherwise, all of the alternatives identified in the Identification of Alternatives Module should undergo evaluation. The number of alternatives to evaluate will typically narrow through the process of evaluation, based on technical, economic, health and safety, and other considerations.

5. Evaluate Alternatives

The assessor has some flexibility in choosing the order in which to implement the assessment modules depending on the framework chosen. However, the goals of an AA must be met, which requires emphasizing the hazard. For most applications, an adequate AA should include the Hazard, Performance Evaluation, Cost and Availability, and Exposure Assessment modules *in that order*.

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. These most favorable alternatives proceed to further evaluation.

Performance Evaluation Module:

[The Performance Module](#) helps the assessor ensure that the alternatives considered are technically feasible for the desired application and that the product meets 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 price competitive and available in sufficient quantity to meet

manufacturing needs. Any alternative that is not found both in sufficient amounts and at an adequate price should be identified as a less favorable alternative. The Cost and Availability Module also helps the assessor identify life cycle costs, i.e., costs that are transferred from one phase to another in the product life cycle.

Exposure Assessment Module:

The [Exposure Assessment Module](#) evaluates potential exposure scenarios and determines whether the alternative poses 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.

At this point, the assessor should also identify which, if any, of the optional assessment modules to include in the AA. Selection of optional modules is left to the assessor although these decisions need to be documented and transparent. The three optional modules include:

Materials Management Module:

The [Materials Management Module](#) evaluates how a potential alternative will impact natural resources and generate both hazardous and non-hazardous waste. Designing products for material recovery and/or benign release into the environment can lead to systemic solutions. This module emphasizes alternatives that can further the concept of '[Cradle-to-Cradle](#)' design.

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 to workers, communities, and societies involved in its manufacture, transport, use, and disposal.

Life Cycle Module:

The [Life Cycle Module](#) provides additional information to decision makers on issues, topics, and impacts not addressed in other modules. The Life Cycle Module is used after the Performance Evaluation, Hazard, Cost and Availability, and Exposure Assessment modules to gather relevant information about the entire product life cycle. The use of life cycle thinking can support selection of alternatives and help avoid the shifting of impacts across the life cycle. It also helps the assessor to consider ways to mitigate negative impacts in order to improve the life cycle profile of an alternative.

Once the selected framework has been decided and the modules applied, the result identifies one or more favorable alternatives. If multiple favorable alternatives are identified, selection of which alternative to employ is left to the assessor. Evaluation of additional module levels or consideration of corporate drivers and principles may help in the final selection.

If, however, no favorable alternative remains, it may be necessary to return to previous decision points and evaluate alternatives that were binned as less favorable. For example after completing a Sequential Decision AA, all of the Benchmark 4 (most favorable) alternatives were eliminated from consideration. In this instance, it may be appropriate to return and evaluate all Benchmark 3 (next most favorable) alternatives. [See the Sequential Framework for more details on this issue.](#)

Figure 1: Five AA Steps

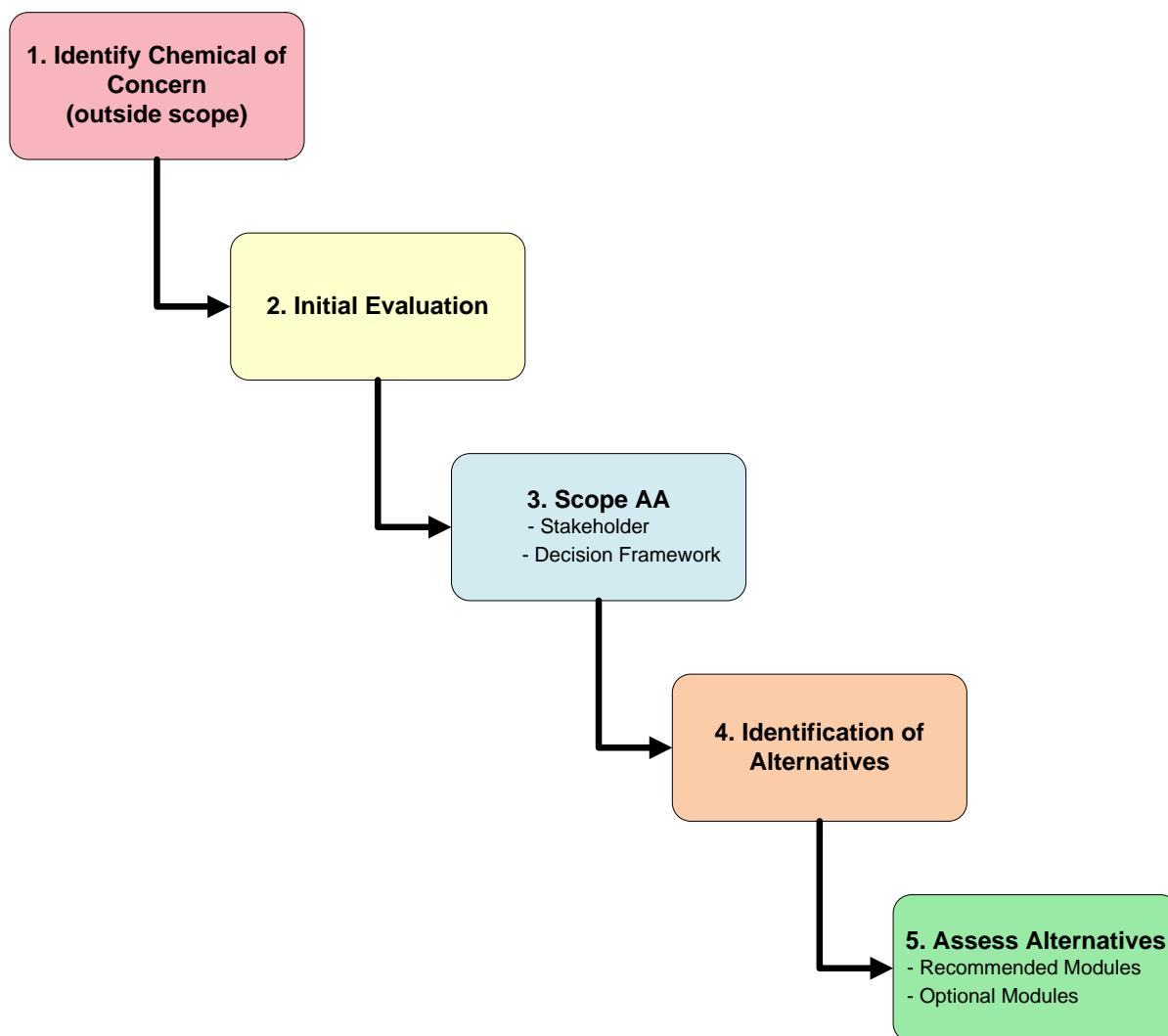
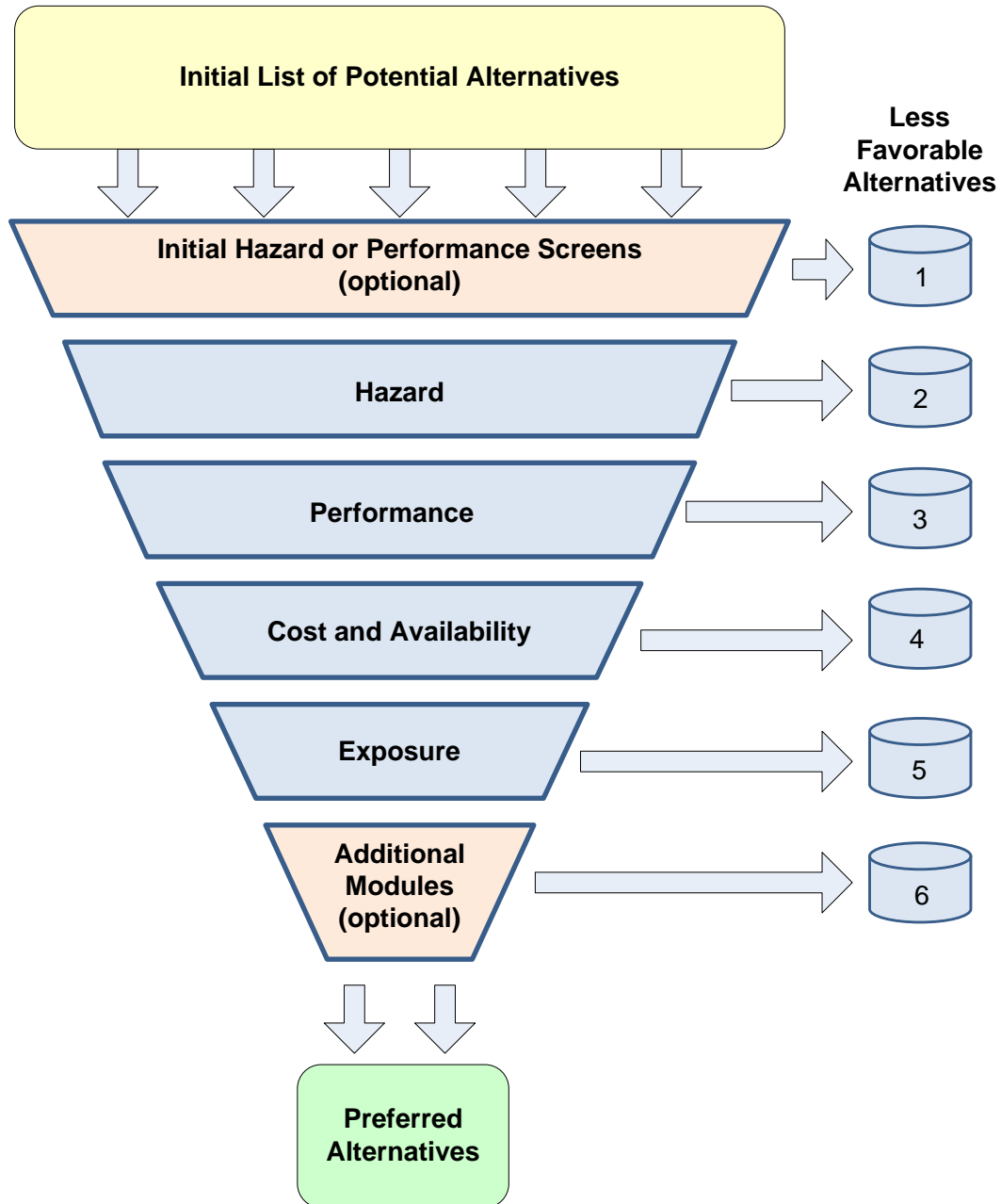


Figure 2: Sequential Framework



If no preferred alternatives are identified following implementation of the selected modules, the assessor may re-evaluate alternatives identified as less favorable, first from bin #6, then bin #5, then bin #4, etc. Potential alternatives determined to be as hazardous as the original chemical of concern should be considered only as a last resort. Chemicals more hazardous than the chemical of concern should never be selected as a potential alternative.

Figure 3: Simultaneous Framework

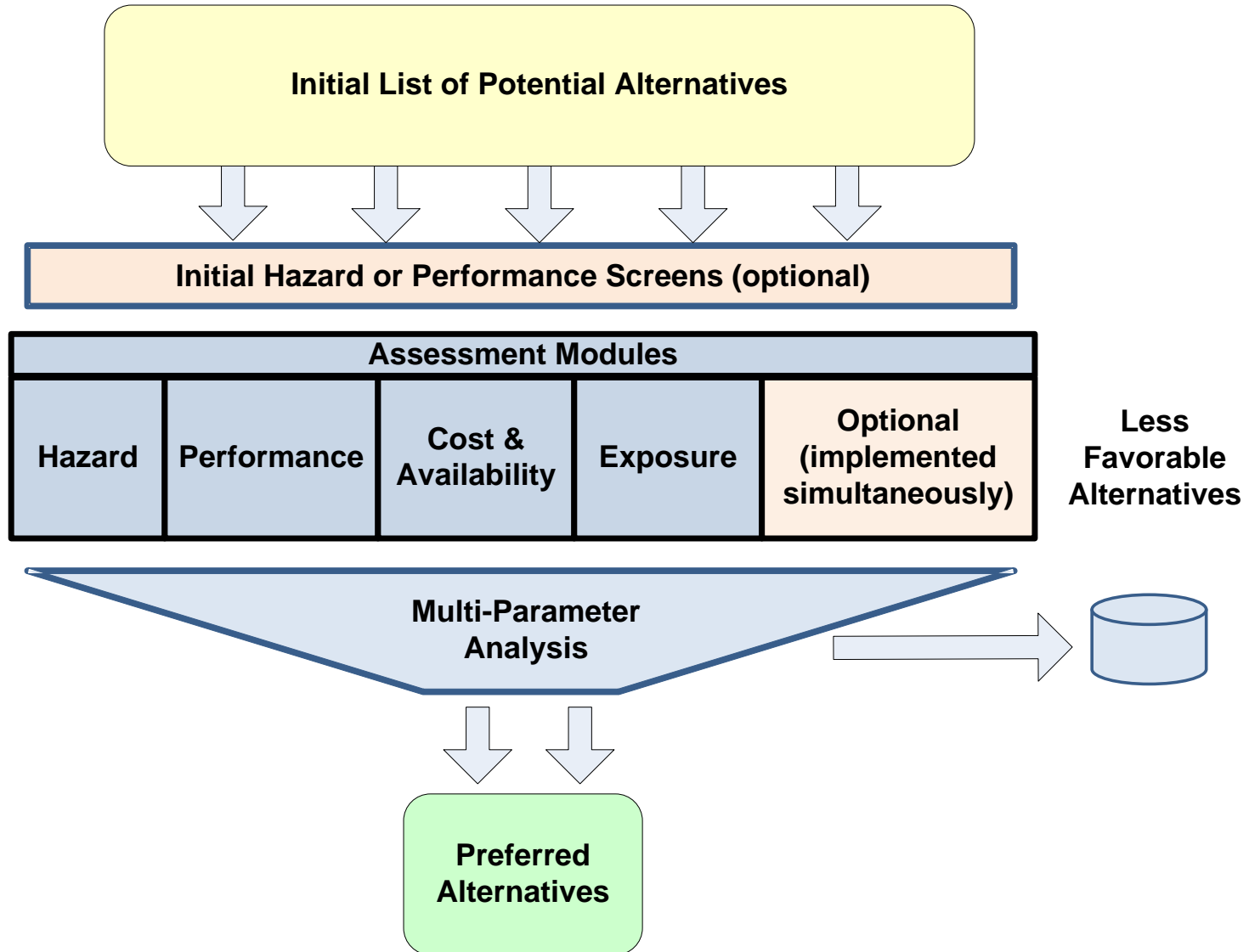
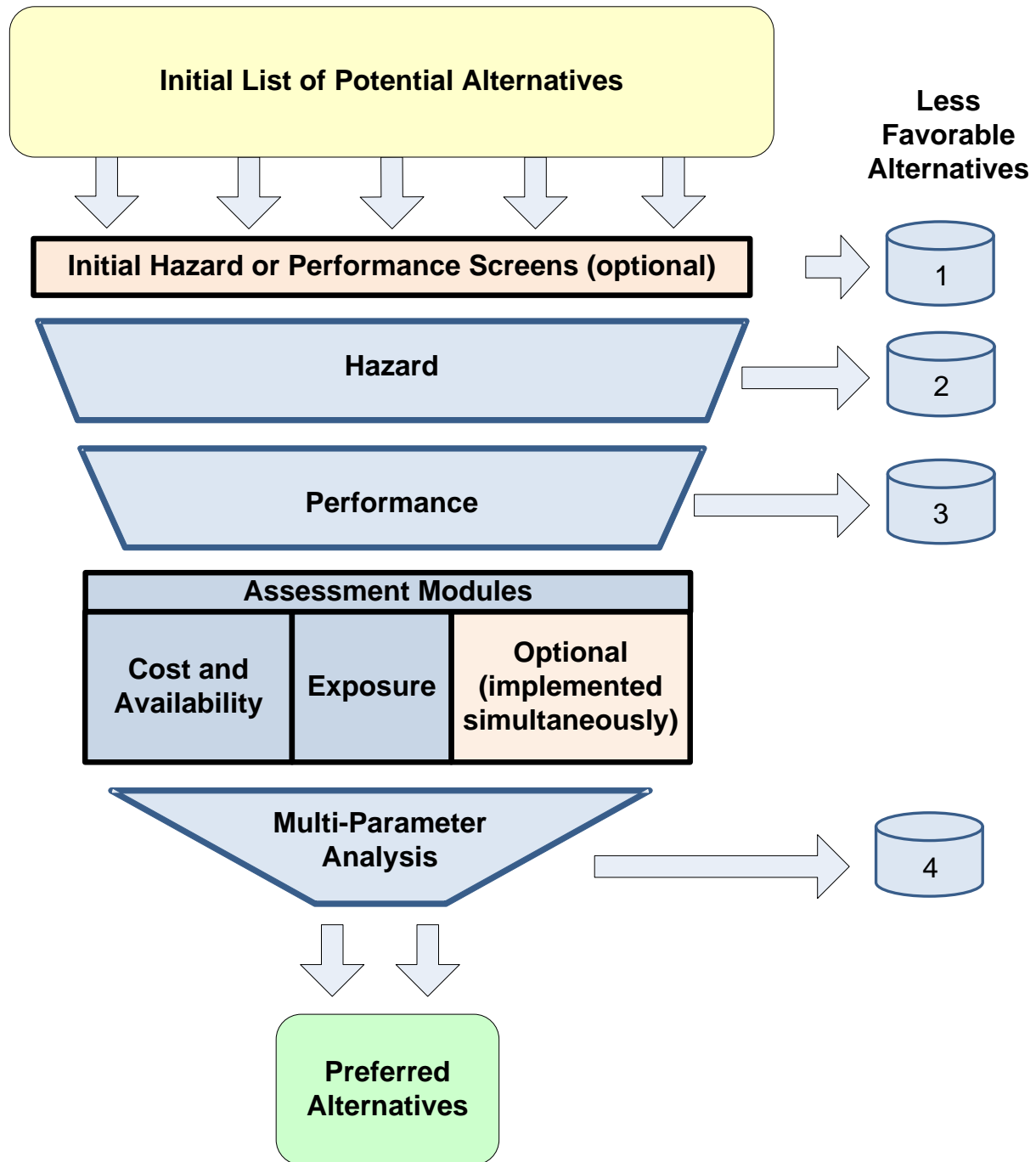


Figure 4: Hybrid Framework



If no preferred alternatives are identified following implementation of the selected modules, the assessor may re-evaluate alternatives identified as unfavorable from bin #4. Potential alternatives determined to be as or more hazardous than the original chemical of concern should only be considered as a last resort.

AA Examples and Approaches

Several publicly available AAs were completed recently using a variety of approaches and different degrees of complexity. This section presents examples of AAs that meet minimum recommendations while showcasing the variety of approaches. This list is not intended to be an exhaustive representation of all the AAs conducted recently; however, several examples were intentionally omitted because they did not meet minimum expectations. For example, two AAs either conducted by or presented to the Maine Department of Environmental Protection (DEP) can be found on the list. Other AAs presented to Maine DEP, however, were found to be deficient and were not included.

The list begins with the most recent AA examples and ends with some of the earliest. 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.

[EPA Design for the Environment Partnership Program](#)

EPA's Design for the Environment (DfE) Program developed the science and general processes used to conduct an AA. DfE has been conducting AAs over the last ten years and is currently working on several assessments. Draft AAs on the use of the chemical [bisphenol A](#) in cash register receipts and the flame retardant [decabromodiphenyl ether](#) (Deca-BDE) were recently published and DfE is working on several others including AAs of the flame retardant [hexabromocyclododecane](#) (HBCD) and [phthalates plasticizers](#) in plastics. DfE's method emphasizes chemical hazard assessment of alternatives, includes an extensive stakeholder process, and recognizes the need to consider performance, cost, and exposure.

Although DfE has conducted several assessments, its [methodology](#) and level of technical review are beyond the capacity of most companies except for the very largest who have dedicated resources and expertise. DfE AAs, however, should be evaluated for the overall technique involved with the realization that such in-depth evaluations may be beyond most users.

[Green Chemistry and Commerce Council Assessment of Phthalates](#)

In 2013, the Green Chemistry and Commerce Council (GC3) issued the results of a project to investigate alternatives to [phthalates](#) used as plasticizers in wire and cable applications. GC3 released chemical hazard assessments of nine phthalate plasticizers. It decided, however, not to pursue performance and cost assessments of the alternative plasticizers. In lieu of a performance assessment, the group compiled links to technical specifications and

performance information for the plasticizers evaluated as provided by plasticizer manufacturers.

[Techlaw Alternatives Analysis Report for Bisphenol-A in Infant Formula Cans and Baby Food Jar Lids](#)

In 2012, Techlaw provided an AA to the Maine Department of Environmental Protection on the use of the chemical bisphenol A in formula cans and lids for jars containing baby food. The assessment emphasized the importance of chemical hazard assessments and considered performance, cost, and exposure potential.

[Deca-BDE in Plastic Pallets, Pure Strategies, Inc.](#)

In 2011, Pure Strategies conducted an AA for the Maine DEP on the flame retardant decabromodiphenyl ether (Deca-BDE) in plastic pallets. In examining potential alternatives, the assessment conducted a detailed analysis of the 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. The production of such a compound using either alternative was found to be less costly or comparable to Deca-BDE. In addition, the assessment identified traditional wood pallets that did 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 working together on chemical issues, released an AA framework in the document 'BizNGO Chemical Alternatives Assessment Protocol.' 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. The alternatives replacing Deca-BDE were used at about the same concentration and resulted in the same potential routes

of exposure. It was assumed there were no substantive exposure differences between Deca-BDE and the alternatives.

Five Chemicals Alternatives Assessment Study, Toxics Use Reduction Institute

In 2006, at the direction of the Massachusetts' Legislature, the Toxics Use Reduction Institute (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 (DEHP). 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. An evaluation of hazard, performance, cost and availability, and exposure potential were an integral part of the assessment.

Initial Evaluation Module

The Initial Evaluation Module determines whether or not an AA is needed for a product or process containing a chemical of concern. If a product may be phased out or if a chemical of concern can be eliminated from a product, an AA may not be needed.

Before investing resources to conduct an AA, businesses should consider the reasons a chemical of concern is used in a product or process.

- Can the product or process containing a chemical of concern be phased out?
- Does the chemical of concern perform a necessary function?
- Is the presence of a chemical of concern required for regulatory purposes?

Some products or processes containing chemicals of concern may meet regulatory requirements while in other cases, the chemicals are redundant in a business' portfolio or are ready to be phased out or redesigned. Likewise, for a variety of reasons, some chemicals of concern are present in products for historical reasons and without serving a useful purpose. For example, recycled materials may contain residual chemicals of concern required by local, state, federal or international regulatory requirements. If a chemical of concern can be simply eliminated without affecting product performance, an AA can be avoided and resources saved.

Initial Evaluation Process

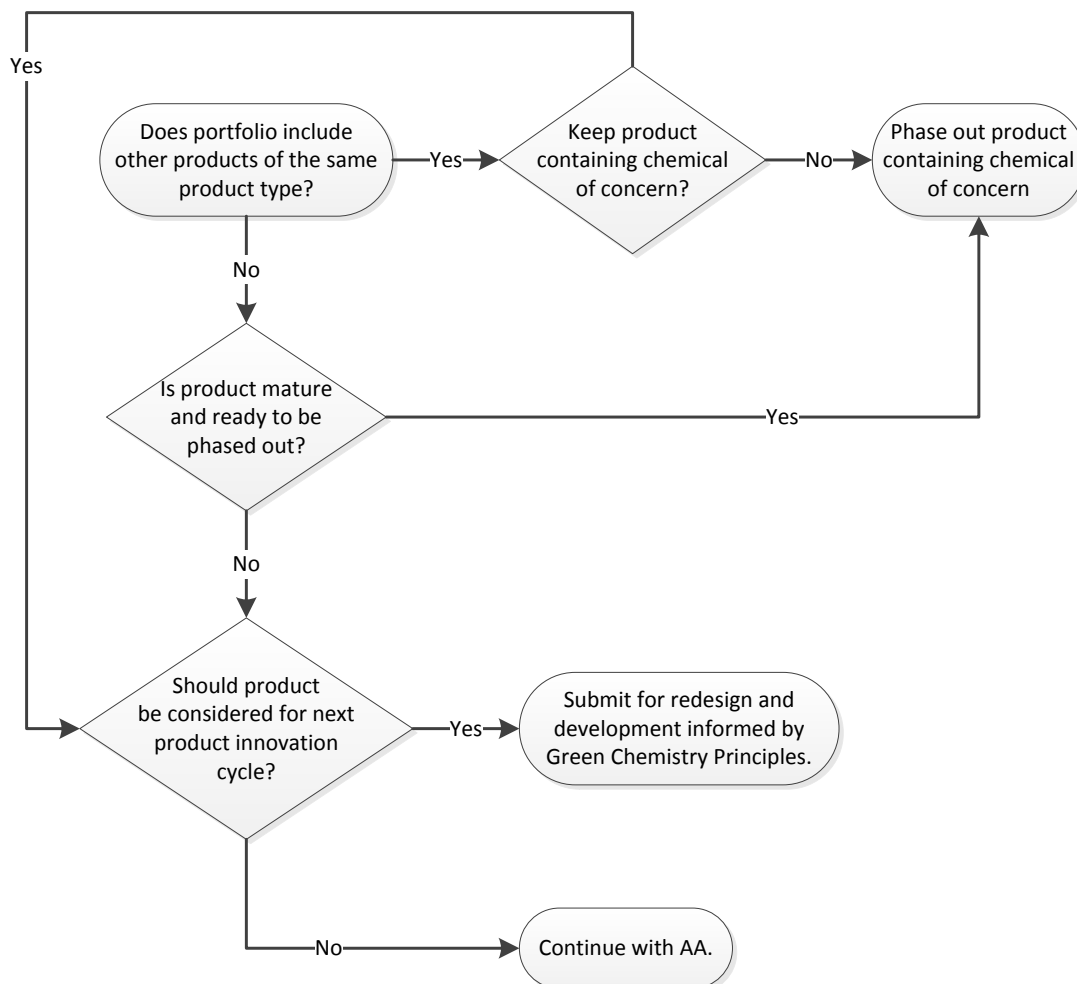
Consider phasing out a product containing a chemical of concern

It may be desirable to phase-out a product containing a chemical of concern and in the process, eliminate the need for an AA. Questions to consider include:

1. Does your business portfolio include other products that cover the same product type?
 - A. If yes, do you still want to keep the product containing a chemical of concern?
 - If yes, continue AA.
 - If no, document decision and phase-out the product containing the chemical of concern.
 - B. If no, continue AA.
2. Has the product containing the chemical of concern reached maturity and should it be considered for sunset?
 - A. If yes, sunset the product. Document the decision. No AA is necessary.
 - B. If no, continue AA.

3. Should the product be considered for the next product innovation cycle?
 - A. If yes, submit the product for redesign and development informed by [Green Chemistry Principles](#). Redesign goes beyond an AA. Rather than eliminating a chemical of concern with a safer alternative, redesign considers all aspects of a product.
 - B. If no, continue AA

Figure 5: Decision Logic for Deciding to Phase-out a Product Containing a Chemical of Concern



Consider Why a Product Contains a Chemical of Concern

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 no longer serve a useful purpose in a product or process. For example, they may be a by-product or impurity of another ingredient, or they may be historical artifacts. It is important to understand why a

chemical of concern is present in a product. If the chemical can be eliminated without affecting the product's performance, a business can avoid the AA and its associated costs.

To begin this assessment, 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?

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 (PCBs) can be created in the process of manufacturing pigments and dyes. It may be a naturally occurring impurity. For example, lead is often found in zinc. Finally, it may be a contaminant. Lead can contaminate water traveling through lead pipes.

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 generating the by-product affect product performance?
 - If no, document the decision and eliminate the chemical. No AA is necessary.
 - If yes, continue AA.
 - B. Are other chemical sources available without the by-product, impurity, or contaminant?

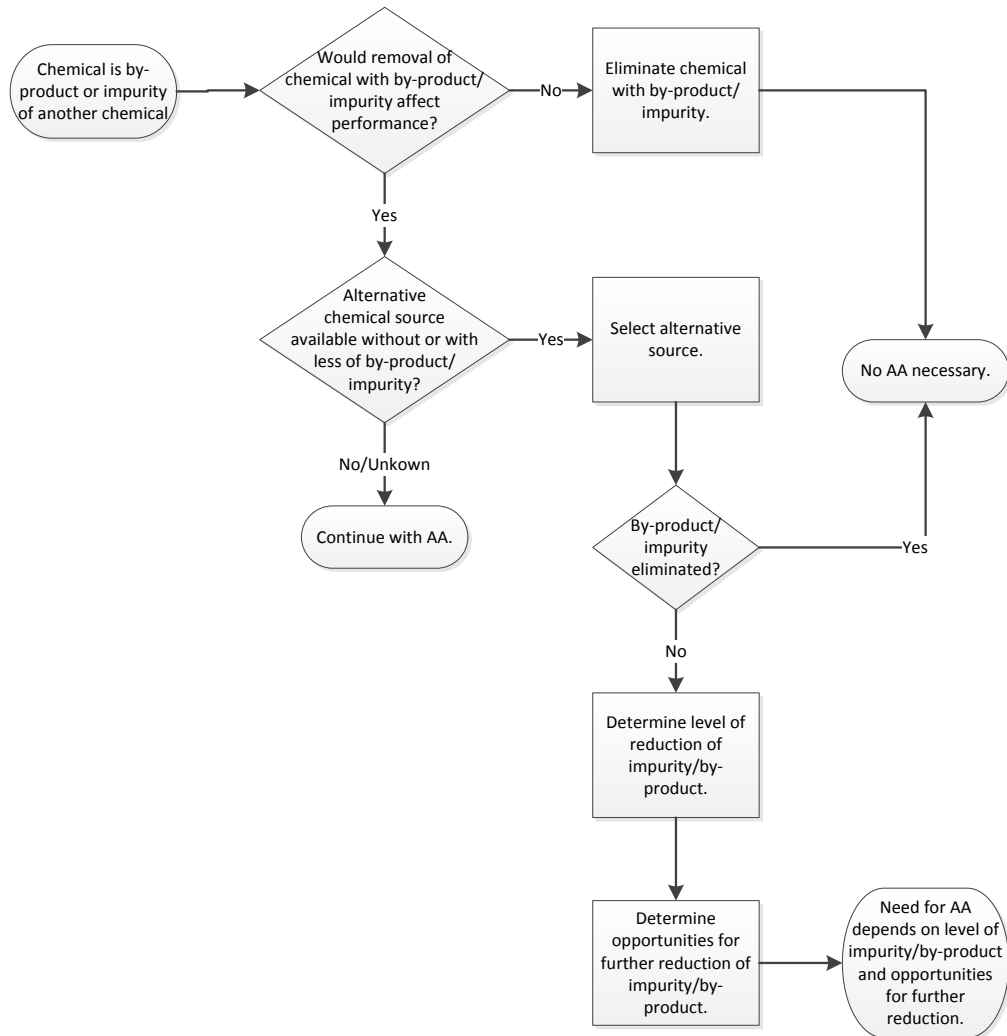
Example 1: Caustic soda produced in a mercury cell process may contain traces of mercury. Caustic soda produced with an alternative process will not contain mercury.

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 and 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 AA.

Figure 6: Unintentionally Added Chemicals



Intentionally added chemicals of concern

1. Is the chemical added to meet regulatory requirements?
 - A. 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 this use of chemical of concern the ONLY method that meets regulatory requirement?

-
- Does the regulation specifically prohibit the use of an alternative chemical?
 - If yes to all of the questions above, document information used to reach the conclusion and identify an AA cannot be performed.
 - If no to ANY of the above questions, conduct an AA on the chemical of concern.

Example: A manufacturer of medical radiation screening equipment may have regulatory requirements to provide radiation protection. Lead may be the only substance that can be used and other alternatives or methods may not meet this regulatory requirement. An AA may still be done in this specific application to determine if a better alternative exists. The information used to reach this decision is documented and provided as justification.

Example: Decabromodiphenyl ether (Deca-BDE) is one of the alternatives used to meet regulatory flame retardant requirements in furniture. However, several other chemical and non-chemical methods also meet this requirement. An AA is necessary to determine which of the regulatorily required alternatives has the lowest impact upon human health and the environment.

- B. 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 AA process.
- 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 AA.
- 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 AA to see if the chemical can be eliminated completely.
- If no, continue AA.
- Is it likely that an alternative might be used in place of the toxic chemical?

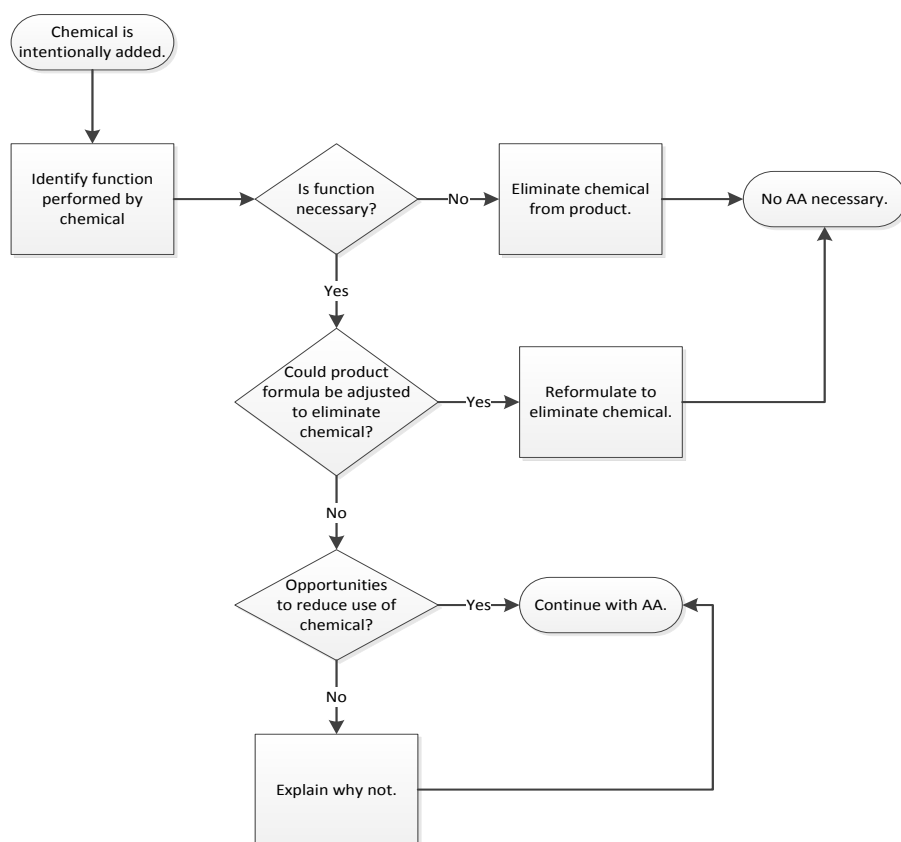
- If no, explain why no alternative is thought to exist. Document information used to reach the conclusion and identify that the AA is complete.

Example: There may be no viable alternative to lead in radioactive shielding.

- If yes, continue 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 7: Intentionally Added Chemicals



Tools

- Material declarations may be requested from suppliers by manufacturers.
- Material Safety Data Sheets.
- [CleanGredients](#)
- [European Union Substitution Portal](#)
- [Innovadex](#), the Search Engine for Product Innovators

Stakeholder Involvement Module

This module ensures stakeholders are considered in the AA process. It provides information so concerned parties can understand what decisions are being made, why these specific decisions were made, and can provide input into that process.

Engaging stakeholders takes time and resources, but can also provide enduring rewards. Stakeholder engagement helps refine proposed initiatives to accomplish goals in ways that satisfy key stakeholder groups. While stakeholder groups may share a desired outcome, groups may have different and often opposing positions and it is often challenging to identify a result that meets the needs of all. In those instances, a solution may be reached that is acceptable to all even though all needs are not fully met. By engaging stakeholders in problem solving about both the “what” and the “how” of various solutions, the discussions can be dynamic and the outcome can be optimized. Stakeholder engagement can lead to greater buy-in and less opposition to change.

An important aspect of stakeholder involvement is transparency in the decision-making process. Even if agreement is not possible, transparency enables all parties to understand how the decision was reached.

This module is structured such that stakeholder involvement increases from an initial screen through three subsequent levels. Depending upon stakeholder response, it may be necessary to solicit input from specific stakeholders or new stakeholders may be identified during the AA development process. The process should remain flexible to allow changes as additional input is identified. An effort should be made to identify all relevant stakeholders.

The initial screen identifies which stakeholders are important to the chemical, product, or process under review. Beyond the initial screen, stakeholder involvement is separated into three distinct levels with increasing amount of stakeholder involvement.

- **Level 1** is primarily an internal corporate exercise run by the decision maker. Stakeholder input is limited to providing specific information when requested.
- **Level 2** increases the amount of stakeholder involvement and provides a structure around which stakeholders will be involved.
- **Level 3** establishes a structure where stakeholders are involved in AA decision-making processes.

For Levels 2 and 3, all stakeholders should be provided the opportunity to be involved in various aspects of the AA. Stakeholders will determine how much involvement is desired from their perspective and no attempt will be made to limit stakeholder involvement externally. The structure of the stakeholder module is summarized in Table 1.

Table 1: Stakeholder Levels

Initial Screen	<i>Identification of pertinent stakeholders:</i> Identifies pertinent stakeholders and those likely to be interested in and important to the proposed AA.
Level 1	<i>Internal exercise:</i> Identifies potential stakeholders, their concerns and how their concerns may be addressed in the AA. There is little external stakeholder involvement unless specific questions are posed where external input is required or recommended.
Level 2	<i>Formal stakeholder process:</i> Identifies potential stakeholders and seeks their input in a formal and structured process. Pertinent AA information is provided for stakeholder review and comment. All comments are collected and responded to.
Level 3	<i>Open stakeholder process:</i> Identifies potential stakeholders invited to participate in all aspects of AA process. Involvement includes all aspects from scoping, development, participation in formal committees (steering, advisory, technical, etc.), and review of final product.

One stakeholder group should not be allowed to assume a dominant role and bias the results in a particular direction. If this should occur, those conducting the AA should take steps to involve other stakeholders or to set boundaries to limit input from the single stakeholder sector.

Other forms of stakeholder input exist outside the structure provided in this module. [Appendix A](#), for example, describes a business model where stakeholders are the driving force behind a company's structure, commonly referred to as a Certified B Corporation (B Corp). Stakeholder involvement in a B Corp may exceed stakeholder requirements in this module but may be a valid alternative to include in an AA. If these more comprehensive plans are used, the assessor should explain how the stakeholder process selected exceeds the requirements of this module.

This module provides a flexible framework that allows stakeholder input to add weight, positive or negative, to the selection of an alternative. Expected users include small, medium, and large businesses, regulatory agencies, non-governmental organizations, etc.

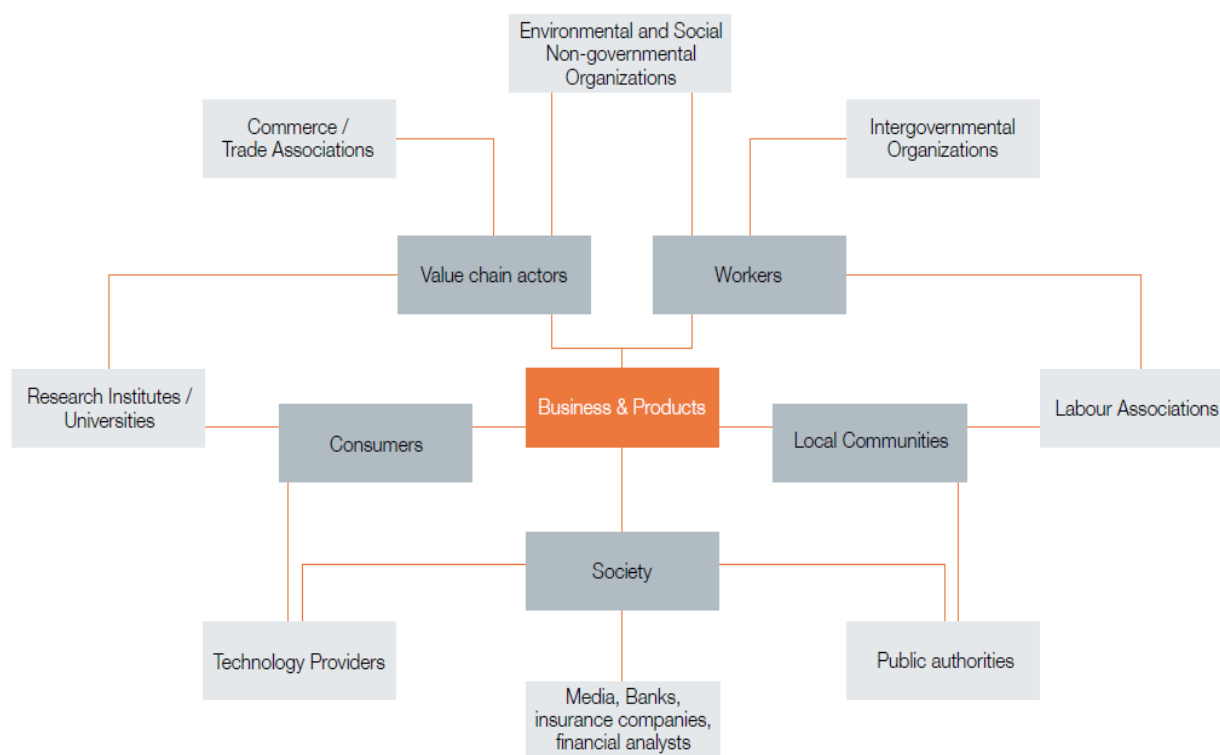
Regardless of the level, all decision or assumptions should be identified. Any assumptions made should be clearly described and documented in the final assessment report.

Stakeholder Involvement Screen

Initial Screening Process

The initial screening process identifies potential stakeholders pertinent to the chemical, product or process being evaluated. Identification of stakeholders can be a difficult process, and the list of stakeholders should remain open to additions, deletions, and other relevant changes. Figure 8 is a generally accepted illustration of company – stakeholder relationships and can help identify potential stakeholders.

Figure 8: [Hub and Spoke Stakeholder Diagram](#)



There are other ways in which stakeholders can be identified, including:

- Considering full life cycle of the chemical of concern and selecting those stakeholders most intimately involved.
- Choosing a potential alternative and identifying those stakeholders most concerned with its function.

If you consider the full life cycle of a chemical of concern, a list of potential stakeholders could include those associated with manufacturing, transport, storage, and product use and disposal. Using this framework, potential stakeholders include:

Potential Stakeholders	
1. Company representatives	Company owner
	Board of Directors
	Stockholders
	Other Management
	Employees/workers
2. Technical Experts	Testing
	Performance
	Process
	Materials
	Product
	Consumer marketing
3. Supply Chain	Tier 1
	Tier 2
4. Customers	Suppliers
	Retailers
	End user
	Recyclers
5. Interest Groups/Concerned Non Government Organizations (NGOs)	Environmental groups
	Environmental Justice representatives
	Stakeholders affected by life cycle impacts (e.g., conflict minerals); (this starts to get to environmental justice issues)
6. Local Community	Local politicians
	Community leaders
	Native Nation representatives (if applicable)
7. Other Governmental Representatives	Federal
	State
	International
8. Other stakeholders unique to your assessment that should be considered?	

During the initial screening, questions that can help identify appropriate stakeholders include:

- Who are the most influential stakeholders within your organization?
- Who are the most influential stakeholders external to your organization?
- Which stakeholders are not typically considered and are they relevant to your business operations and to the products or process with chemicals of concern?

-
- At what point in the AA process is specific stakeholder input particularly relevant?
For example, technical experts are needed during performance evaluation.

Using this process, potentially interested or concerned stakeholders are identified. The list should be maintained and revisited periodically to determine if new stakeholders have been identified or if input from specific stakeholders is crucial during a specific phase of the AA process.

Stakeholder Involvement Levels

Level 1: Potential Stakeholder Identification and Limited Data Collection

This level conducts an internal evaluation of how stakeholders might be affected by the chemical of concern and potential alternatives. Potential stakeholder concerns should be identified and factored into the AA. Using the list of potential stakeholders developed in the initial screen, potential stakeholder concerns should be evaluated to determine if they might have an impact on the final decision. Seeking input from specific stakeholders is not necessary although some limited discussions between the assessors and potential stakeholders may be desirable. The approach used will depend upon the level of knowledge and expertise of the individuals assessing the chemical, product, or process. The important point is that stakeholders would typically have minimal involvement in this process although their potential concerns would be considered.

During this assessment process, the follow questions/steps should be addressed/taken:

1. Identify potential stakeholders who might be interested and concerned with the chemical, product or process being considered.
2. Identify potential stakeholder concerns.
 - Are limited discussions with potential stakeholders warranted to clarify concerns?
 - If yes, contact stakeholders, obtain input and continue evaluation.
 - If no, continue evaluation.

-
3. Can the concerns identified be addressed or mitigated?
 - If yes, list actions that can be taken to address these concerns. Document how these actions will eliminate or mitigate the concern. Continue evaluation.
 - If no, document the conclusions reached and the information used to reach the conclusion. Continue evaluation.
 4. Incorporate stakeholder concerns into the decision-making process. Document how this has been done. Continue evaluation.
 5. Are any identified concerns serious enough to identify the alternative as unfavorable?
 - Document the information has been used to reach the conclusion. Evaluation complete.

Level 2: Solicit Information from Stakeholders

This level seeks limited input on how stakeholders are affected by the chemical of concern and potential 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. Pertinent stakeholders should be approached to understand their perspectives and to consider those perspectives in the evaluation of alternatives.

Some stakeholders may be useful sources of information and data for the evaluation of alternatives. For example, customers may be important stakeholders as their needs and preferences may be important in the quality of the final product.

Using potential stakeholders developed in the initial screen, identify the approach to solicit input from different groups of stakeholders. Focus groups may be useful when dealing with customers, technical meetings with suppliers, strategy sessions with company management and employees, etc.

1. Identify potential stakeholders who might be interested and concerned with the chemical, product, or process being considered.
 - Contact potential stakeholders to confirm their interest. Continue evaluation.
2. Identify potential concerns of stakeholders.
 - Have those concerns been validated for the chemical, product, or process under evaluation?
 - If yes, continue the evaluation.

-
- If no, document the decision reached and the information used to reach the conclusion. Continue evaluation.
3. 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.
 - If no, document the decision reached and the information used to reach the conclusion. Continue evaluation.
 4. Incorporate stakeholder concerns into the decision-making process. Document how this has been done. Continue evaluation.
 5. Are the concerns identified serious enough to identify the alternative as unfavorable?
 - 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. Evaluation complete.
 - If no, document the reasons for failure to accept stakeholder input and make it available to stakeholders. Evaluation complete.
 - If no, continue evaluation.

Case Example

AA Guide: During the development of this Guide, stakeholders were not involved in the development of the Guide, but their input was actively sought and when possible, incorporated into the final Guide. As the Team completed portions of the Guide, the results were posted for stakeholder review and comment. Team members reviewed the input and made changes to the document as warranted. All input was retained and, at the end of the development of the final Guide, all stakeholder input was incorporated in a response-to-comment document.

Level 3: Stakeholder Advisory Involvement

This level actively involves stakeholders as advisors during the AA process to determine how the chemical of concern and potential alternatives impact stakeholders. Stakeholders should be approached to participate in the AA process and their input actively sought. An advisory committee may be formed to provide advice during the development process. Stakeholder concerns should be identified and acknowledged in the final report. Those stakeholders pertinent to the AA should be approached to understand their perspectives and to consider those perspectives in the evaluation of alternatives.

Using the list of potential stakeholders developed in the initial screen, identify individual stakeholders to approach. When and how you involve the advisory committee may vary depending upon specific details of the AA. Advisory committees may be formed and their input solicited before the AA process begins as with the case of EPA's Design for the Environment Program. An advisory committee may be called together after much of the initial scoping work was done as in the case with Washington State's Chemical Action Plan process. Other options may also be possible and involvement of an advisory committee can be adapted to fit the unique qualities of specific AAs.

The following are questions that may be applicable to a specific AA:

1. What potential stakeholders might be interested and concerned with the chemical, product, or process being considered?
 - a. Have stakeholders been contacted and asked if this is of concern to them?
 - b. Have stakeholders been asked to serve on an advisory committee?
2. For the stakeholders identified, what are their potential concerns?
 - a. Have these concerns been brought to the advisory committee for comment and review?
 - b. Have these concerns been validated for the chemical, product, or process under evaluation?
3. Can the concerns identified be addressed or mitigated?
 - a. What actions can be taken to address these concerns?
 - b. How will these actions eliminate or mitigate the concern?
 - c. Have these actions been presented to the advisory committee for their review or comment?
4. Have the concerns identified been factored into your decision process?
 - a. How have these concerns affected your decision process?
 - b. Has the input from stakeholders affected your decision process? If so, how?
 - c. Have those changes been presented to advisory committee for their comment and review?
5. Are the concerns identified serious enough to eliminate the alternative from consideration?
 - a. What information has been used to reach the conclusion?
 - b. Have these decisions been offered to the advisory committee for review and comment?

Case Examples:

[Toxics Use Reduction Institute 5 Chemical Alternatives Assessment Study](#): In 2006, the Massachusetts Toxics Use Reduction Institute (TURI) instituted an evaluation of five chemicals: lead, formaldehyde, perchloroethylene (PCE), hexavalent chromium and, di(2-ethylhexyl)phthalate (DEHP). As part of the development process, TURI conducted extensive stakeholder review and input. Pertinent stakeholders were convened before the process began. This initial meeting was to ‘... *review the objectives of this project, share information about the proposed methodology and receive feedback...*’ Two subsequent, daylong stakeholder meetings were held to evaluate use and prioritize activities. In addition, stakeholders were provided a draft copy of the final evaluation and given the opportunity to review and comment before the document was finalized.

Washington State Chemical Action Plan: In 2006, the Washington State Department of Ecology (Ecology) published its [Persistent, Bioaccumulative and Toxic \(PBT\) rule](#). The rule established a process to evaluate PBTs and to provide recommendations on how to address the problems PBTs pose to human health and the environment. Ecology summarizes issues associated with a particular PBT in a Chemical Action Plan (CAP). The development of each CAP includes a stakeholder process. A stakeholder advisory committee is convened several times during the development process. Ecology requests input from the committee on specific issues and provides updates on progress. In addition, a draft CAP is released and any interested party is welcomed to review and provide input. All comments obtained are captured in a response-to-comment document and Ecology indicates how the input was or was not implemented, as appropriate.

Appendix A

U.S. EPA Design for the Environment Program Stakeholder Engagement

U.S. EPA’s [Design for the Environment Program](#) (DfE) includes an extensive stakeholder engagement process as an integral part of identifying and assessing alternatives for chemicals of concern. “Convening stakeholders” is the third step in DfE’s process, after determining the feasibility and collecting information on chemical alternatives.

DfE uses input from many perspectives to inform the project scope, identify alternatives, and facilitate manufacturer and user adoption of safer chemicals. Stakeholders are drawn from the entire supply chain and all life cycle stages of the chemical of concern. Involvement throughout the project helps to ensure that stakeholders contribute to, understand and support the outcome, enhance credibility, and promote adoption of the safer alternatives.

Typical stakeholders include:

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

Chemical and technology innovators are critical members of the group.

DfE begins an AA by convening all interested stakeholders in a face-to-face meeting where issues are discussed and scoping input is received from all interested parties. Once the scope has been clarified, stakeholder committees are formed to provide guidance to DfE. Stakeholder committees have included a Steering Committee, which helps oversee progress, a Technical Committee to provide information on potential alternatives, etc. Completed AA sections are released to stakeholders for review and comment.

Through literature review and discussion with stakeholders, DfE collects information about viability on a range of potential alternatives. The focus is on finding alternatives that are functional with minimum disruption to the manufacturing process. To identify the most likely alternatives, DfE may also include viability demonstrations by chemical and product manufacturers.

Evaluation of a robust set of hazard endpoints is central to the AA. Once the hazard assessment has been completed, DfE prepares a report containing the AA results to inform stakeholders, the public, and decision makers. The report provides contextual and supplemental information designed to aid in decision-making and may include descriptions of manufacturing processes, use patterns, and life cycle stages that may pose special exposure concerns. The report may contain a description of the cost of use and the potential economic impacts associated with alternative selection and may also contain information on alternative technologies that might result in safer chemicals, manufacturing processes, and practices.

Appendix B

[Benefit Corporations and Stakeholder Engagement](#)¹

Many forward-thinking corporations increasingly appreciate the competitive benefits of proactive stakeholder engagement, a systematic process of managing and identifying risk and the subsequent maximization of fresh business opportunities. Companies see these efforts as a natural expansion of a traditional market research and development (R&D) focus targeting customers, employees, shareholders, and regulators to a broader set of organizations that hold a stake in the company's operations: NGOs, academics, community groups, and shareholder activists.

In this context, stakeholders are bellwethers that help companies do the following:

- Anticipate and respond to problems before they reach crisis points that lead to loss of brand and shareholder value.
- Identify opportunities for growth, particularly in developing markets.

More proactive systems for integrating stakeholder feedback into operations help a company to grow in a sustainable way and to develop more enduring competitive advantages. With a strategic and systematic stakeholder engagement program, a company is better equipped to anticipate and respond to tomorrow's social and environmental problems and to avoid conflicts that can tarnish brands and hinder growth and ultimately, shareholder value. Additionally, a company is better positioned to leverage its stakeholder network to capitalize on market opportunities, such as launching a product in a new market or country.

Businesses that develop ways to solicit stakeholder input can achieve benefits such as increased buy-in for products and programs, increased opportunities for innovation and decreased risk from conflicts with affected stakeholder groups. Organizations may develop policies, practices and organizational structure to anticipate stakeholder needs and address them proactively.

An example of how to integrate stakeholder considerations into organizational structure is illustrated by the creation of the [Benefit Corporation](#) (B Corp) as a legal model for corporate structure. To qualify as a B Corp, a firm must have an explicit social or environmental mission and a legally binding fiduciary responsibility to take into account the interests of workers, the community, and the environment¹, as well as its shareholders. It must also publish independently verified reports on its social and environmental impact alongside its financial results. As of July 2013, nineteen states and the District of Columbia

¹ This section adapted from *Stakeholder Engagement: Lessons for Google* by Erik Wohlgemuth, May 9, 2006, accessed 7/2012.

in the United States have passed [legislation](#) allowing B Corp and eighteen more states have such legislation in process.

Example:

Patagonia is an example of a Certified B Corp company. As noted in an article on Patagonia published in the [Economist](#) on January 7, 2012, Patagonia '*...creates the legal framework for firms like his [the founder of Patagonia] to remain true to their social goals. To qualify as a B Corp, a firm must have an explicit social or environmental mission, and a legally binding fiduciary responsibility to take into account the interests of workers, the community and the environment as well as its shareholders. It must also publish independently verified reports on its social and environmental impact alongside its financial results. Other than that, it can go about business as usual.*'

Frameworks Module

Three possible frameworks for implementing the modules of the Guide are provided. While the three differ in approach, all achieve the objective of AA, i.e., identification of preferred 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 desired performance requirements.

The three frameworks (see [Table 2](#)) guide the assessor through the process of comparing large amounts of often conflicting data to select preferred alternative(s) to replace a chemical of concern. This list is not prioritized or comprehensive; it describes three commonly used approaches. Assessors should employ the approach that gives the most robust, dependable results with the available information and their available resources. Assessors can weight individual criteria within the context of the objective of an AA, particularly as described in this document.

Table 2: Frameworks

Framework	Description
1	Sequential: Modules are applied in a set order one at a time, with potential alternatives deemed unfavorable progressively “screened out.” Only most favorable alternatives proceed to the next module (Figure 9).
2	Simultaneous: Data from all modules are evaluated simultaneously for all potential alternatives. Once the data are collected, the potential alternatives are compared simultaneously using one of three decision methods (Figure 10).
3	Hybrid: Fundamental modules (minimally including Hazard and Performance Evaluation) are first performed sequentially, with unfavorable alternatives screened out. Data from remaining modules may be evaluated simultaneously (Figure 11).

Decisions Inherent within Modules

The three frameworks use information derived from the assessment modules. Each assessment module contains decision criteria that enable separation of the potential alternatives into “bins:” favorable, less favorable, or unfavorable for that specific module. Assessors will decide which modules to use and at what levels within each module. These decisions are left primarily to the assessor although the Guide does include minimum

recommendations. Decisions will vary among organizations about which framework to use and which modules to include. Selection will likely consider drivers both internal and external to the organization including:

- Corporate constraints – company-wide values and parameters regarding sustainability and the company’s available resources.
- Product requirements – regulatory standards, product claims, and brand identification, particularly as these factors relate to performance.
- Chemical policy ideals and requirements – e.g., safer, less toxic, more sustainable alternatives.

Given the three different framework and possible module combinations, different assessors may arrive at different conclusions. The AA process should not be used to justify the continued use of chemicals of concern but rather search for safer alternatives. In rare instances when no safer alternatives are available, exposure controls should be identified, along with a plan to continue searching for a safer alternative.

Decision Criteria and Trade-offs

The most important aspect of any AA, regardless of the selected framework, is transparency. The thought process used, including all assumptions and rationales, must be explicit so decisions made can be clearly understood by all readers. Most decisions incorporate the following steps:

1. *Define the issue* –What decision will be made based on the assessment?
2. *Identify the decision-making framework* – Which approach is best for the situation?
3. *Identify the decision criteria* – Which modules, at which levels, will be used? Note that four modules are recommended as a minimum.
4. *Collect information regarding the criteria* – both qualitative and quantitative data are useful for assessing the criteria. Sometimes data are not available or are unreliable, which makes comparisons more difficult. Data quality in each module is an important factor to consider in the final decision.
5. *Compare the alternatives to the original chemical of concern.* Note how criteria are weighted relative to each other in the comparison.

The comparison step can be straightforward when the alternatives and criteria are few and the data are clear. For example, if the AA process centers upon the replacement of one chemical with another and an alternative has been identified that meets all relevant criteria

(i.e., non-toxic, low cost, functions in both the manufacturing process and final product, low exposure, etc.), the decision may be simple. The comparison quickly becomes complex when comparing options with a range of pros and cons based on many criteria. For example, in California's AA process, the health criteria alone incorporates 19 endpoints. Determining which toxicological endpoint is more 'important' than another can be a difficult process.

A number of methods can be used to address complex decisions. Complex decisions can be broken down into more manageable decisions in which pairs of criteria are compared in a stepwise fashion. The criteria are aggregated and these groups of criteria are compared with each other. In some applications, large numbers of criteria are compared simultaneously in a multi-criteria analysis. The criteria values often need to be normalized to enhance comparison and the relative importance of each criterion and their relative weight need to be defined.

Typically, in comparisons of more than a very few simple criteria, some form of hierarchy among the relevant criteria is established. For example, the AA objective is to identify a "safer" alternative. "Safer" is defined as posing fewer hazards to human health and the environment. Criteria associated with health and ecological impacts are often the most important. This preference can be reflected in the comparison in different ways, depending on the complexity of the comparison and the quality of the data.

Initial screening methods typically begin by screening potential chemical substitutes and eliminating those that exhibit certain characteristics, such as chemicals that appear on lists of chemicals that are carcinogenic, mutagenic, or reproductive hazard. In this case, these hazard traits form the top of this criteria hierarchy. If the remaining candidates are then compared against persistent, bioaccumulative and toxic lists, those hazard traits form the next step of this hierarchy. Similarly, pairwise comparisons reveal the hierarchy of the criteria through the structure of the comparisons, and criteria groupings indicate which criteria are most important by inclusion in the group. Although the ranking of criteria can be inherent in the process, transparency requires an explicit understanding 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.

Figure 9: Implementation of the Sequential Framework

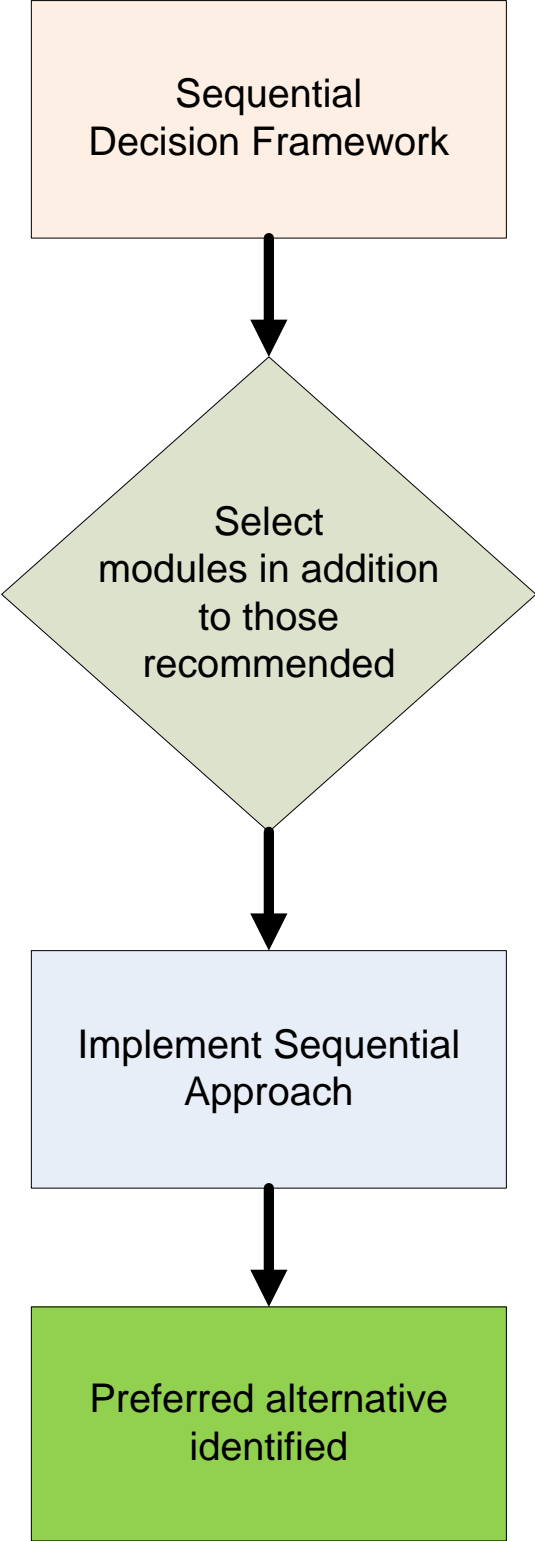


Figure 10: Implementation of the Simultaneous Framework

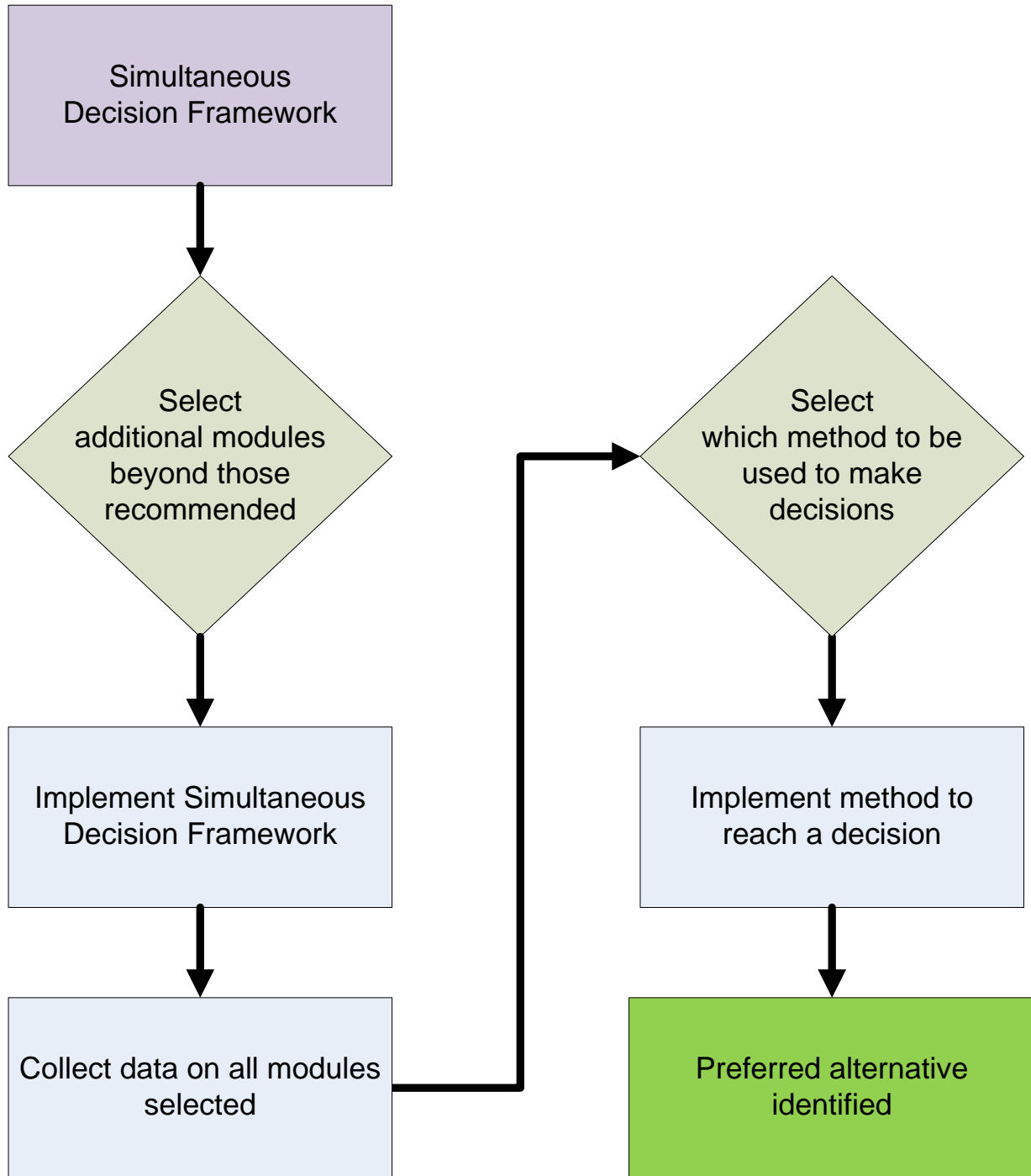
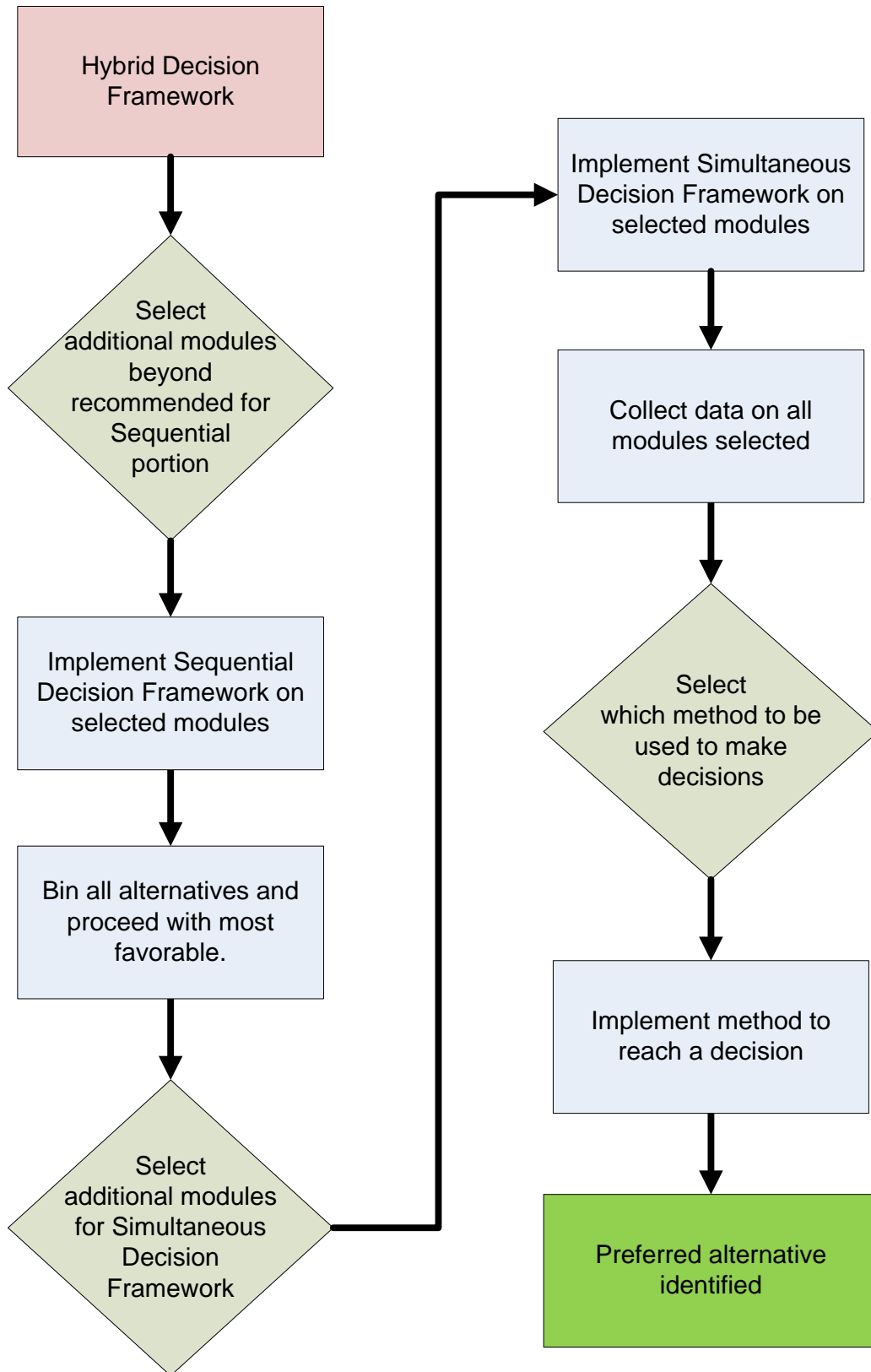


Figure 11: Implementation of the Hybrid Framework



Sequential Framework

If the Sequential Framework is selected, the AA should meet minimum recommendations. An initial screen may be conducted to bin those alternatives that have clearly been identified as having serious concerns and therefore, should be eliminated from further consideration. By removing alternatives that have clearly identified concerns, limited resources are conserved and potential favorable alternatives are prioritized for further evaluation. Several modules have an initial screen built in that may be used before initiating the AA. For example, the Hazard Module includes a screening method that compares alternatives against lists of toxic chemicals. More information on screening opportunities is found in each individual module.

None of the initial screens is adequate to meet minimum AA requirements; however, incremental improvement is fundamental to the AA process and these screening methods could also be used by small and medium businesses with limited resources and expertise to conduct some basic review. If used in this manner, businesses should understand that the decisions reached using these screening methods contain considerable risk of making a regrettable substitution. Hence, initial screens are not recommended in stand-alone AAs since they do not meet minimum AA requirements.

Minimum Recommendations

Minimum recommendations include using the lowest level of 4 modules including:

1. Hazard
2. Performance Evaluation
3. Cost and Availability
4. Exposure Assessment

Module order is important. The Hazard Module is implemented first. Alternatives with the lowest hazard assessment are identified and continue on through the assessment process. Those alternatives identified as unfavorable are binned and removed from further consideration unless subsequent modules eliminate all of the most favorable alternatives. If that occurs, it may be necessary to cycle back and review alternatives in less favorable bins. [More details are available in the Hazard Module.](#)

The most favorable alternatives are evaluated using the Performance Evaluation Module. A broad definition of performance is used to evaluate alternatives. This includes not only a simple evaluation of a one-to-one substitution but also of whether or not changes can be made to the product or process that allows the alternative to be used. [More information on this assessment is available in the Performance Evaluation Module.](#)

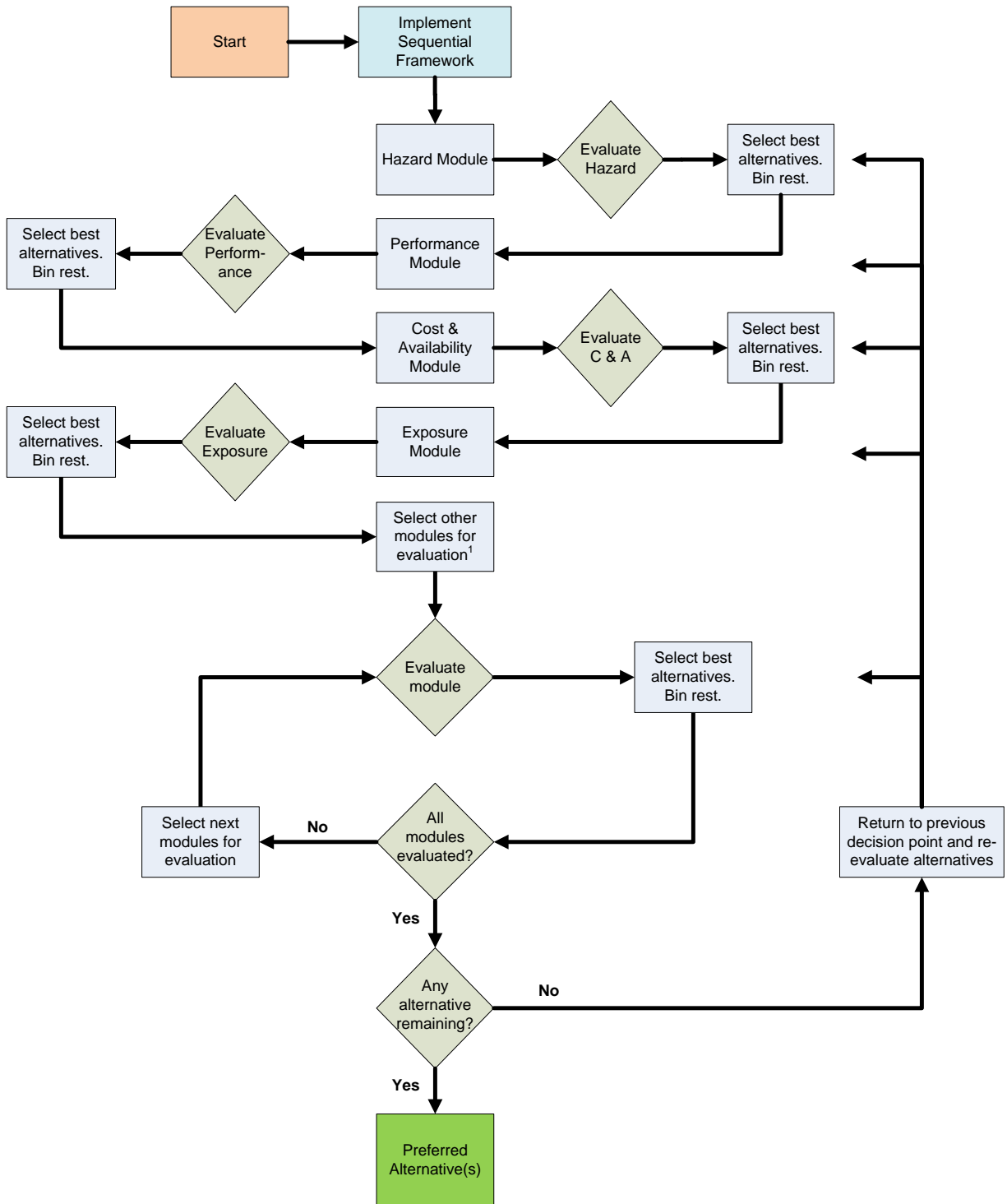
Those alternatives remaining after evaluation in the Hazard and Performance Evaluation modules are evaluated in the Cost and Availability (C&A) Module. The C&A module removes alternatives that are neither cost effective nor available in sufficient quantities to meet manufacturing needs. Alternatives are evaluated using broad definitions in the C&A module. This requires an evaluation of not only current cost and availability but also whether use of the alternative would either drive down cost or increase availability. [More details are available in the Cost and Availability Module.](#)

Remaining alternatives are evaluated in the Exposure Assessment Module where alternatives are identified that present the lowest risk potential. Those that have serious exposure concerns are binned and removed from further consideration. [More details are available in the Exposure Assessment Module.](#)

Once the minimum recommended evaluation is complete, additional modules may be selected and implemented. The assessor decides which additional modules to use, their order, and the level of evaluation within each module. The process used to reach these decisions must be documented and explained.

If successful, the alternative or alternatives identified at the end of the process are the preferred alternatives based upon the combined assessment as shown in [Figure 12.](#)

Figure 12: Minimum Recommendations 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.

In some instances, no alternatives will remain after all alternatives have been evaluated using the selected modules. In those instances, the assessor returns to previous, less favorable bins. The assessor would step back to a prior module assessed and look more closely at the alternatives binned as less favorable. As all of the alternatives had been found to be favorable at this point, the assessor should evaluate whether the concerns identified in the previous review were sufficient to remove a favorable alternative completely from review. If so, the decision is documented including the reasoning and/or data used to reach this decision 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.

Lastly, the Sequential Framework has no need for an additional decision method, which simplifies its implementation. Decision methods are contained within each individual module and applied as the alternatives are binned during the specific module evaluation. Only the most favorable alternatives proceed to the next module for evaluation. This winnowing approach reduces the need for an additional decision-making method found in the Simultaneous and Hybrid Frameworks.

Simultaneous Framework

The modules selected and the degree of evaluation within each module will vary depending upon the product or process being assessed. The four modules recommended as a minimum in the Sequential Framework should also be included in the Simultaneous Framework. Selection of additional modules is left to the assessor but must be documented and justified prior to implementation. Module order in this framework is assumed to be unimportant.

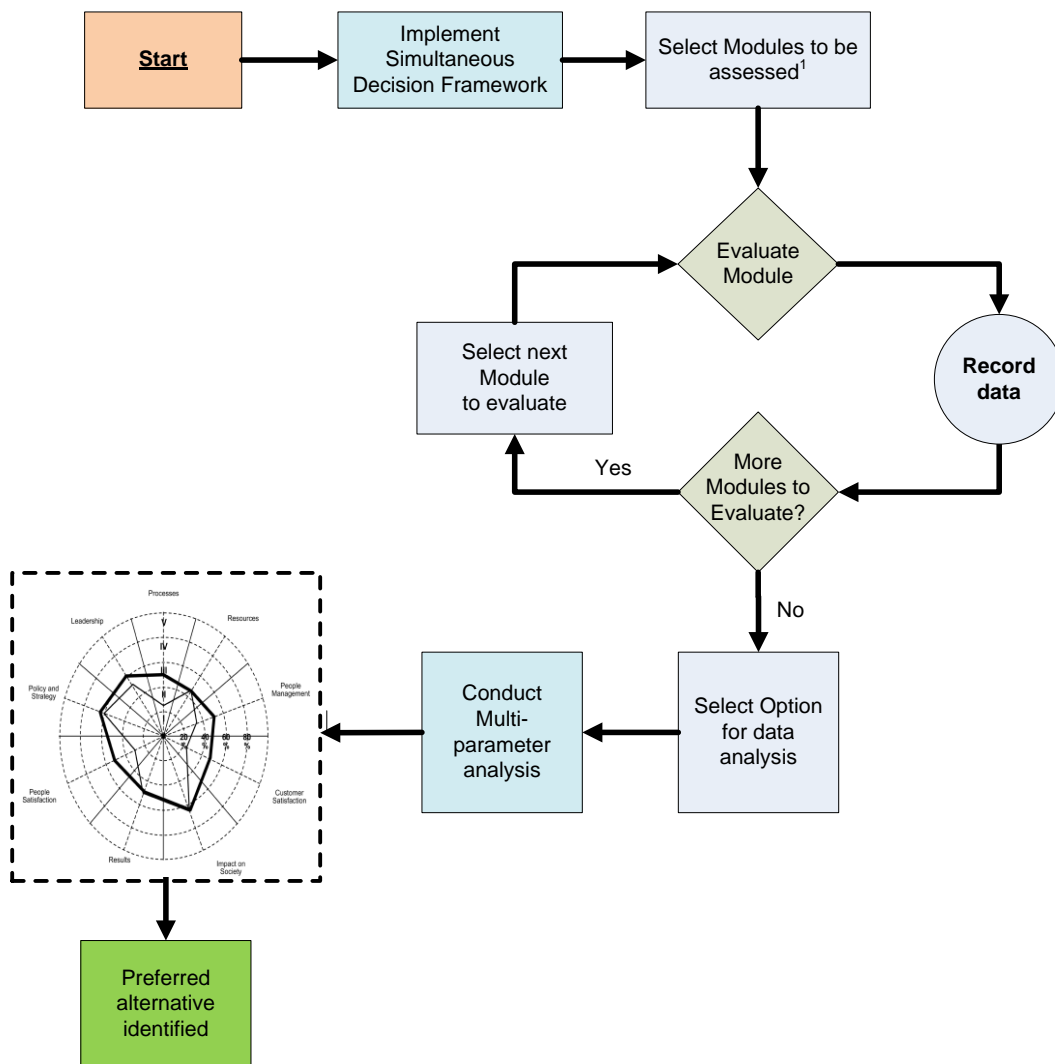
The first step in the Simultaneous Framework is to define the issue. This may be focused on an internal decision, such as deciding which health criteria to consider, or an overall decision point, such as the comparison of alternatives. Depending upon the Decision Method ([Appendix A](#)) selected, it may be necessary to conduct an Initial Screen ([Appendix B](#)) to determine which endpoints should be included in the decision process.

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 as shown in [Figure 13](#).

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. For example, two alternatives may have the same degree of toxicity and exposure; however, during the life cycle assessment, one is found to have a higher carbon footprint while the other might have a higher greenhouse gas generation potential. The decision methodology will have to identify which of these two issues is of a higher concern in order to differentiate between the two alternatives. Regardless of the decision method used, all decisions need to be documented and explained. [More information on how these decisions can be made is provided in Decision Methods \(Appendix A\).](#)

Figure 13: Simultaneous Framework



¹ The following modules should be included in all analyses: performance, cost & availability, hazard and exposure.

Expectations of the Simultaneous Framework

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. However, as identified previously, all AAs must meet the objective of replacing toxic chemicals with safer alternatives and the following basic requirements are necessary to meet this goal:

- The relative weight placed on the results from specific modules used in the assessment must reflect the values identified previously. For example, as the objective of an AA is to replace toxic chemicals with safer alternatives, reducing hazard must be emphasized in any decision method.
- Results of scientific studies yielding specific data must be given greater emphasis than data based upon assumptions. For example, assumptions about exposure control cannot be used as a reason to justify the continued use of toxic chemicals.
- Four modules should be included in all analyses, specifically Performance Evaluation, Cost and Availability, Hazard, and Exposure Assessment. The assessor may select any additional modules and the levels within each module. These decisions must be documented and explained. Transparency is a requirement for all decisions made during the AA process.

Hybrid Framework

The [Hybrid Framework](#) ([Figure 14](#)) 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 two modules (Hazard and Performance Evaluation) are 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. The first step in the Simultaneous Framework is to define the issue. This may focus on an internal decision, such as deciding which health criteria to consider, or an overall decision point, such as the comparison of alternatives. Depending upon the Decision Method ([Appendix A](#)) selected, conducting an Initial Screen ([Appendix B](#)) to determine endpoints may be included in the decision process.

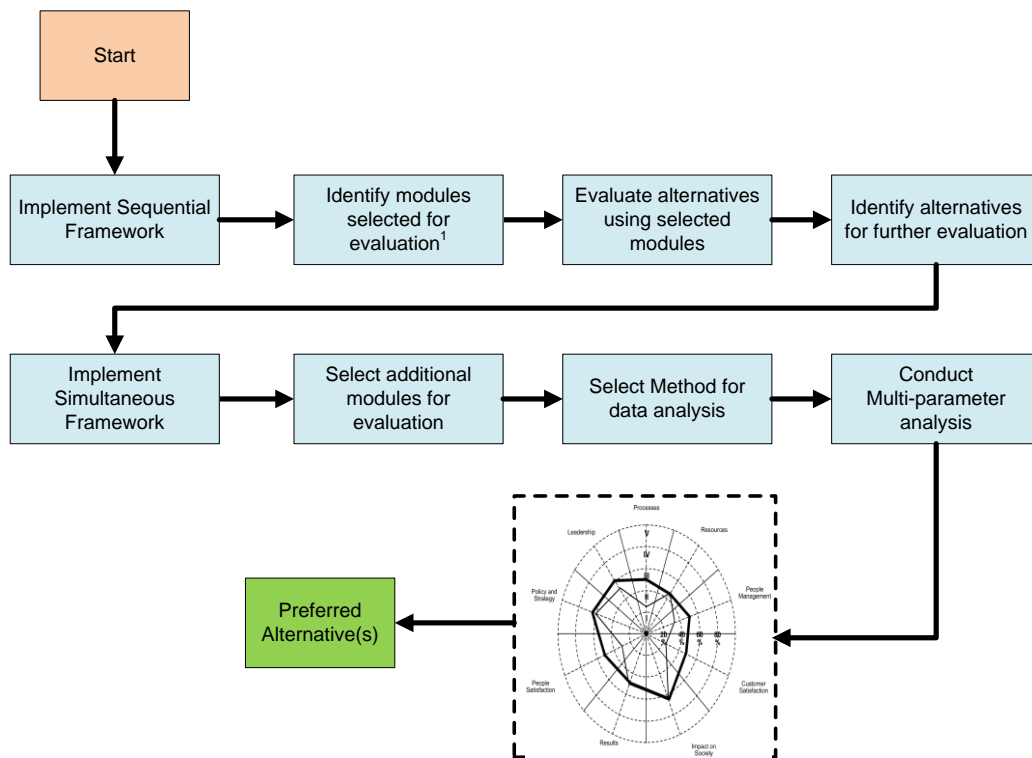
Once the endpoints have been determined, if appropriate, all alternatives are evaluated by all selected modules. The data from these remaining modules are evaluated using one of the three decision tools and the most favorable alternative selected. As with the Simultaneous

Framework, all decisions must be transparent and documented including the weights and priorities assigned to the different criteria and the justification for these decisions. Analysis of all data can be challenging and prioritization of trade-offs is an important consideration. Numerous decision methodologies exist that can assist in this process. [More information on the methodologies is found in Decision Methods in Appendix A.](#)

Once the most favorable alternatives have been identified through implementation of the Sequential Framework, the assessor will need to prioritize the remaining modules. For example, two alternatives may have the same degree of toxicity and exposure; however, during the life cycle assessment, one may be found to have a higher carbon footprint while the other might have a higher greenhouse gas generation. During implementation of the Decision Methods, the assessor will have to identify which of these two issues is of a higher concern in order to differentiate between the two alternatives.

Regardless of what decision tool is used, it is important to document how the decision was made and why. More information on how these decisions can be made is provided in Decision Methods section.

Figure 14: 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.

Expectations for the Hybrid Framework

The [Hybrid Framework](#) provides a great deal of flexibility to the assessor and allows an AA to be tailored to address a specific product or process. However, all AAs must meet the objective of replacing toxic chemicals with safer alternatives. The following basic requirements are necessary to meet this goal:

- The relative weight placed on results from specific modules used in the Simultaneous Framework must reflect the values identified previously. For example, as the objective of an AA is to replace toxic chemicals with safer alternatives, reducing hazard must be emphasized in any decision method.
- Results of scientific studies yielding specific data must be given greater emphasis than data based on assumptions. For example, assumptions about exposure cannot be used as a reason to justify the continued use of toxic chemicals.
- Two modules should be included in the Sequential Framework, specifically hazard and performance. The assessor may select any additional modules and the levels within each module to be used both in the Sequential and Simultaneous Frameworks. These decisions must be documented and explained. Transparency is a requirement for all decisions made during the AA process.

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. In order 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 evaluation.
 - Do any of the potential hazards affect the environment to nonhuman receptors? This includes impacts to water, air, soil, etc. Continue evaluation.

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- If yes, document information used to reach the conclusion and include environmental and ecological hazards as relevant criteria. Continue evaluation.
 - Do any of the potential hazards impact effectiveness of the product or alternatives?
 - If yes, document information used to reach the conclusion and include effectiveness as a relevant criterion. Continue evaluation.
 - If no to all of the above, identify the information used to reach the conclusion and identify that hazard is not a decision criteria used for 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 evaluation.
 - If no to all of above, document the information used to reach this conclusion and identify that hazard is not a decision criteria used for the assessment. Continue 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 evaluation.
 - If no, document the information is not available and identify the criteria as unknown. Continue evaluation.
 - Is qualitative information available for the criteria values?
 - If yes, document the available information.
 - If no, can the information be generated through structure analysis? If yes, document available information. Continue evaluation.
3. Create a matrix depicting the relevant criteria, the original condition and alternatives, including the values for the criteria.
- Are any of the alternatives inferior to the original condition with regard to health and exposure?

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- If yes, document information used to reach the conclusion and these alternatives may be excluded from consideration.
 - If no, these alternatives should remain under consideration.
 - Are any of the alternatives superior to the original condition with regard to health and exposure?
 - If yes, document information used to reach the conclusion and these alternatives should be preferred over the original.
 - If no, these alternatives may remain under consideration.
 - Are any of the alternatives inferior to the original condition with regard to environmental and ecological impacts?
 - If yes, document information used to reach the conclusion and these alternatives may be excluded from consideration.
 - If no, these alternatives should remain under consideration.
 - Are any of the alternatives superior to the original condition with regard to environmental and ecological impacts?
 - If yes, document information used to reach the conclusion and these alternatives should be preferred over the original.
 - If no, these alternatives may remain under consideration.
 - Are any of the alternatives inferior to the original condition with regard to effectiveness?
 - If yes, document information used to reach the conclusion and these alternatives may be excluded from consideration.
 - If no, these alternatives should remain under consideration.
 - Are any of the alternatives superior to the original condition with regard to effectiveness?
 - If yes, document information used to reach the conclusion and 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 principle criteria of health and exposure, environmental and ecological impacts, or effectiveness?
 - If yes, such an alternative is clearly superior to the original and may be eligible for selection. Document information used to reach the conclusion and proceed with assessment.

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- If no, are any of the alternatives superior, and not inferior, with regard to one or more of the three guiding principle 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, are any of the alternatives neither superior nor inferior with regard to the three guiding principle criteria of health and exposure, environmental and ecological impacts, or effectiveness?
 - If yes, such an alternative may be considered equivalent to the original and may be eligible for selection. Document information used to reach the conclusion and continue with analysis.
 - If no, 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 original condition and alternatives, including the values for the criteria.
- Are any of the alternatives superior with regard to 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 with regard to the remaining criteria?
 - If yes, alternative may be considered equivalent to original and may be eligible for selection. Document information used to reach the conclusion and continue evaluation.
 - If no, all alternatives are inferior and may be rejected. Continue 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 determined by the assessor to define preferences among criteria and thresholds defined by the assessor to facilitate comparison. This type of approach is typically used for screening by eliminating those options that do not achieve minimum thresholds. If all of the alternatives are rejected in an initial analysis, the assessor can adjust the hierarchy of criteria and selected thresholds and reiterate the assessment.

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. 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 evaluation.
 - If no, can the information be generated through structure analysis or other models?
 - If yes, document available information. Continue evaluation.
 - If no, continue 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 after being compared to all of the 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 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. Evaluation 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 available information. Continue evaluation.
 - If no, document result and continue 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 analysis with standardized weights.
 - If no, develop valid weights. Continue evaluation.
 - If no, continue evaluation.
 - Are calculated weights appropriate for the criteria and alternatives?
 - If yes, continue 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 analysis with derived weights.
 - If no, seek lower resource-intensive options.

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- Are other rating models available and appropriate for the analysis?
 - If yes, continue 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 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

Identify potential impacts associated with the original product and its alternatives, and identify relevant criteria. Document all 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.

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- 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 is 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 is 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 is not a factor in the evaluation.

References

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.

Identification of Alternatives

This module clarifies the process used to identify the universe of potential alternatives considered during the AA. Alternatives may include chemical substitutions, alternative materials, and changes to the product process or product redesign to eliminate a particular chemical. The widest range of possible alternatives should be researched, including emerging technologies. In subsequent modules, the range of alternatives to evaluate is narrowed on the basis of technical, economic, and health and safety considerations.

This module assumes that a chemical of concern in a product or process:

- Performs a useful function, either in the manufacture of the product or as part of the product itself.
- Is not restricted due to local, state, federal, or international legislation.
- Is not required by local, state, federal, or international legislation.

Chemicals restricted by legislative requirements are not favorable alternatives to the chemical of concern and should be removed from consideration. If a chemical is required, an alternatives assessment process might still be appropriate to determine if any viable alternatives exist.

Specific chemicals may be considered chemical of concern either because of their inherent toxicity or the inherent toxicity of unavoidable contaminants. Chemical function is part of the [Initial Evaluation Module](#). Initial identification of potential alternatives should begin as a brainstorm of the widest range of solutions possible. Alternatives may include chemical substitutions, the use of alternative materials, emerging technologies or product redesign to eliminate the need for a particular chemical in the first place.

Identification of Alternatives Process

There are two key considerations in exploring potential alternatives for a chemical of concern: the availability of 1) functionally equivalent alternatives and 2) alternatives in the marketplace.

1. Availability of functionally equivalent alternatives

A functionally equivalent alternative is an alternate way of achieving the function performed by a chemical of concern. Functionally equivalent alternatives may include direct chemical replacements or potential chemical replacements dependent on changes to production

processes, for example, changing plastics, temperature, flow rate, etc. A functionally equivalent alternative may also include a product design change that precludes the need for a replacement chemical.

Use the following questions to generate the broadest list of potential alternatives possible.

- A. Is the alternative restricted in use 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 evaluation.
- B. Is the chemical of concern required by local, state, federal, or international legislation and no viable alternatives exist? The legislation must identify that no other alternative exists and specifically dictate the use of the chemical of concern in a specific application. If a chemical of concern is only one of a range of possible alternatives, the chemical of concern should be subjected to an AA. If the chemical of concern is required and no viable alternative exists, the AA process is not appropriate. Document information used to reach the conclusion and exit the AA process. If not, continue evaluation.
- C. Does an existing alternative meet a similar or equivalent functional requirement? If not, explain.
- *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.
- D. Are there technical resources available that identify chemicals, materials, or design changes with similar or equivalent required functionality? A list of potential resources is included in the separate [Resources](#) section for this module. If not, explain and continue evaluation.
- E. Can changes potentially be made to the manufacturing process or product design to allow the use of the alternative?
- If yes, document potential changes your process engineer can make to the product/manufacturing process to allow the use of an alternative.
 - If no, continue evaluation.

-
- F. Can the functional equivalency be achieved in reasonable time through design of new chemicals or materials applying green chemistry principles or product redesign?
- If yes, is the chemical necessary after re-design of the product?
 - If no, then an AA is not necessary.
 - If yes, continue evaluation.
 - If no, continue evaluation.

2. Alternatives available in the marketplace

A second consideration when identifying alternatives is their availability in the marketplace. Use the following questions to guide the brainstorm process:

- 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?
- Does your supplier offer an alternative?
- Does your supplier's competition 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?

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

Identification of Alternatives Initial Screen

An assessor can focus the list of potential alternatives by conducting an initial screen using the lowest levels of the [Hazard](#) and [Performance Evaluation](#) modules. For example, chemicals identified as equal or potentially greater hazard as the chemical of concern can be eliminated from further consideration. Chemicals that do not perform as identified in Level 1 of the Performance Evaluation Module may also be identified as unfavorable and removed from further consideration. The advantage of these screens is they concentrate potentially

limited resources on the most viable alternatives. Any removals from consideration must be transparent and the data used to reach these conclusions documented in the final AA report. This module requires assessors to consider as many as alternatives as possible to foster innovation and to spur the development of new products that don't depend on the continued use of toxic chemicals. For more information on potential screening mechanisms, see Level 1 of the [Hazard](#) and [Performance Evaluation](#) modules.

Hazard Module

This module determines what hazard concerns exist for the chemical of concern and potential alternatives. It provides guidance for evaluating the hazard of a potential alternative at three different levels. Greater expertise is required as the level increases including evaluating data for a greater number of hazard traits and from a greater number of data sources. As a result, Level 3 provides the most complete information about the hazard posed by the chemicals or processes being evaluated.

An initial screening method, based on authoritative lists, identifies chemicals known to be hazardous. These chemicals should not be considered as viable alternatives to the chemical of concern. If the initial screening does not identify hazard concerns, further analysis is needed to identify undocumented hazards.

Hazard Module Levels

This module establishes an initial screen that looks solely at authoritative lists and three evaluation levels ranging from a basic assessment of limited hazard criteria using specific data sources, through increasing detail and broadening scope, ending with an expanded verified GreenScreen® assessment ([Table 3](#)).

Table 3: Initial Screen and Three Levels within a Hazard Module

Initial Screen	<i>Initial Screen:</i> Uses several readily available sources to evaluate whether a chemical, product or process appears on authoritative lists of hazard criteria.
Level 1	<i>Basic Evaluation:</i> Utilizes the Quick Chemical Assessment Tool to determine if hazards exist for specific hazard criteria using well-defined, readily available data sources.
Level 2	<i>GreenScreen Evaluation:</i> Uses the GreenScreen for Hazard Assessment tool (GreenScreen™) to conduct a thorough hazard evaluation. The GreenScreen™ is a free, publicly available hazard assessment tool.
Level 3	<i>Expanded GreenScreen Evaluation:</i> Expands upon Level 2 by eliminating data gaps and requiring an independent, third party verification.

Introduction

Hazard is the set of inherent properties of a substance, mixture of substances or processes that, under production, usage, or disposal, makes it capable of causing adverse effects to humans, animals, and the environment. Hazard can be measured for a number of human and environmental traits. Information on each trait may come either from experimental data or,

lacking experimental data, from modeling results. Modeled data is based on extrapolations from known information about similar chemicals. Experimental data is generally considered more reliable than modeled data. For the vast majority of chemicals in commerce today, data is available for only a limited number of hazard traits, resulting in data gaps. Confidence in the hazards posed by a chemical increases as the amount and quality of data increases.

Background

As concerns have increased about the widespread use of toxic chemicals in products and their effects on human and environmental health, replacement of chemicals of concern with safer alternatives has received greater emphasis. In order to eliminate chemicals of concern, businesses have at times replaced them with chemicals of equal or greater hazard resulting in ‘regrettable substitution.’

The replacement of chlorinated solvents in the auto repair industry with hexane is a well-documented example of a [regrettable substitution](#). In response to increasing regulation of methylene chloride, several manufacturers switched from chlorinated solvents to hexane in brake cleaners. No attempt was made to determine if any known hazards were associated with the substitute. Hexane had been shown to cause nerve damage as early as 1964.² A few years after the substitution, workers in auto repair shops in California began to report health concerns eventually tied to hexane.³ 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 toxic chemical. The [National Toxicology Program](#) recently indicated n-propyl bromide is ‘reasonably anticipated to be a human carcinogen.’

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 as a truly safer 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 substitution.

U.S. EPA Design for the Environment Program

EPA’s Design for the Environment (DfE) Program pioneered work in the field of AAs in the late 1990’s. DfE developed a series of hazard criteria ([Table 4](#)) that can be used to compare

² Yamada S, 1964. An occurrence of polyneuritis by n-hexane in the polyethylene laminating plants. *Jpn J Ind Health*, vol.6, p. 192.

³ 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.

chemical substitutes. [Revised criteria](#) were released in 2011. These criteria form the basis of a chemical hazard assessment methodology that DfE continues to use in its AA program.

In addition, DfE established a voluntary product evaluation and labeling program for industrial, institutional, and consumer products. Ingredients in products are evaluated against the DfE hazard criteria. To earn the DfE label, each ingredient in a formulation must have the lowest possible impact upon human health and the environment in its functional class while maintaining product function at a reasonable cost. Since the inception of the labeling program, more than 2,800 products carry the [DfE label](#). Importantly, however, chemical evaluations and scoring information used by EPA are not public and the criteria can be difficult to implement without substantial expertise. As a result, while the work of DfE provides an excellent foundation, others cannot simply adopt DfE's methods. To address these concerns, in 2012, DfE released a list of [preferable chemicals](#) identified by the safer products labeling program.

GreenScreen® for Safer Chemicals

To build on the work of DfE and adapt DfE's method for use by a wider audience, [Clean Production Action](#) (CPA), a non-profit organization, created the [GreenScreen® for Safer Chemicals](#) (GreenScreen®) in 2007. The GreenScreen® translates the DfE criteria into a transparent score or benchmark. The GreenScreen® streamlines the DfE method and enables organizations with fewer resources and expertise to evaluate chemical hazards. The GreenScreen® also standardizes the hazard assessment process and addresses the issue of data gaps. As most assessors will not have the level of technical expertise found at EPA, all assessments will have data gaps. The GreenScreen® method prioritizes hazard criteria, identifies the most serious data gaps and adjusts the benchmarking system based on the number and severity of data gaps. Chemicals lacking data are no longer assumed safe and the GreenScreen® emphasizes the need for quality data before an alternative can be identified as better than the chemical of concern.

GreenScreen® is free and available to all assessors. Numerous United States and International companies, state and local government agencies, and alliances between industry and non-governmental organizations have used the GreenScreen® to evaluate toxicity of chemicals, products, or processes. If an organization, however, wishes to use the GreenScreen® to market their chemicals, products, or processes, CPA requires an independent, authorized third party review with a resultant cost to the manufacturer. This sole limitation was placed upon use of the GreenScreen® because of concerns associated with potential misuse of the GreenScreen® benchmarking results.

CPA piloted the GreenScreen® methodology by conducting an AA of the flame retardant, [decabromodiphenyl ether](#). A publicly available example of a GreenScreen® assessment can be found as part of [Ecology's assessment](#) of decabromodiphenyl ether historically used in electronic enclosures and residential upholstered furniture.

Table 4: US EPA Design for the Environment Program Hazard Traits

Abbr.	Hazard Trait	Definition
Group I Human Health		
C	Carcinogenicity	A chemical is termed carcinogenic if it is capable of increasing the incidence of malignant tumors, reducing their latency, or increasing their severity or multiplicity. ⁴
M/G	Mutagenicity and Genotoxicity	<p>Mutagen: The term mutagenic and mutagen will be used for 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.⁵</p> <p>Genotoxicity: The more general terms 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.⁶</p>
R	Reproductive toxicity	<p>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.⁷</p>

⁴ 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>.

⁵ 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>.

⁶ 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.

⁷ 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>.

Table 4: US EPA Design for the Environment Program Hazard Traits

Abbr.	Hazard Trait	Definition
D	Developmental toxicity (including Developmental Neurotoxicity)	Developmental toxicity: Adverse effects in the developing organism that may result from exposure prior to conception (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. ⁸
E	Endocrine Activity	Endocrine activity refers to a change in endocrine homeostasis caused by a chemical or other stressor from human activities (e.g., application of pesticides, the discharge of industrial chemicals to air, land, or water, or the use of synthetic chemicals in consumer products. ⁹)
Group II and II* Human Health		
AT	Acute Mammalian Toxicity	Acute mammalian toxicity refers to those 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. ¹⁰
ST single	Systemic Toxicity & Organ Effects (including Immuno-toxicity)	<p>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.¹¹</p> <p>Single (dose): Total amount of a substance administered to, taken up, or absorbed by an organism, organ, or tissue in one application.¹²</p> <p>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.¹³</p>

⁸ 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>.

⁹ 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>.

¹⁰ 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.

Table 4: US EPA Design for the Environment Program Hazard Traits

Abbr.	Hazard Trait	Definition
ST repeat	Systemic Toxicity & Organ Effects (including Immunotoxicity)	<p>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.¹⁴</p> <p>Repeat (dose): Total amount of a substance administered to, taken up, or absorbed by an organism, organ, or tissue in multiple applications.¹⁵</p> <p>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.¹⁶</p>
N single	Neurotoxicity	Neurotoxicity: Adverse change in structure or function of central and/or peripheral nervous system following exposure to chemical, physical, or biological agent. “Single” refers to single instance of exposure or single dose.
N repeat	Neurotoxicity	Neurotoxicity: Adverse change in structure or function of central and/or peripheral nervous system following exposure to chemical, physical, or biological agent. ¹⁷ “Repeat” refers to repeated exposure or repeat dose.
SnS	Sensitization: Skin	Skin sensitizer: A substance that will lead to an allergic response following skin contact. ¹⁸

¹¹ 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.

¹² Ibid.

¹³ Ibid.

¹⁴ Ibid.

¹⁵ Ibid.

¹⁶ Ibid.

¹⁷ 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>.

¹⁸ 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.

Table 4: US EPA Design for the Environment Program Hazard Traits

Abbr.	Hazard Trait	Definition
SnR	Sensitization: Respiratory	Respiratory sensitizer: A substance that will lead to hypersensitivity of the airways following inhalation of the substance. ¹⁹
IrS	Irritation/ Corrosivity: Skin	Skin irritation: production of reversible damage to skin following application of test substance for up to 4 hours. ²⁰ Skin corrosion is the 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. ²¹
IrE	Irritation/ Corrosivity: Eyes	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. ²² 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. ²³
Ecotoxicity		
AA	Acute Aquatic Toxicity	Acute aquatic toxicity means the intrinsic property of a substance to be injurious to an organism in a short-term, aquatic exposure to that substance. ²⁴
CA	Chronic Aquatic Toxicity	Chronic aquatic toxicity means 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. ²⁵

¹⁹ Ibid.

²⁰ 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.

²¹ 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>.

²² 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.

²³ Ibid.

²⁴ 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.

Table 4: US EPA Design for the Environment Program Hazard Traits

Abbr.	Hazard Trait	Definition
Environmental Fate		
P	Persistence	Persistence: The length of time the chemical can exist in the environment before being destroyed (i.e., transformed) by natural processes. ²⁶
B	Bioaccumulation	Bioaccumulation is a 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 competing processes of chemical uptake into the organism at the respiratory surface and from the diet and chemical elimination from the organism including respiratory exchange, fecal egestion, metabolic biotransformation of the parent compound and growth dilution. ²⁷
Physical Characteristics		
Rx	Reactivity	Reactivity: A chemical that exhibits any of the following traits: ²⁸ 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 if heated under confinement, 7) Is readily capable of detonation or explosive decomposition or reaction at standard temperature and pressure.
F	Flammability	Flammability: Ability of a substance to be easily ignited and capable of burning with great rapidity. ²⁹

²⁵ Ibid.

²⁶ 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>.

²⁷ 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.

²⁸ 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.

²⁹ Based upon definition for flammable found in Webster’s II New Riverside University Dictionary, The Riverside Publishing Company, 1988, Houghton Mifflin Company publishers.

Quick Chemical Assessment Tool (QCAT)

The GreenScreen® is an excellent tool and provides a high degree of certainty against regrettable substitution. However, it also requires considerable technical expertise and resources to use correctly. These limitations make it very difficult for small and medium businesses to use. Ecology developed the Quick Chemical Assessment Tool (QCAT) to address some of these concerns.

QCAT is based on the GreenScreen®, though it neither as comprehensive nor as detailed. QCAT is designed to be a simpler tool that smaller businesses can implement. QCAT users should realize there is a greater risk of making a regrettable substitution compared with a full GreenScreen® assessment. Given this limitation, the QCAT does allow small and medium businesses to become familiar with the hazard assessment process. It enables them to identify potential alternatives that are clearly poor substitutes. If a comprehensive assessment is done, resources are focused on the most promising potential alternatives.

Data Sources

The GreenScreen® (Levels 2 and 3) identifies two types of lists for hazard data:

- **Authoritative list:** Authoritative lists are developed by governmental bodies or government recognized expert bodies and include chemicals based upon the review of test data and scientific literature by experts in the field.
- **Screening list:** Screening lists are either 1) lists developed by authoritative bodies to target chemicals for additional scrutiny and testing and are often generated by models or screening tests or 2) lists developed by non-governmental bodies or experts not sanctioned by government.

Few authoritative lists exist for neurotoxicants, vPTs, vBTs, and endocrine disruptors. For endocrine disruptors, available lists are preliminary screening lists that identify chemicals that are prime candidates for high concern; however, these chemicals need further assessment before they can be identified as endocrine disruptors. The same can be said for neurotoxicants. Grandjean and Landrigan³⁰ have identified 201 chemicals that appear to be developmental toxicants. These chemicals also require further research to determine if they pose a developmental threat. Since neurotoxicity and endocrine activity are endpoints of high concern, these “watch” lists are used as they flag chemicals that may meet these criteria. While these chemicals are under assessment, precautionary avoidance is warranted.

³⁰ Grandjean, P & PJ Landrigan. 2006. "Developmental neurotoxicity of industrial chemicals." *The Lancet*, v368: 2167-2178.

The authoritative lists are based upon evaluation of only a limited set of the approximately 80,000 chemicals in commerce. Many chemicals simply have not been tested. Therefore it is important to assess the available toxicological literature on chemicals, which are not listed, and to use modeling tools and analogs to determine whether the weight of evidence indicates that a chemical is a chemical of concern. The authoritative and watch lists provide a starting point for identifying chemicals of concern.

Summary of Levels 1 – 3

As the number of hazard traits evaluated and the number of sources examined increase, confidence in the accuracy of the assessment outcome also increases. No level can provide 100% certainty that an alternative is truly safer than the chemical of concern. New data are always being published and modeled data range in their level of certainty. The hazard traits evaluated for Levels 1-3 are summarized in [Table 5](#). Data sources used for Levels 1-3 are summarized in [Table 6](#).

Table 5: Hazard Traits Evaluated for Levels 1-3

Data Sources	Levels		
	1	2	3
Human Health			
Carcinogenicity	x	x	x
Mutagenicity and Genotoxicity	x	x	x
Reproductive Toxicity	x	x	x
Developmental Toxicity (including Developmental Neurotoxicity)	x	x	x
Endocrine Activity	x	x	x
Acute Mammalian Toxicity	x	x	x
Systemic Toxicity & Organ Effects (including Immunotoxicity)		x	x
Neurotoxicity		x	x
Sensitization: Skin		x	x
Sensitization: Respiratory		x	x
Ecological			
Acute Aquatic Toxicity	x	x	x
Chronic Aquatic Toxicity		x	x
Environmental			
Persistence	x	x	x
Bioaccumulation	x	x	x
Physical			
Reactivity		x	x
Flammability		x	x
Additional environmental hazard traits			
Domesticated animal toxicity			x
Eutrophication			x

Table 5: Hazard Traits Evaluated for Levels 1-3

Data Sources	Levels		
	1	2	3
Impairment of waste management organisms			X
Loss of genetic diversity, including biodiversity			X
Phytotoxicity			
Wildlife developmental impairment			X
Wildlife growth impairment			X
Wildlife reproductive impairment			X
Wildlife survival impairment			X

Table 6: Data Sources Used for Levels 1-3

Data Sources	Levels		
	1	2	3
Authoritative Lists	X	X	X
GHS listings	X	X	X
ECOTOX database	X	X	X
EPA PBT Profiler	X	X	X
EU Risk Assessments	X	X	X
OECD-IUCLID datasheets	X	X	X
OECD-SIDS datasets	X	X	X
RTECS	X	X	X
TOXNET HSDB	X	X	X
Review of scientific literature		X	X
Review of toxicological databases		X	X
Review of QSAR analog information		X	X
Professional judgment		X	X
Development of QSAR determination			X
Development of laboratory studies			X
Peer review and validation of analysis			X

Initial Screen: List Translator

Several government bodies and expert groups have performed comprehensive hazard assessments of chemicals and published lists of chemicals of concern for various hazard traits. Performing an initial screen using these lists can eliminate chemicals of concern and help identify those best suited for a more comprehensive assessment. List Translators enable assessors to identify less favorable alternatives and remove them from further consideration. Clean Production Action has created a list translator, called the [GreenScreen® List Translator](#) for use with chemical hazard assessments.

Automated versions of the List Translator are currently available for a fee. [Healthy Building Network](#) included a List Translator in its [Pharos Database](#). [The Wercs](#), a hazard

communication authoring software platform and regulatory content provider, has developed a List Translator tool as part of the services it provides. Both List Translators compare alternatives against authoritative lists for the 18 hazard traits and identify any chemicals, products, or processes for which concerns have been identified.

Expertise Required for the Initial Screen

The Initial Screen requires little technical review or expertise and only a basic understanding of the hazard traits. The assessor simply determines whether or not a chemical appears in the authoritative 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 a less favorable alternative and removed from further consideration.

Who should use this tool?

Assessors who want to know whether a chemical has been identified as hazardous by a limited number of authoritative bodies should complete a Screening assessment.

What resources and knowledge are required to use this tool?

A Screening assessment can be completed with access to free, publicly available, authoritative lists. An assessor with limited chemical or toxicology background can complete it.

What level of confidence does this level provide?

A Screening assessment should be used as an initial screening tool. A Screening assessment 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 a list of potential alternatives for more comprehensive assessment.

If a chemical does not appear on a specified list in a Screening assessment, no conclusions can be drawn regarding the chemical's hazard. Further assessment is required.

Process

1. Is the chemical on any of the specified authoritative lists for a high level of concern?
 - If yes, bin the chemicals found on these lists as an unfavorable alternative and document the information used to reach the conclusion.
 - If no, consider chemical as a potential alternative and continue with analysis.

-
2. 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.

Level 1: Quick Chemical Assessment Tool

Level 1 uses the [Quick Chemical Assessment \(QCAT\) Tool](#) developed by Ecology. Ecology has developed a guidance document for the QCAT, which provides extensive detail on its use and limitations.

Who should use this tool?

QCAT is designed to be used by small- and medium-size businesses with limited knowledge and experience with AAs. It may also be useful for larger businesses that want to eliminate unsuitable alternatives before performing a more comprehensive AA.

What resources and knowledge are required to use this tool?

QCAT assessments use the authoritative lists included in the Initial Screen as well as additional, specified data sources. Information on interpreting these sources is included in the QCAT methodology.

What level of confidence does this level provide?

QCAT does not conduct a detailed evaluation of potential alternatives as it looks only at a subset of hazard criteria from limited data sources. Unlike the Initial Screen, however, a Level 1 QCAT assessment goes beyond authoritative lists to consider some measured and modeled data.

The QCAT focuses on important hazard endpoints, lowers data requirements, and provides a significant amount of information with relatively low investment of resources in comparison with a more comprehensive assessment. A Level 1 assessment provides a quick and easy method to identify chemicals that are equally or more toxic than the chemical of concern. A Level 1 assessment can also be used to prioritize potential alternatives for more comprehensive Level 2 or 3 assessments.

What level of confidence does this level provide?

As a Level 1 assessment looks only at a select group of hazard criteria and collects data only from specific data sources, the results are not as complete as more comprehensive assessments conducted in Levels 2 or 3. However, because it goes beyond the authoritative lists used in the Initial Screen, it provides an improved evaluation of potential concerns with the chemical, product, or process under evaluation.

Level 2: GreenScreen® for Safer Chemicals

Level 2 uses the GreenScreen® methodology. The 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. Chemicals receive a benchmark score based on the combination of the hazard assessments of 19 endpoints (18 required and 1 optional).

Clean Production Action has written [GreenScreen® guidance](#). For further details, assessors should refer to the [GreenScreen® website](#).

Who should use this tool?

The GreenScreen® is designed for assessors skilled in toxicology, chemistry, computer modeling, and other scientific areas.

What resources and knowledge are required to use this tool?

The GreenScreen® requires a high level of technical expertise. Specialists in toxicology, chemistry, computer modeling, and other scientific areas are needed to generate data, evaluate sources, review technical information, and assign benchmark scores to the chemicals that have undergone the screening process. This is particularly true when information from peer-reviewed journal articles and computer modeling are used to fill in data for all hazard endpoints.

The GreenScreen® also requires a commitment of time and resources that can be costly to implement. In order to address some of these concerns, the GreenScreen® coordinates with other regulatory requirements (GHS³¹, REACH,³² etc.) and uses authoritative lists to provide established criteria for those chemicals for which toxicity concerns have already been identified. This enables different individuals and organizations to implement the GreenScreen® and reach similar conclusions, i.e., consistent results from different individuals. If data gaps exist, more technical sources are used to provide a more complete data set for evaluation, where possible.

As with many aspects of the GreenScreen®, the level of expertise required to evaluate data increases as the data sources become more technical and detailed. Individuals with

³¹ Globally Harmonized System (GHS) for Classification and Labelling of Chemicals

³² European Union's Registration Evaluation and Authorisation of Chemicals (REACH) legislation. REACH establishes data requirements for chemicals manufactured or imported into the European Union.

specialized degrees such as toxicologists, chemists, (Q)SAR³³ specialists, etc., may be needed to provide a professional evaluation of specific sources. For example, Ecology commissioned consultants SRC Inc. to collect and analyze data and generate (Q)SAR estimates for hazard endpoints on the polybrominated diphenyl ether (PBDE) family of flame-retardants (Ecology, 2006). The data were subsequently used for the deca-BDE AA.

What level of confidence does this level provide?

The GreenScreen® can provide a higher degree of certainty because the hazard assessment is detailed and comprehensive. Data gaps may still exist. Because of the evolving nature of science, some degree of uncertainty will always exist for any hazard evaluation methodology. Therefore, all chemicals and products should be subjected to periodic review to evaluate the impact of improvements in data and scientific understanding upon the chemicals hazards and final benchmark.

This benchmarking process enables safer alternatives of existing chemicals of concern to be identified and emphasizes the removal of chemicals of high concern (Benchmark 1) from manufacturing and product design. Benchmark 1 chemicals are typically one or more of the following:

- Persistent, bioaccumulative and toxic (PBT).
- Very persistent and very bioaccumulative (vPvB).
- Possessing a high level of hazard for a priority human health effect, such as CMR (carcinogenicity, mutagenicity, or developmental toxicity), etc.

Based upon this analysis, safer alternatives to chemicals of concern can be identified in a clear and reproducible manner.

Level 3: GreenScreen® Plus

Level 3 uses the GreenScreen® methodology, but examines additional hazard traits and fills in any data gaps by generating 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 larger businesses that want the highest level of confidence possible that their alternative poses no threat to human health and the environment.

³³ (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.

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 benchmark.

Chemical Comparison

Depending on the level, chemicals can be compared against each other and against the chemical of concern. The end results are grouped into the four benchmarks ([Table 7](#)). The chemical of concern is included to enable a comparison between the existing chemical and potential alternatives.

Table 7: Grouping of Alternatives

Preferable-Benchmark 4
Alternative a
Alternative b
Improvement Possible-Benchmark 3
Alternative c
Alternative d
Alternative e
Use but search for safer alternative-Benchmark 2
Alternative f
Alternative g
Alternative h
Alternative i
Alternative j
Alternative k
Avoid-Benchmark 1
Alternative l
Alternative m
Alternative n
Alternative o
Chemical of Concern

The hazards associated with the alternatives have now been compared with the chemical of concern. For the purposes of the hazard module, the most favorable alternatives have been identified (Benchmark 4) and can undergo further evaluation. For example, the two chemicals identified as 'Preferred' (i.e., 'green') would now be evaluated in other modules to determine if any issues exist that prevent the chemicals from being viable alternatives. A chemical could be too costly or it may not perform the desired function. These concerns might reject the 'green' chemicals as viable alternatives.

A similar comparison could then be done for the next benchmark chemicals and so forth until a chemical has been identified that has the lowest feasible hazard while meeting all module concerns. The assessor would need to document the why less hazardous chemicals are rejected and the information used to reach that conclusion. Depending on the benchmark of the chemical alternative selected, the review might emphasize the need for continual review and improvement.

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 are unlikely to adopt the safer alternatives for their products or processes. Companies are encouraged to create performance-based specifications that allow for innovation using safer alternatives.

The module is based primarily on [AA work](#) by the [Toxics Use Reduction Institute](#) of 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 ([Table 8](#)) of performance evaluation.

Table 8: Performance Levels

Level 1	<i>Basic Performance Evaluation:</i> Identifies 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	<i>Extended Performance Evaluation:</i> 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	<i>Detailed Performance Evaluation:</i> Expands upon the previous levels. It uses quantitative information to evaluate alternatives based upon results of specified tests reviewed and validated by technical experts.

The module identifies a series of questions to help determine viability of the alternative.

This module provides sufficient flexibility to allow a wide range of assessors to determine if performance characteristics are a barrier to the use of an alternative. Expected assessors include small, medium and large businesses, regulatory agencies, non-governmental organizations, etc. Depending upon the decision methodology, the module levels can be used either in different assessments or at different stages of the same assessment. More information on how the performance module may be used in combination with the other modules can be found in [Frameworks](#).

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.

1. What are the performance needs for the application, process, or product that contains the chemical of concern (COC)? Why is the COC being used in this specific application?
 - 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 non-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 its performance? For example, if a plasticizer is added to a hard plastic, the plastic becomes more flexible as 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 resistance is very important for many. Adding chemical flame retardants is one way to improve performance in case of a fire.
 - 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.

2. Has the alternative(s) already been identified as a favorable alternative with respect to performance?
 - 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 evaluation.

-
3. Has an authoritative body³⁴ 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 evaluation.

 4. 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 fulfill the necessary function less satisfactorily?
 - 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 evaluation.
 - If no, continue evaluation.

 5. Has the proposed alternative(s) been identified by expert sources 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 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.

³⁴ 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.

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. The independence and veracity of the technical experts consulted is of critical importance to the validity of the assessment.

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.
- End users of the products or processes using the chemicals of concern or the alternative.
- Marketing or sales staff familiar with customer requirements.
- Consultants with expertise in similar product development.

To assure the experts are independent and offer accurate information, consider the questions in Box 1:

Box 1: Screening Questions to Assess Technical Reviews

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, either 1) obtain the opinion of an independent technical expert, or 2) document the data used to reach the conclusion and how the data may have impacted your assessment.
2. Has the information used to assess technical feasibility been corroborated by at least two independent technical experts?
 - If no, obtain a review by independent technical experts.
 - If yes, proceed with the evaluation.

Questions to ask technical experts include:

1. 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 evaluation.
 - If no, continue with performance evaluation.
- If no, can the technical feasibility be determined through other means? As indicated in the ECHA Guidance ([see Appendix](#)), a performance scale may be necessary for each of the performance measures. If a performance scale is used, it must be based on objective characteristics that can be measured and documented.
 - If yes, conduct evaluation and determine if alternative is technically favorable. Document information used to reach the conclusion. Proceed with evaluation.
 - If no, identify the alternative as not technically viable or proceed to the next level.

2. Would use of the alternative(s) have an 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?
 - If yes to any of the above, are there known modifications that could mitigate these impacts?
 - If yes, test the modifications against performance requirements. Document the conclusions of the tests and determine if any affect the performance of the product when the alternative is used. Continue evaluation.
 - 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. Evaluation complete.
 - If no, document the information used to reach the conclusion. Continue evaluation.
 - If no, consider the alternative as a technically favorable based on performance. Document information used to reach the conclusion. Continue evaluation.

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). 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.

Assessment of the alternative's performance feasibility is made using the 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 evaluation.
 - If yes, does the alternative(s) pass the thresholds according to the test protocols?
 - If yes, the alternative is technically favorable. Proceed with product/process design/development using the alternative. Continue evaluation.
 - If no, can the product or process design be modified to accommodate the alternative?
 - If yes, proceed with modifications and product/process design/development and validate the results. Continue 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?
 - If yes, proceed with product/process development using the alternative 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 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 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.

Appendix

Excerpt from [ECHA Guidance](#):³⁵

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.

³⁵ 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](#)³⁶):

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.

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.

³⁶ Based on the US EPA document: US Environmental Protection Agency: Cleaner Technologies Substitutes Assessment - Office of Pollution Prevention and Toxics Washington, DC 20460 EPA Grant X821-543

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](#)).³⁷

1. Review functional requirements of 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.

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³⁷ Based on the US EPA document: *Flexographic Ink Options: A Cleaner Technologies Substitutes Assessment*, EPA Design for the Environment Program, February 2002, EPA 744-R-02-001A, accessed 2/2013.

In the first instance, the evaluation would rely on compiling the 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

Purpose

This module evaluates the cost and availability of potential alternatives in the AA process. Many alternatives that appear feasible may either be cost prohibitive or not available in sufficient quantities to remain a favorable alternative. Any alternative that can't be found both in sufficient amounts and adequate quantities should be identified and potentially eliminated from consideration as a favorable alternative.

Not only should the immediate cost of a chemical or material be considered but also the cost of chemicals in the product (e.g., if the alternative allows for or results in a product redesign, which causes the cost to be at least comparable at the product level) and over the product's life cycle, including those "externalities" that may become "internalized." Economies of scale should be evaluated and used to determine whether or not a chemical that is not currently manufactured in sufficient amounts or is too costly to be favorable *could* be produced in sufficient amounts or at a lower cost if demand increased. An alternative should not be eliminated solely because it is currently unavailable at sufficient quantities or at too high of a cost when, if demand increased, it could be produced at both an amount and cost to compete with the chemical of concern.

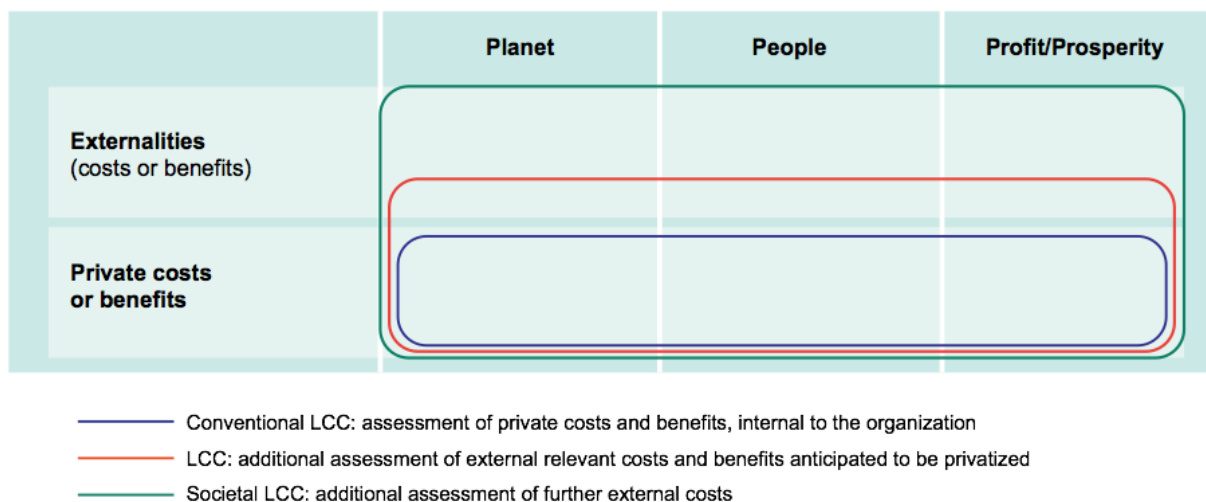
A frequently used example of where cost and availability can prove prohibitive is when an alternative is prohibitively expensive or rare and there are no opportunities to mitigate the cost and availability concerns through recycling, restricting use, etc. In these instances when looking solely at hazard and exposure, the alternative could appear to be favorable from the risk perspective; however, when cost and availability are included in the evaluation process, the prohibitively high cost or limited availability and inability to address these concerns remove the alternative from consideration.

In other cases, a more expensive chemical or material alternative may result in a product redesign that is cost competitive at the product level. Some chemicals, materials, or product redesigns may result in net cost decreases or benefits over the life cycle of the product. Costs and benefits initially external to the decision may become privatized by regulations or by societal demand. Examples include take-back of electronic products, bottle recycling bills, or fees associated with disposal costs to consumers or communities.

The first level of this module considers only cost and availability of the actual alternative while later levels include the complete cost, including externalized costs not included in typical cost evaluations. For example, higher levels consider life cycle impacts on cost and

availability. The full cost to society for manufacture, transport, use, and disposal of a particular product is considered in the [Life cycle 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 life cycle perspective ([Figure 15](#)).

Figure 15: [Consideration of Life Cycle Costs](#)³⁸



Externalities refer to costs or benefits directly or indirectly created by a product and 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 (i.e., users or local governments) for proper disposal. Health costs are an example of externalities that have received considerable attention. Health costs associated with lead are well-documented and can be quantified. Health costs associated with poorly documented chemicals must be estimated through the use of surrogates or models. When in doubt, an environmental and health economics expert should be consulted. LCC has been used in building design to consider internal and external costs. LCC application to broader product environmental and social externalities is more recent.³⁹

The following identifies the specific life cycle concerns associated with LCC. [More details can be found in the Life Cycle Module.](#)

Impacts Associated with Life Cycle Costing

Human Health and Environmental

³⁸ United Nations Environment Programme, *Towards a Life Cycle Sustainability Assessment*, 2011, 86 pages.

³⁹ Ibid.

These impacts 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 of externalities associated with emissions from raw material extraction or processing and from the transport, storage, use, and disposal of chemical or materials. Information on the quantity of associated emissions may be available. However, for the purposes of the life cycle, more analysis might be useful. The quantity of use or emissions and the severity of the impacts associated with these quantities are important. For example, it is important to assess how many people are exposed or if some groups of people are exposed more than others, or if certain environmental sectors are impacted more than others.

Economic

These 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. Economic impacts to society are covered under “human health and environmental impacts.” 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. The production of alternatives is likely to induce business opportunities, which should be included in the analysis of wider economic impacts.

Social

These 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. Issues of environmental justice are addressed in the [Social Impact Module](#).

This module establishes four levels and an advanced review ([Table 9](#)), ranging from a simple assessment of chemical cost and availability to combined chemical and material cost and availability and overall cost of product redesigned. A full cost/benefit analysis is included in the [Life Cycle Module](#).

Table 9: Four Levels and Advanced Review within a Cost and Availability Assessment

Level 1	<i>Basic Cost and Availability Evaluation:</i> 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	<i>Extended Basic Cost and Availability Evaluation:</i> This evaluation builds upon the information obtained in Level 1 to determine if the alternative is both available and

	cost effective. This evaluation goes beyond whether or not the alternative is currently being used to determine if it could be available and cost effective if selected.
Level 3	<i>Chemical and Material Cost and Availability Evaluation:</i> This evaluation expands upon the previous level to include not only the cost and availability of the chemical but also the material in which it will be used. It also introduces LCC and requires an initial review of possible impacts due to LCC.
Level 4	<i>Chemical, Material and Re-designed Cost and Availability Evaluation:</i> This level adds requirements 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 LCC evaluation.
Advanced (see LC Module, Level 3)	<i>Full Cost/Benefit Analysis Evaluation:</i> This level implements a full cost/benefit analysis and a more detailed LCC evaluation including externalities as appropriate. It is the most complete and comprehensive evaluation of cost and available considerations.

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. Expected assessors include small, medium, and large businesses, regulatory agencies, non-governmental organizations, etc. Depending upon the decision methodology used, different module levels can be used either for different assessments or within different stages of the same assessment. More information on how the cost and availability module may be used in combination with the other modules can be found in [Frameworks](#).

An important component of all modules is 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.

Level 1: Basic Cost and Availability Evaluation

This level conducts a limited cost and availability evaluation of the available alternatives and factors these results into the AA. It requires only limited knowledge and expertise by the AA assessor. The assessor determines if the alternative is currently being used in cost-effective products. If an alternative meets the requirements of this review, it is a favorable alternative. No further evaluation is required.

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.

-
2. Is the alternative currently offered for sale for the application of interest? Is the price of the alternative close to the current? Identify information sources used to reach the conclusion.

If the answer to either question is positive, the alternative is considered favorable for both cost and availability and the AA process continues.

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.⁴⁰

Level 2: Extended Cost and Availability Evaluation

This level expands on the cost and availability evaluation of alternatives compared to the chemical of concern and factors the information into the AA. The approach will depend on the level of knowledge and expertise of the assessors evaluating the chemical, product, or process. An internal evaluation determines how cost and availability might affect a comparison between the chemical of concern and potential alternatives.

The first step is to determine alternatives currently on the market and their cost and availability based on information readily available for a cost comparison. 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.

Step two is to identify the cost and potential availability of all alternatives, identify all supply sources involved and prices and availability of the alternatives from different sources and compare each alternative against the current chemical, product, or process. The following questions guide this process:

1. Is the alternative being offered for sale for the application of interest?
 - If yes, document prices quoted by suppliers for alternative. Continue evaluation.
 - If no, document information used to reach the conclusion. Continue evaluation.

⁴⁰ *pers. comm.*, Alex Stone, Washington Department of Ecology, January 14, 2013.

-
2. Is the price of the alternative close to the current chemical? Identify what sources of information to reach the conclusion.
 - If yes, can chemical of concern be replaced with alternative while maintaining cost effectiveness?
 - If yes, the alternative is favorable.
 - If no, continue evaluation.
 - If no, can price of the alternative chemical be reduced if alternative production increases?
 - If yes, the alternative is favorable.
 - If no, continue evaluation.

 3. Is the alternative currently being used for the application of interest? Identify what sources of information to reach the conclusion.
 - If yes, is the price of the product containing the alternative competitive with the price of the product containing the chemical of concern?
 - If yes, the alternative is favorable.
 - If no, continue 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 evaluation.

 4. Is the alternative being produced in sufficient quantity to meet demand if alternative is used in place of chemical of concern? Identify sources of information that 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 evaluation.
 - If no, can the price of the alternative be reduced if the purchased amount of the alternative increases?
 - If yes, if demand continues to rise, is the price forecasted to increase or supply decrease to produce unacceptable conditions for long-term use of the alternative?
 - If yes, document the information used to reach the conclusion. Identify the alternative as non-favorable for this round of evaluation.
 - If no, identify the alternative as favorable. Continue evaluation.
 - If no, document the reasoning used to reach the conclusion. 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 decabromodiphenyl ether \(Deca-BDE\) 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, the Toxics Use Reduction Institute (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 (DEHP). 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. An evaluation of cost and availability was an integral part of the assessment.

Level 3: Chemical and Material Cost and Availability Evaluation

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.

These types of evaluations require a broader perspective of how the alternative could possibly be used and evaluates more than simple cost and availability of a drop-in alternative. In addition, a final mitigation review is added to determine if there are any other possible steps that can be taken to eliminate potential limitations. The approach used will depend on the level of knowledge and expertise of the individuals assessing the chemical, product, or process.

The initial step is to determine cost and availability from readily available sources used in the previous two levels. In addition to this review, however, it is necessary to work with technical experts to evaluate the materials used to determine if changes can be made that will increase the viability of the alternative.

Identify the cost and potential availability of the (all) alternative(s). Identify all suppliers involved along with prices and availability of the alternative from different sources. During this assessment process, the following questions will assist this process:

1. Is the alternative being offered for sale for the application of interest? Identify what sources of information to reach the conclusion.
 - If yes, can chemical of concern be replaced with alternative while maintaining cost effectiveness?
 - If yes, document information used to reach the conclusion and identify alternative as favorable.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, can the price of the alternative be reduced if the production of the alternative increases?
 - If yes, document information to reach the conclusion and identify alternative as favorable.
 - If no, document information used to reach the conclusion. Continue evaluation.

2. Is the alternative currently being used for the application of interest? Identify what sources of information to reach the conclusion.
 - If yes, is the price of the product containing the alternative competitive with the price of the product containing the chemical of concern?
 - If yes, document information to reach the conclusion and identify alternative as favorable.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, is the price difference prohibitive?
 - If yes, document reasoning used to reach the conclusion. Identify the alternative as non-favorable for this round of evaluation.
 - If no, document information used to reach the conclusion. Continue evaluation.

3. Is the alternative being produced in sufficient quantity to meet the demand if the alternative is used in place of the chemical of concern? Identify what sources of information to reach the conclusion.
 - If yes, can the chemical of concern be replaced with the alternative while maintaining cost effectiveness?

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- If yes, document information to reach the conclusion and identify alternative as favorable.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, can price of the alternative potentially be reduced if the purchased amount increases?
 - If yes, document information to reach the conclusion and identify alternative as favorable.
 - If no, document information used to reach the conclusion. Continue evaluation.
4. Can changes be made to the material to affect the overall cost of the product? Identify what sources of information to reach the conclusion.
- If yes, is the overall cost of the material incorporating the alternative equal to or less than the current comparable material and chemical of concern?
 - If yes, document information to reach the conclusion and identify alternative as favorable.
 - If no, document the reasoning used to reach the conclusion and bin the alternative as non-favorable for this round of evaluation.
 - If no, document the reasoning used to reach the conclusion and bin the alternative as non-favorable for this round of evaluation.
5. Are there substantive increases or decreases 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 will be based on an analysis of readily available technical information accessible to the general assessor. The reasoning for inclusion or exclusion of the LCC components must be explained in the final AA report.
- If yes, the LCC component 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 life cycle costing.
 - If no, note that LCC is not a limiting factor and document the information used to reach the conclusion. Continue evaluation process.
6. 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, setting volume and price for defined period, 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 general assessor.

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- If yes, note that the specific cost and availability component is not a limiting factor and document the information used to reach the conclusion. Continue 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 component and continue with the life cycle evaluation process until all life cycle components have been evaluated.

Level 4: Chemical, Material, and Re-designed Cost and Availability Evaluation

This level builds upon the previous levels. In addition to evaluating readily available information on cost and availability and an evaluation of possible changes to the material used, this level evaluates possible changes to product design that can eliminate potential limitations. By altering the product design to better incorporate the alternative, do the combine costs and availability of all product components change to make the alternative more appealing?

For example, an alternative may not be cost effective because its use in a product would require the addition of a much larger amount; however, if the product was re-designed, the amount of the alternative used would be equal to or less than the original toxic chemical now making it cost effective. These evaluations take a broader, whole product perspective to determine if changes at the product level could make the alternative more favorable. In addition, a final mitigation review is added to determine if there are any other possible steps to eliminate potential limitations. The approach will depend on the level of knowledge and expertise of the individuals assessing the chemical, product, or process.

The initial step is to determine cost and availability from readily available sources and evaluation of material changes as shown in the previous three levels. In addition to this review, however, 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.

Identify the cost and potential availability of the (all) alternative(s). Identify all supply sources involved, prices, and availability of the alternative from different sources. During this assessment process, the following questions will be asked and answered:

1. Is the alternative being offered for sale for the application of interest? Identify what sources of information to reach the conclusion.
 - If yes, can chemical of concern be replaced with alternative while maintaining cost effectiveness?

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- If yes, document information to reach the conclusion and identify alternative as favorable.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, can the price of alternative be reduced if the alternative production increases?
 - If yes, document information to reach the conclusion and identify alternative as favorable.
 - If no, document information used to reach the conclusion. Continue evaluation.
2. Is the alternative currently being used for the application of interest? Identify what sources of information to reach the conclusion.
- If yes, is the product containing the alternative price competitive with the product containing the chemical of concern?
 - If yes, document information to reach the conclusion and identify alternative as favorable.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, is the price difference prohibitive?
 - If yes, document reasoning used to reach the conclusion. Identify alternative as non-favorable for this round of evaluation.
 - If no, continue evaluation.
3. Is the alternative being produced in sufficient quantity to meet the demand if the alternative is used in place of the chemical of concern? Identify what sources of information to reach the conclusion.
- If yes, can the chemical of concern be replaced with the alternative while maintaining cost effectiveness?
 - If yes, document information to reach the conclusion and identify alternative as favorable.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, can the price of the alternative potentially be reduced if the amount of the alternative purchased increases?
 - If yes, document information to reach the conclusion and identify alternative as favorable.
 - If no, document information used to reach the conclusion. Continue evaluation.
4. Can changes be made to the material to potentially affect the overall cost of the product? Identify what sources of information to reach the conclusion.
- If yes, is the overall cost of the material incorporating the alternative less than the current comparable material and chemical of concern?

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- If yes, document information to reach the conclusion and identify alternative as favorable.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, document the concern. Continue evaluation.
5. Can changes be made to the overall product design to potentially affect the cost of the product? Identify what sources of information to reach the conclusion.
- If yes, is the overall cost of the redesigned product competitive with the current comparable product containing the chemical of concern?
 - If yes, document information to reach the conclusion and identify alternative as favorable.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, continue evaluation.
6. Are there other steps that can be taken to make the alternative cost effective or that make the re-designed product 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 to reach the conclusion and identify alternative as favorable.
 - If no, document the reasoning used to reach the conclusion. Identify the alternative as non-favorable for this round of evaluation. Evaluate all other alternatives.
7. 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 will be based on an evaluation of detailed technical information available or test data completed by experts. The reasoning for inclusion or exclusion of the LCC components must be explained in the final AA report.
- If yes, the LCC component 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 LCC. Continue evaluation.
 - If no, note that LCC is not a limiting factor and document the information used to reach the conclusion. Continue evaluation process.
8. 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 setting volume and price for defined period, 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 general assessor.

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- If yes, note that the specific cost and availability component is not a limiting factor and document the information used to reach the conclusion. Continue evaluation process until all negative cost and availability impacts have been evaluated to determine if mitigation is possible.
 - If no, document information used to reach the conclusion and bin the alternative as potentially warranting more review for this life cycle component and continue with the life cycle evaluation process until all life cycle components have been evaluated.

Advanced: Full Cost/Benefit Analysis Evaluation

This level results in the most complete and detailed evaluation of cost and availability information using traditional cost benefit analysis (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 in order to reduce risk. The selection of alternatives having the lowest hazard prior to the assessment of exposure allows the assessor to be confident the risk is reduced even if the exposure level increases at a later date. Additionally, an alternative with a low hazard but a higher exposure could have a means to reduce the exposure found for it. In this case, if the exposure was reviewed first, that alternative would have been deemed unfavorable prior to the realization of the reduced hazard level for it. Therefore, by applying hazard screening first, options are identified that are more likely to be favorable.

Exposure assessment can support selection of alternatives *when the inherent hazards are equivalent, for example when the functional use of one alternative would result in increased risk due to the quality and quantity of the resulting exposure (exposure profile)*. Not all alternatives will result in the same exposure scenarios. Both near field (direct consumer) and far field (environmental) exposures are considered. The exposure module may also be used independently of the other modules and applied to all options depending upon which framework is selected for data evaluation. This is particularly true if the Sequential Framework is selected but may not be applicable if the other two are chosen.

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 are integrated into the AA Guide and 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 personal protective equipment (PPE) are frequently

used in the work environment. They may be inexpensive in the short term but costly over time.

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. This module consists of an Initial Screen, Three Levels and an Advanced Approach ([Table 10](#)).

Table 10: An Initial Screen, Three Levels and an Advanced Approach for Exposure Assessment

Initial Screen	<i>Initial Exposure Assessment Evaluation:</i> Identifies whether sufficient similarities exist between the chemical of concern and potential alternative(s), such that an exposure assessment is not necessary. If so, differences in exposure concerns between the chemical of concern and potential alternatives are inconsequential to the AA.
Level 1	<i>Basic Exposure Evaluation:</i> Identifies potential exposures concerns along with how the concerns may be addressed. Decisions in this level are based upon a qualitative assessment using readily available data.
Level 2	<i>Expanded Exposure Evaluation:</i> Builds on the previous level by increasing the quality and quantity of information. More detailed quantitative data is required to evaluate the importance of exposure in the AA process.
Level 3	<i>Detailed Exposure Evaluation:</i> This level builds on previous levels and requires detailed scientific studies as the basis for decisions. If these studies are not available, they are conducted and the data used to determine the importance of exposure in the AA process.
Advanced	<i>Full Exposure Assessment:</i> This level requires a complete and detailed exposure assessment as defined in the Risk Assessment Process by the National Academy of Sciences.

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. Depending on the decision methodology used, different module levels can be used either for different assessments or within different stages of the same assessment. More information on how the Exposure Assessment Module may be used in combination with the other modules can be found in the Framework Module.

An important component of all modules is 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 decision or assumptions should be identified.

Initial Screen

The initial screen determines if the exposure pathways and potentials are similar enough between the chemical of concern and potential alternatives that no further exposure evaluation is necessary. If the screen determines no exposure assessment is necessary, the assessor should evaluate this decision throughout the AA process to guarantee that no other subsequent decisions affect this assumption.

1. Compare exposure pathways between the chemical of concern and alternative.
 - Are the exposure pathways similar? For example, are the chemical properties for the chemical of concern and alternative similar for any of the following characteristics? Only evaluate pertinent criteria for the alternatives.
 - Volatility/vapor pressure
 - Molecular weight
 - Molecular size
 - Solubility
 - Log K_{ow} ⁴¹
 - Boiling point
 - Melting point
 - Density/specific gravity
 - pH
 - Corrosivity
 - Dissociation constant
 - Use characteristics (binding properties) or synergistic effects
 - Other

⁴¹ Log of the octanol water partition coefficient which evaluates a chemicals tendency to dissolve either in water or organic solvents.

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2. Compare the manufacturing criteria for the chemical of concern and alternative.
 - Are the manufacturing criteria similar?⁴² 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.
 - 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?
 3. Compare the fate, transport, and partitioning in environmental media for the chemical of concern and alternative.
 - Are the fate, transport, and partitioning in environmental media similar? For example, are the manufacturing criteria for the chemical of concern and alternative similar for any of the following media with regards to fate, transport, and partitioning characteristics? Only evaluate pertinent criteria for alternatives.
 - Air
 - Water
 - Sediment/soil
 4. Compare the release mechanisms for the chemical of concern and the potential alternative.
 - Are the release mechanisms similar during the different life cycle phases? For example, are the release mechanisms for the chemical of concern and the alternative likely to be similar for any of the following life cycle characteristics? Only evaluate pertinent criteria for alternatives.
 - Product
 - Manufacturing
 - Transport
 - End-of-life

Many examples exist that demonstrate the importance of asking these questions. One recent example is the replacement of one plasticizer 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? Another example is the replacement of a halogenated flame retardant with another, safer flame retardant. The new flame retardant is used in the same amounts, in the same

⁴² More information on manufacturing criteria is available in the Performance Evaluation Module.

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?

5. Based upon the above evaluation, are there any substantive differences between the use and physical characteristics that could affect exposure?
 - If no, exposure assessment complete. Identify that uses, fate and transport, and potential exposure pathways are similar and exposure concerns become irrelevant.
 - If yes, continue with the exposure assessment.
6. Have you assessed the chemical options for hazard?
 - If no, start with Level 1.
 - If yes, has the alternative been fully assessed and been defined as inherently benign for all hazard criteria (i.e., GS Benchmark 4)?
 - If yes, a full exposure assessment is not necessary. Document the information used to reach the conclusion. Exposure assessment complete.
 - Engineering controls and proper risk management should always be applied (the dose makes the poison, even water can kill you!).
 - If no, continue evaluation.
7. Could the alternative pose a risk based on its physical and biological hazard characteristics? To what extent is the product designed to avoid such risks?
 - Inhalation (dust, oxygen displacement)
 - Temperature
 - Electrocution
 - Mold
 - Entrapment

Level 1: Basic Exposure Evaluation

Level 1 evaluates specific exposure concerns using readily available qualitative data to the general assessor. Specifically, alternatives found in monitoring studies, that are persistent, bioaccumulative and/or toxic or that pose a substantial exposure concern are eliminated from consideration. However, alternatives that have potential mitigation efforts may still be considered.

Level 1 Process:

1. Consider the presence of the alternative in monitoring studies:

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- Has the alternative been found in bio- or environmental monitoring studies?⁴³
 - If yes, classify it as a non-favorable alternative 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. For this simplified initial evaluation, presence in monitoring studies is assumed to be a concern.
 - 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 serious data gap that may affect the alternative's viability as a safer alternative. Eliminate the alternative from consideration.
2. Consider the alternative's presence in the product. *Qualitatively*, what are the pathways of exposure during manufacture, transportation, and/or storage, use, end-of-life, etc.?
- Are any a substantial exposure pathway?
 - If yes, identify the exposure pathway 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 pathways?
 - If yes, document information used to reach the conclusion and identify exposure is not a concern for the alternative(s) being evaluated. Continue evaluation.
 - If no, identify exposure as a serious data gap that may affect the alternative's viability as a safer alternative. Proceed to question #5.
3. Consider the persistence, bioaccumulative, and toxic properties of the alternative.
- Have you screened the alternative for persistence, bioaccumulative, and toxic properties based on risk and hazard phrases ([Level 1 of Hazard Module](#))?
 - If yes, highly persistent and/or highly bioaccumulative and/or toxic alternatives (vPvB, vPT, vBT, PBT) should be removed from consideration.
 - If no, screen the alternative using hazard lists and risk or hazard phrases as defined in Level 1 of the Hazard Module. Based upon this review, does the alternative have persistence, bioaccumulative, and/or toxic properties of concern?
 - If yes, note the information used to reach the conclusion and proceed to question #5. Highly persistent and/or highly bioaccumulative and/or toxic chemicals (vPvB, vPT, vBT, PBT) are removed from consideration.
 - If no, document information used to reach the conclusion. Continue evaluation.
4. Consider other inherent chemical properties of the alternative relevant to exposure.

⁴³ See Exposure Module Resources

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- Does the alternative have properties that contribute to exposure? For example, is it very water soluble, does it volatilize readily into the air, is it easily inhaled or ingested, is it likely to escape into the indoor or outdoor environment (refer to [Appendix⁴⁴](#)), etc.?
 - If yes, are these properties likely to increase exposure beyond acceptable levels?
 - If yes, document information used to reach the conclusion and proceed to question #5.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, document information used to reach the conclusion. Continue evaluation.
5. Consider mitigation of potential problems.
- Have steps been taken during the design and manufacture of the product 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 and volatilization?
 - If yes, document mitigation activities and identify the alternative as favorable.
 - If no, document information used to reach the conclusion and bin alternative as unfavorable.

Level 2: Expanded Exposure Evaluation

Level 2 builds upon information in the previous level and asks additional specific questions related to exposure. It uses more detailed quantitative information to assess the potential exposure impacts of replacing a chemical of concern with a safer alternative.

1. Consider the presence of the alternative in monitoring studies:
 - Has the alternative been found in bio- or environmental monitoring studies?⁴⁵
 - If yes, what are the levels at which it is found, how broadly is it found in humans and in the environment, has it been found in sensitive populations, or are there known hazards associated with this alternative (See [Level 3 of Hazard Module](#))? Based on this information, is the alternative an exposure concern?
 - If yes, how do the levels compare to toxicity thresholds for the spectrum of hazard endpoints in an AA? How do they compare to ambient levels? How do these levels compare to levels with known adverse effects, particularly for sensitive populations? Are any of these issues a concern?

⁴⁴ See Appendix: Examples of Exposure Pathways and Chemical Properties that May Enhance Exposure

⁴⁵ See Exposure Module Resources

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- 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 #6.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, document information used to reach the conclusion. Continue 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 evaluation.
 - If no, identify exposure as a serious data gap that may affect the alternative's viability as a safer alternative. Eliminate the alternative from consideration.
2. Consider the alternative's presence in the product. What data are available to evaluate exposure during manufacture, transportation, and/or storage of the alternative or the product, use of the product or end-of-life?
- Have worker, user or environmental exposures to the alternative been reported or measured during manufacture, transportation, and/or storage, use, or end-of-life?
 - If yes, do these levels pose a potential threat?
 - If yes, document information used to reach the conclusion and proceed to question #6.
 - If no, continue evaluation.
 - If no, are there adequate data including data in the appropriate hazard category to support the conclusion alternative does not pose an exposure concern for any 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 #6.
3. Consider the quantity of the alternative involved.
- What quantity is used during manufacture of product, in product as it is used, released after use or at end-of-life, etc.? Do differences in quantity affect the exposure at any of those stages?
 - If yes, does the increase in quantity used pose a potential exposure threat?
 - If yes, document information used to reach the conclusion and proceed to question #6.

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- If no, continue 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 #6.
4. Consider the persistence, bioaccumulative, and toxic properties of the alternative.
- Has the alternative been screened for persistence, bioaccumulative, and toxic properties based on risk and hazard phrases ([Level 1 of Hazard Module](#))?
 - If yes, highly persistent and/or highly bioaccumulative and/or toxic alternatives (vPvB, vPT, vBT, PBT) should be removed from consideration.
 - If no, screen the alternative using hazard lists and risk or hazard phrases as defined in Level 1 of the Hazard Module. Based on this review, does the alternative have persistence, bioaccumulative, and/or toxic properties of concern?
 - If yes, note the information used to reach the conclusion and proceed to question #6. Highly persistent and/or highly bioaccumulative and/or toxic chemicals (vPvB, vPT, vBT, PBT) are removed from consideration.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - Using estimated or measured data ([Level 1 of Hazard Module](#)), is the persistence and bioaccumulation a concern?
 - If yes, document information used to reach the conclusion and eliminate the alternative from consideration.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - Using reviews of scientific literature, test data, and public data repositories ([Level 2 of Hazard Module](#)), are persistence, bioaccumulative, or toxic properties a concern?
 - If yes, document information used to reach the conclusion and proceed to question #6.
 - If no, document information used to reach the conclusion. Continue evaluation.
5. Consider other inherent chemical properties of the alternative relevant to exposure.
- Does the alternative have properties that contribute to exposure? For example, is it very water soluble, does it volatilize readily into the air, is it easily inhaled or ingested, is it likely to escape into the indoor or outdoor environment (refer to [Appendix](#)⁴⁶), etc.?

⁴⁶ See [Appendix: Examples of Exposure Pathways and Chemical Properties that May Enhance Exposure](#)

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- If yes, will these properties increase alternative exposure to beyond acceptable levels?
 - If yes, document information used to reach the conclusion and proceed to question #6.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, document information used to reach the conclusion. Continue 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 information used to reach the conclusion and proceed to question #6.
 - If no, document information used to reach the conclusion. Continue evaluation.
6. Consider redesign options using the alternative.
- Can the product be redesigned to reduce exposure during manufacture, transportation, and/or storage, use and end-of-life? Does redesign affect type or extent of exposure or quantity used?
 - If yes, does it allow for elimination, substitution, or reduction in use or do changes in quantity affect the exposure?
 - If yes, document information used to reach the conclusion. Continue evaluation.
 - If no, document information used to reach the conclusion and proceed to question #6.
 - If no, proceed to question #6.
7. 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 bin alternative as favorable based on exposure evaluation.
 - If no, document information used to reach the conclusion and bin alternative as unfavorable. Evaluation complete.

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. If important data is lacking, validated studies are conducted to fill in any data gaps.

1. Consider the presence of the alternative in monitoring studies:⁴⁷
 - 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 #7.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, document information used to reach the conclusion. Continue 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 evaluation.
 - If no, identify exposure as a serious data gap that may affect the alternative's viability as a safer alternative. Eliminate the alternative from consideration.
2. Consider 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?

⁴⁷ See [Exposure Assessment Module Resources](#)

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- If yes, document information used to reach the conclusion and proceed to question #7.
 - If no, continue evaluation.
 - If no, are there adequate data to support that the alternative 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 #7.
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 information used to reach the conclusion and continue with evaluation.
 - If no, continue 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 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 #7.
4. Consider the persistence, bioaccumulative, and toxic properties of the alternative.
- Have you screened the alternative for persistence, bioaccumulative, and toxic properties based on risk and hazard phrases ([Level 1 of Hazard Module](#))?
 - If yes, highly persistent and/or highly bioaccumulative and/or toxic alternatives (vPvB, vPT, vBT, PBT) should be removed from consideration.
 - If no, screen the alternative using hazard lists and risk or hazard phrases as defined in Level 1 of the Hazard Module. Based upon this review, does the alternative have persistence, bioaccumulative, and/or toxic properties of concern?
 - If yes, note the information used to reach the conclusion and proceed to question #7. Highly persistent and/or highly bioaccumulative and/or toxic chemicals (vPvB, vPT, vBT, PBT) are removed from consideration.
 - If no, document information used to reach the conclusion. Continue evaluation.

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- Using estimated or measured data ([Level 2 of Hazard Module](#)), are persistence, bioaccumulation, or toxicity a concern?
 - If yes, document information used to reach the conclusion and bin alternative as unfavorable.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - Using reviews of scientific literature, test data, and public data repositories ([Level 2 of Hazard Module](#)), are persistence, bioaccumulative, or toxic properties a concern? Have the data been reviewed by technical experts or peer reviewers to authenticate its quality?
 - If yes, are the data determined to be of good quality and scientifically sound?
 - If yes, document information used to reach the conclusion and proceed to question #7.
 - If no, supplement data gaps with analytical data from scientific studies. Once the studies are complete, return to the beginning of question #4.
 - If no, have the data reviewed by technical experts. Once the review is complete, return to the beginning of question #4.
5. Consider other inherent chemical properties of the alternative that are relevant to exposure.
- Does the alternative have properties that contribute to exposure? For example, is it very water soluble, does it volatilize readily into the air, is it easily inhaled or ingested, is it likely to escape into the indoor or outdoor environment (refer to [Appendix](#)⁴⁸), etc.?
 - If yes, are these properties likely to increase exposure beyond acceptable levels?
 - If yes, document information used to reach the conclusion and proceed to question #7.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, document information used to reach the conclusion. Continue 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 information used to reach the conclusion and proceed to question #7.
 - If no, document information used to reach the conclusion. Continue evaluation.
6. Consider exposure scenarios.

⁴⁸ See [Appendix: Examples of Exposure Pathways and Chemical Properties that May Enhance Exposure](#)

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- 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 information used to reach the conclusion and proceed to question #7.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, conduct exposure scenarios. Once scenarios are complete, return to question #6.
 - Have potential exposure scenarios for populations that may have a greater sensitivity to the alternative (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 information used to reach the conclusion and proceed to question #7.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, conduct exposure scenarios. Once scenarios are complete, return to question #6.
 - 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 information used to reach the conclusion and proceed to question #7.
 - If no, document information used to reach the conclusion. Continue evaluation.
 - If no, conduct exposure scenarios. Once scenarios are complete, return to question #6.
7. Consider redesign options using the alternative.
- 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 information used to reach the conclusion. Continue evaluation.
 - If no, document information used to reach the conclusion and proceed to question #8.

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- If no, proceed to question #8.

8. 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 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.

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
 - Ingestion
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
5. Products intended for use on skin.
6. Products that have the potential to be in contact with skin.
7. Water used for washing/cleaning.
 - A. Injection
8. Products for use in medical treatment.
9. Products for cosmetic use (e.g., tattoos).
10. Presence in the environment and in living organisms.
 - A. Biomonitoring
 - B. Environmental monitoring

11. Inherent properties of the chemical including:

- A. Persistence
- B. Bioaccumulation potential
- C. Volatility
- D. Particle size and shape
- E. Bioavailable
- F. Other

From [ECHA guidance](#)⁴⁹

Exposure Assessment

Exposure assessment aims to make a quantitative or qualitative estimate of the dose / concentration of the substance to which humans and the environment are or may be exposed.

Exposure assessment under REACH consists of two steps:

1. *Development of Exposure Scenarios.*
2. *Exposure Estimation, which have to be iterated until it can be concluded that the resulting exposure scenarios would ensure adequate control of risks upon implementation.*

Exposure scenario

Set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life cycle and how the manufacturer or importer controls, or recommends downstream users to control exposure of humans and the environment.

Run through module considering alternatives that are:

- Completely low hazard (e. g., Benchmark 4)
- Mixed hazard
- High hazard
- What has been done to address exposure?
- Use scenarios and exposure estimates over the life cycle.

⁴⁹ European Chemical Agency, *Guidance on Information Requirements and Chemical Safety Assessment Chapter R.20: Table of terms and abbreviations*, Version 1.1, November 2012, 15 pages.

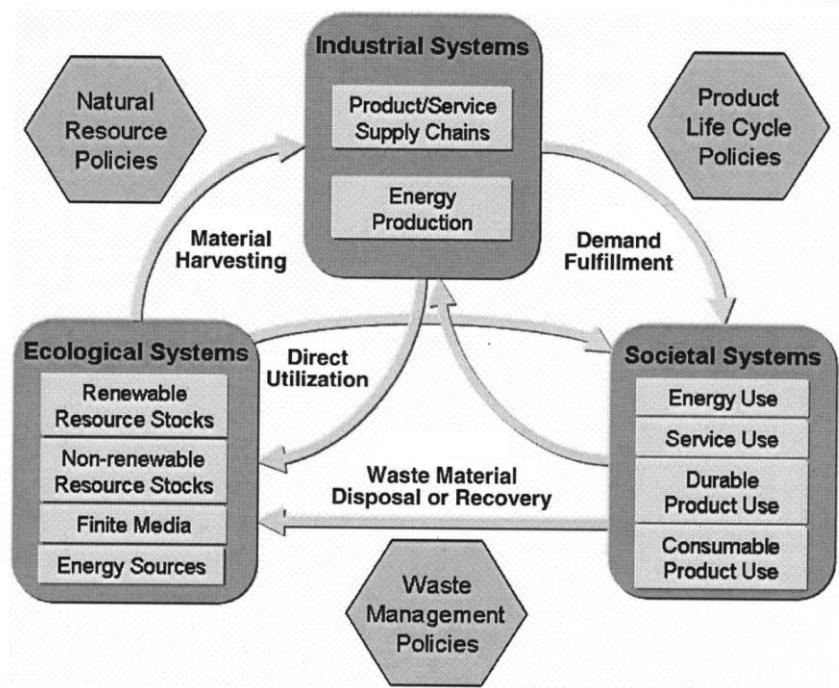
Materials Management Module

The Materials Management Module (M3) is recommended primarily for comparing alternatives at the level of the whole product and for products containing materials derived from very different sources. This module may not discriminate at the chemical substitution level.

The M3 helps practitioners consider how different options can impact natural resources and generation of both hazardous and non-hazardous waste, and to use the information to mitigate impacts to achieve sustainable materials management. Designing or redesigning products for material recovery and/or benign release into the environment can lead to systemic solutions. This module emphasizes alternatives that further the concept of “Cradle to Cradle”⁵⁰ design through materials management.

Materials management is a process that is directly connected to industrial, ecological, and societal systems. [Figure 16](#) demonstrates how materials flow among the three systems and how decisions in each can affect materials management.

Figure 16: [Mapping of Material Flows](#)⁵¹



⁵⁰ Braungart, Michael & William McDonough, *Cradle to Cradle: Remaking the Way We Make Things*, 2002.

⁵¹ Fiksel, J. (2006), A Framework for Sustainable Materials Management, *Journal of Materials (JOM)*, August 2006, pp.15- 22, accessed 12/2013.

Sustainable Materials Management (SMM) is a relatively new approach that represents a shift from waste management to materials management in support of sustainable development. Historically, governments have focused on managing wastes as a means of managing the impact of materials on the environment. While much success has been achieved with waste management policies, research has shown that waste management is often neither the key nor the most efficient and 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.

The Organisation for Economic Cooperation and Development (OECD) [defines 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.*”⁵²

[OECD policy principles for SMM](#) states that SMM preserves natural resources that are the source of raw materials needed to support life.⁵³ Natural resources include abiotic and biotic resources. Abiotic resources are non-living resources such as water, air, oil, coal, minerals, etc. Biotic sources are living resources such as trees, fish, animals, etc.

The OECD also established a set of Policy Principles for SMM. These include preserving natural capital and designing and managing materials, products, and processes for safety and sustainability from a life cycle perspective.⁵⁴

The U.S. Environmental Protection Agency (EPA) has developed an extensive SMM program with [four focus points](#):

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 be substituted for products.

The M3 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 impacts associated with the use of raw materials and wastes generated.

The goals of the M3 are based on the goals for SMM including:

1. Using sustainable raw materials:

⁵² OECD, *Sustainable Materials Management: Making Better Use of Resources*, OECD Publishing. 2012, p. 15.

⁵³ OECD, *Policy Principles for Sustainable Materials Management*, April 2011, 55 pages.

⁵⁴ IBID, p. 23.

- A. Less resource intensive materials. Some raw materials require fewer natural resources to produce, or have less impact on natural resources. For example, identical materials may be generated using innovative technology that reduces impacts upon resources and potentially provide other benefits.
 - B. Sustainably renewable or recyclable materials. Just because a material is renewable does not mean that it is being managed in a way that is “sustainable.” For example, trees are renewable resources. To provide evidence they are harvested sustainably, one might use wood certified by the [Forest Stewardship Council](#). Likewise, the use of recycled materials also requires stewardship and monitoring to ensure that the recycling occurs in a safe manner and that the resulting materials do not contain toxins from contaminated input.
2. Using fewer materials in products: Using a reduced amount of materials or using materials that have benign impacts in place of materials with negative impacts across the life cycle or substituting products with services (i.e., leasing models).
 3. Designing for value recovery: Materials in products designed to facilitate material recovery for reuse or recycling. Reuse or recycling may also 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 M3 incorporates these concepts into two Levels and an Advanced Option ([Table 11](#)):

Table 11: Two Levels and an Advanced Option within the M3

Level 1	<i>Basic Materials Management Evaluation:</i> Identify raw materials used and wastes generated after use by the baseline product and compare to those for the alternative(s). Consider opportunities to mitigate impacts to achieve sustainable materials management. Document information used and conclusions reached.
Level 2	<i>Extended Materials Management Evaluation:</i> Quantify raw materials used and wastes generated after use for the baseline product and compare to those for the alternative(s). Evaluate the impacts to prioritize those that may be mitigated. Consider and evaluate opportunities to mitigate impacts to achieve sustainable materials management. Document information and tools used and conclusions reached.
Advanced (See LCM, Level 3)	<i>Advanced Materials Management Evaluation:</i> Material Flow Analysis or best practices 1) from the International Organization for Standardization (ISO) 14040 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 1) to inventory the raw materials used, and 2) to inventory 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue evaluation.
 - Does the alternative use less raw materials?
 - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue evaluation.
 - Does the alternative use recycled materials?
 - If yes, document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue evaluation.
3. Based on the Initial Evaluation:
- 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue evaluation.
4. Develop a strategy to mitigate impacts from the choice of raw materials to support SMM. 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 the 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 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 evaluation.
5. Develop a strategy to mitigate impacts after product use to support SMM through (1) reuse/recycling or (2) design for degradation
- 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.

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- 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 most further the materials management objectives. Level 2 also helps 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 less raw materials?
 - If yes, quantify and document information used to reach the conclusion and identify the alternative as favorable for these considerations. Continue evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue evaluation.
 - Does the alternative use less 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.

-
- If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.
 - If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.
 - If no to any, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Continue 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 evaluation.

-
- If no, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Identify the concerns associated with the alternative and identify it as non-favorable for these 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, document the positives and negatives associated with the alternative along with the information used to reach these conclusions. Assessment complete.

Advanced Materials Management Evaluation

As an advanced inventory option, perform a full Material Flow Accounting (MFA) or a full Life cycle Assessment (LCA) 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.⁵⁵

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 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](#) provides 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”).

⁵⁵ Finnveden, Göran and Åsa Moberg, 2005, Environmental systems analysis tools – an overview, *Journal of Cleaner Production*, 13, 1165-1173.

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.

$$\text{TMR} = \text{DMI} + \text{I} + \text{uDE} + \text{iF}$$

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 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.

$$\text{DMI} = \text{domestic extraction (fossil fuels, minerals, biomass) + imports}$$

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.

$$\text{DMC} = \text{DMI} - \text{exports}$$

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 (GDP). 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 (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. MIPS 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 MIPS 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 (SFA) is similar to material flow analysis, except that the analysis focuses on substances instead of materials.

In general, a 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.

“Cradle to Cradle” Design or Equivalent

Resources exist that can help evaluate products from a “Cradle to Cradle” or equivalent perspective. The following are two examples of these resources and are not intended to represent the only information available.

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 ensures that the AA process does not result in unduly shifting a burden from one community of people to another. It requires the evaluation of impacts of an alternative upon the workers, communities, and societies involved in its extraction, manufacture, transport, use, and disposal.

Elements in the SIM may also be important components of other modules, already addressed. For example, workers are important stakeholders and their concerns should be addressed in the stakeholder module. Worker health and safety impacts are important components of hazard and exposure, which are addressed in those modules.

This module, however, draws attention to specific worker health and safety, 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. If these concerns have been adequately addressed elsewhere, there is no need to address them again in the SIM.

Tables 11, 12, and 13 list concerns in the areas of worker health and safety, communities, and global society. 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 12: 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 individual, synergistic or other 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	

<ul style="list-style-type: none"> • Generation of toxic wastes 	<ul style="list-style-type: none"> • Use of hazardous chemicals
<ul style="list-style-type: none"> • Product recycling, extraction of valuable resources and final disposition of wastes generated 	<ul style="list-style-type: none"> • Adequate training and hazard communication training
Financial	
<ul style="list-style-type: none"> • Compensation: overtime, lost time and wages 	<ul style="list-style-type: none"> • Pay equality • Part-time workers
<ul style="list-style-type: none"> • Number and quality of jobs 	<ul style="list-style-type: none"> • Educational level of workers

Table 13: Community Considerations Across the Product Life Cycle *(not exhaustive)*

Demographics	
<ul style="list-style-type: none"> • Quality of life including historical, cultural or religious priorities, etc. 	<ul style="list-style-type: none"> • Use of forced or child labor
Health	
<ul style="list-style-type: none"> • Quality of life including recreational activities 	<ul style="list-style-type: none"> • Communities over-burdened by pollution
<ul style="list-style-type: none"> • Sale of products banned in other, regulated areas in unregulated markets 	
Environment	
<ul style="list-style-type: none"> • Disproportionate impacts on ‘fenceline’ communities 	<ul style="list-style-type: none"> • Potential generation of toxic wastes or use of hazardous chemicals
<ul style="list-style-type: none"> • Impacts upon local water, air, land, etc. 	<ul style="list-style-type: none"> • Product recycling, extraction of valuable resources and final disposition of remains
Financial	
<ul style="list-style-type: none"> • Quality and type of jobs 	<ul style="list-style-type: none"> • Corruption
<ul style="list-style-type: none"> • Crime 	
Community	
<ul style="list-style-type: none"> • Establishment of partnerships with local, state, tribal and federal organizations to achieve healthy and sustainable communities • Product availability 	<ul style="list-style-type: none"> • Empowerment of communities to take action to improve their health and environment • Discrimination, harassment, intimidation or retaliation

Table 14: Global Societal Considerations Across the Product Life Cycle (not exhaustive)

Demographics	
<ul style="list-style-type: none"> • Use of forced or child labor 	
Health	
<ul style="list-style-type: none"> • Sale of products banned in other, regulated areas in unregulated markets 	<ul style="list-style-type: none"> • Changes to quality of life
Environment	
<ul style="list-style-type: none"> • Product recycling, extraction of valuable resources and final disposition of remains 	<ul style="list-style-type: none"> • Body burden of chemicals with unknown individual, synergistic or other impacts
Financial	
<ul style="list-style-type: none"> • Wealth of society 	
Global	
<ul style="list-style-type: none"> • Discrimination, harassment, intimidation or retaliation • Product availability 	<ul style="list-style-type: none"> • Contributes to unhealthy societies such as support of military actions, genocide, etc.

The above concerns may not cover all important issues for a comprehensive AA but should be considered as indicative of the types of concerns that might arise. Additional concerns may exist and should be addressed if important to the specific AA. The [Resources](#) section contains other issues that, although not included above, may be important to a specific assessment.

This module establishes three levels of assessment, beginning with a limited, qualitative evaluation, then increasing in detail and with an expansion of scope and an advanced option, a complete social life cycle assessment as outlined in the Life Cycle Module ([Table 16](#)).

Table 15: Three levels and an Advanced Option within the SIM

Level 1	<i>Basic Social Impact Evaluation:</i> Emphasizes impacts on a local level and includes an evaluation of social impacts on a broader scale using a qualitative approach based upon readily available information and a limited appraisal scope.
Level 2	<i>Extended Social Impact Evaluation:</i> Builds upon Level 1 and broadens the evaluation to require more detailed review of social impacts upon manufacturers in the supply chain. It also expands upon the evaluation of global societal impacts.
Level 3	<i>Detailed Social Impact Evaluation:</i> Builds upon Level 2 and broadens the evaluation to require more detailed review of all social impacts including local, supply chain, and global concerns.
Advanced (see LCM, Level 3)	<i>Full Social Life cycle Assessment Evaluation:</i> Conducts a full social life cycle assessment (SLCA) related to the alternative.

This module draws from the Environmental Justice, the United Nations Environment Programme (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 if social impact considerations can add weight, positive or negative, to the selection of an alternative. Expected assessors include small, medium, and large businesses, regulatory agencies, non-governmental organizations, etc. Depending upon the decision methodology, different module levels can be used either for different assessments or within different stages of the same assessment. More information on how the SIM can be used in combination with the other modules can be found in Frameworks.

All modules must state clearly what assumptions were made during the evaluation of social impacts and how these assumptions impact the AA. Regardless of what level is used, all assumptions must be identified and justified.

Level 1: Basic Social Impact Evaluation

Level 1 identifies potential differences in social impacts to local workers, affected communities, and societies including “fenceline” communities and product users. It emphasizes whether alternatives result in 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. Impacts to workers, the community and the global society from a broader perspective are also evaluated using a qualitative approach with information readily available to the general assessor.

Level 1 Process:

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 12](#) that affect local worker health and safety?
 - If yes, document the information used to reach the conclusion(s) and how the concern(s) may impact the potential use of the alternative. Identify that the concern(s) may eliminate this alternative from consideration unless mitigation or control are feasible. Continue AA.
 - If no, document information used to reach the conclusion and continue 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 13](#) that affect local worker health and safety?

-
- If yes, document the information used to reach the conclusion(s) and how the concern(s) may impact the potential use of the alternative. Identify that the concern(s) may eliminate this alternative from consideration unless mitigation or control is feasible. Continue AA.
 - If no, document information used to reach the conclusion and continue 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 14](#) that affect local worker health and safety?
 - If yes, document the information used to reach the conclusion(s) and how the concern(s) may impact the potential use of the alternative. Identify that the concern(s) may eliminate this alternative from consideration unless mitigation or control is feasible. Continue AA.
 - If no, document information used to reach the conclusion and continue AA.
4. Are there any other local concerns not addressed?
- 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 conclusion(s) and how the concern(s) may impact the potential use of the alternative. Identify that the concern(s) may eliminate this alternative from consideration unless mitigation or control is feasible. Continue with AA.
 - If no, document information used to reach the conclusion and continue 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 13](#) that affect larger community concerns?
 - If yes, document information used to reach the conclusion(s) and how concern(s) may impact the potential use of the alternative. Identify that broader concern(s) may eliminate this alternative from consideration unless it can be mitigated or controlled. Continue AA.
 - If no, document information used to reach the conclusion and continue 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 14](#) that affect global societal concerns?
 - If yes, document information used to reach the conclusion(s) and how concern(s) may impact the potential use of the alternative. Identify that the broader concern(s) may eliminate this alternative from consideration unless it can be mitigated or controlled. Continue AA.

-
- If no, document information used to reach the conclusion and continue 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 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 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 bin the alternative as potentially warranting more review for this module and 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 and expands upon the review to include more potential impacts along the supply chain. It also includes a more detailed evaluation of potential global concerns and requires some quantitative data to support this broader perspective.

The supply chain includes those workers, communities, and societies producing components that are a major portion of the chemical, product, or process at the local level. For example, a factory may build airplanes and there are local impacts for the workers, community, and society assembling the plane. There are also external impacts to the supplier providing parts of the plane assembled at the local level. Both local and distant supply chains should be considered. Potential impacts upon both local and supply chain workers, community and society are included in the AA. In addition, a more quantitative approach is included to evaluate the possible global impacts are built upon the assessment found in Level 1.

Level 2 process:

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 12](#) that affect local and supplier worker health and safety?
 - If yes, document the information used to reach the conclusion(s) and how the concern(s) may impact the potential use of the alternative. Identify that the concern(s) may eliminate this alternative from consideration unless mitigation or control is feasible. Continue AA.
 - If no, document information used to reach the conclusion and continue 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 13](#) that affect local and supplier communities?
 - If yes, document the information used to reach the conclusion(s) and how the concern(s) may impact the potential use of the alternative. Identify that the concern(s) may eliminate this alternative from consideration unless mitigation or control is feasible. Continue AA.
 - If no, document information used to reach the conclusion and continue 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 14](#) that affect local workers and supply chain global concerns?
 - If yes, document the information used to reach the conclusion(s) and how the concern(s) may impact the potential use of the alternative. Identify that the broader concern(s) may eliminate this alternative from consideration unless it can be mitigated or controlled. Continue AA.
 - If no, document information used to reach the conclusion and continue AA.
4. Are there any remaining local worker and community concerns not addressed?
 - Using quantitative information readily available to the general population, are there any additional concerns not addressed?
 - If yes, document the information used to reach the conclusion(s) and how the concern(s) may impact the potential use of the alternative. Identify that the concern(s) may eliminate this alternative from consideration unless mitigation or control is feasible. Continue AA.
 - If no, document information used to reach the conclusion and continue 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 conclusion(s) and how the concern(s) may impact the potential use of the alternative. Identify that the broader concern(s) may eliminate this alternative from consideration unless it can be mitigated or controlled. Continue AA.
 - If no, document information used to reach the conclusion and continue 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 question(s), note that the specific component is not a limiting factor and document the information used to reach the conclusion. Continue 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 bin the alternative as potentially warranting more review for this module. Continue 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 and the potential impactions to workers, communities, and society at the local, supplier, and global levels. In addition, a more quantitative data is required to evaluate impacts from the alternatives at all three levels.

Questions in this level include:

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 12](#) that affect local, supplier, or larger societal worker health and safety?
 - If yes, document the information used to reach the conclusion(s) and how the concern(s) may impact the potential use of the alternative. Identify that the

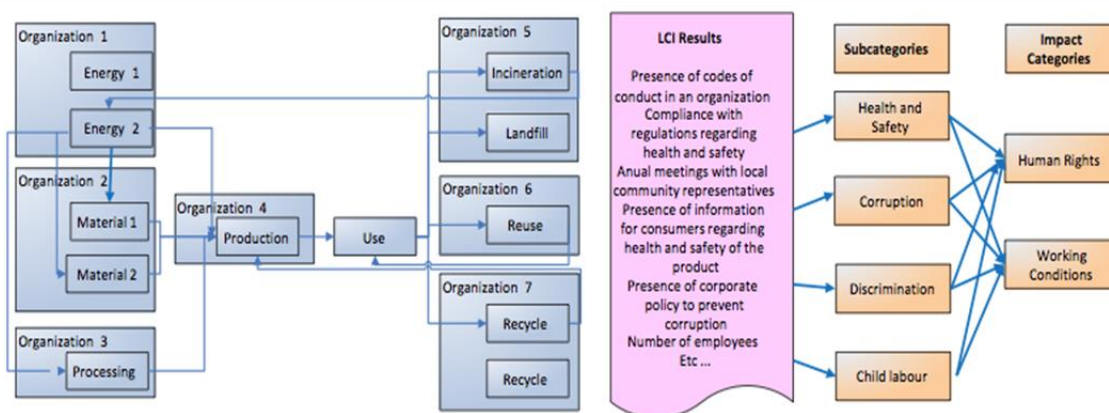
-
- concern(s) may eliminate this alternative from consideration unless mitigation or control is feasible. Continue AA.
- If no, document information used to reach the conclusion and continue AA.
2. Are there local, supply chain, or global community impacts not addressed by other modules?
- Using quantitative information, are there any concerns in [Table 13](#) that affect local, supplier, or the larger community issues?
 - If yes, document the information used to reach the conclusion(s) and how the concern(s) may impact the potential use of the alternative. Identify that the concern(s) may eliminate this alternative from consideration unless mitigation or control is feasible. Continue AA.
 - If no, document information used to reach the conclusion and continue 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 14](#) that affect local, supplier, or the larger society?
 - If yes, document the information used to reach the conclusion(s) and how the concern(s) may impact the potential use of the alternative. Identify that the broader concern(s) may eliminate this alternative from consideration unless it can be mitigated or controlled. Continue AA.
 - If no, document information used to reach the conclusion and continue AA.
4. Are there any remaining local, supply chain, or larger societal concerns not addressed?
- Using quantitative information readily available to the general population, are there any additional concerns not addressed?
 - If yes, document information used to reach the conclusion and how the concern may impact the potential use of the alternative. Identify that these broader concerns may eliminate this alternative from consideration unless it can be mitigated or controlled. Continue AA.
 - If no, document information used to reach the conclusion and continue AA.
 - Using quantitative information readily available to the general population, are there any additional concerns not addressed?
 - If yes, document information used to reach the conclusion and how the concern may impact the potential use of the alternative. Identify that the concern may eliminate this alternative from consideration unless mitigation or control are feasible. Continue AA.
 - If no, document information used to reach the conclusion and Continue 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 yes to any or all question(s), note that the specific component is not a limiting factor and document the information used to reach the conclusion. Continue evaluation process until all negative impacts have been evaluated to determine if mitigation is possible.
 - If no, document information used to reach the conclusion and bin the alternative as potentially warranting more review for this module. Continue evaluation process until all components have been evaluated.

Advanced: Full Social Life Cycle Assessment Evaluation

The advanced option conducts a full Social Life cycle Assessment (SLCA) evaluation. It builds upon the work in the previous three levels and conducts a full SLCA related to the production of the chemical or product. The [United Nations Environmental Programme \(UNEP\)](#) describes an SLCA 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.’⁵⁶ [UNEP](#) further suggests SLCA concerns can be complicated. Examples of social life cycle inventory and interrelationships are shown in [Figure 17](#).⁵⁷ [Further information can be found in the Life Cycle Module.](#)

Figure 17: [Examples of a Social Life Cycle Inventory and Interrelationships to Subcategories and Impact Categories](#)



⁵⁶ *Guidelines for Social Life cycle Assessment of products*, UNEP/SETAC Life Cycle Initiative, Paris, 2009, p. 37.

⁵⁷ *Towards a Life cycle Sustainability Assessment: Making Informed Choices on Products*, UNEP, 2011, 86 pages, p. 23.

Resources

The following resources provide additional guidance and frameworks for considering social impacts.

[ISO 26000 - Social Responsibility](#)

ISO 26000 provides guidance on how businesses and organizations can operate in a socially responsible way. ISO 26000 provides guidance rather than requirements, so it cannot be certified as ISO 26000 compliant unlike some other well-known ISO standards. Instead, it helps clarify what social responsibility is, helps businesses and organizations translate principles into effective actions and shares best practices relating to social responsibility, globally. It is aimed at all types of organizations regardless of their activity, size, or location.

[SA8000® Standard](#)

The SA8000® standard is one of the world's first auditable social certification standards for decent workplaces, across all industrial sectors. It is based on conventions of the International Labour Organization (ILO), United Nations (UN), and national laws. The SA8000® 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. The management system supports sustainable implementation of the principles of SA8000®: child labor, forced and compulsory labor, health and safety, freedom of association and right to collective bargaining, discrimination, disciplinary practices, working hours, and remuneration.

[Global Reporting Initiative](#)

The mission of the Global Reporting Initiative (GRI) is to make sustainability reporting standard practice for all organizations. GRI's core product is the Sustainability Reporting Framework; the cornerstone of the Reporting Framework is GRI's Sustainability Reporting Guidelines. The G3.1 Guidelines are an update and completion of the third generation of the Sustainability Reporting Guidelines, G3. G3.1, launched in March 2011, includes expanded guidance for reporting on human rights, local community impacts, and gender.

Life Cycle Module

The Life Cycle (LC) Module supports an AA by helping to inform decision makers about life cycle impacts associated with the baseline product and the alternative(s) so that they may:

- Further discriminate between safer alternatives by comparing life cycle tradeoffs.
- Identify opportunities to mitigate any undesirable impacts.
- Avoid an alternative with undesirable life cycle impacts that cannot be mitigated.

The LC module helps the assessor address issues or impacts not included in other modules.

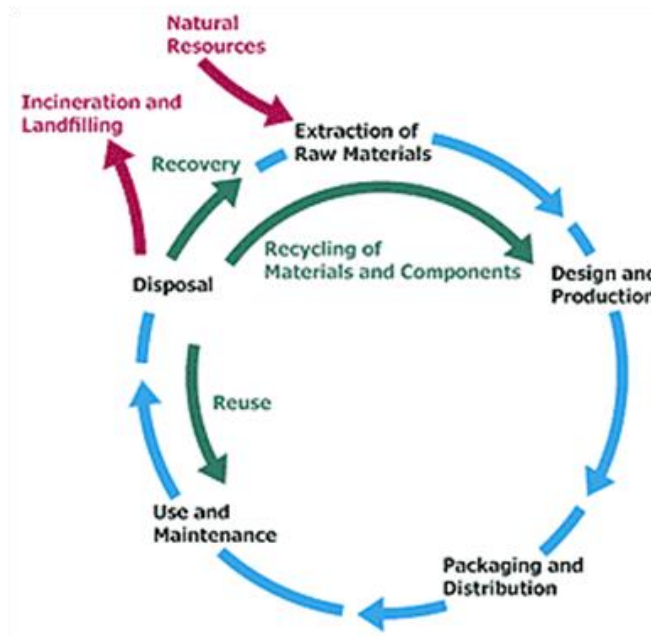
The LC module is designed to be used after the Hazard, Performance Evaluation, Cost and Availability, and Exposure Assessment modules. Because life cycle impacts can be broad, many life cycle considerations are included in other modules, including the Cost and Availability Module, the Social Impact Module and the Materials Management Module. Completion of each of those three modules is beneficial before using the LC module. The LC module expands what was done in those modules to include life cycle costing, SLCA, and LCA. Hence, the LC 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 LC module to gather more information to assess and address outstanding impacts.

The LC module evaluates life cycle impacts from the product level rather from an individual chemical perspective. Although alternatives may involve replacing a chemical of concern with another chemical, evaluating the life cycle impacts from the full product perspective provides a more detailed and comprehensive evaluation of the impacts involved in the substitution. This is particularly true if more complicated substitutions are involved such as reformulation of a product or changing from one type of material to another.

Life Cycle Thinking (LCT) and Life Cycle Assessment (LCA)

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 value recovery ([Figure 18](#)).

Figure 18: [The Scope of Life Cycle Thinking](#)⁵⁸



LCT uses the approach and principles behind LCA to determine whether impacts associated with a given alternative chemical, material, activity, or process are likely to be greater, lesser, or similar to those associated with product or process containing the chemical of concern. The product containing the chemical of concern is the baseline product, which defines the “functional unit” under consideration. 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 to identify potential environmental, economic, or social impacts for each life cycle phase, in order 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 has become an important tool on which businesses increasingly rely to inform decision-making. Product design and development decisions impact not only how the product is made and what benefits it provides, but also ways in which the product will be used and its end-of-life disposition. LCT can be used to modify processes in manufacturing to improve energy and raw materials use and to reduce or eliminate the use or generation of hazardous

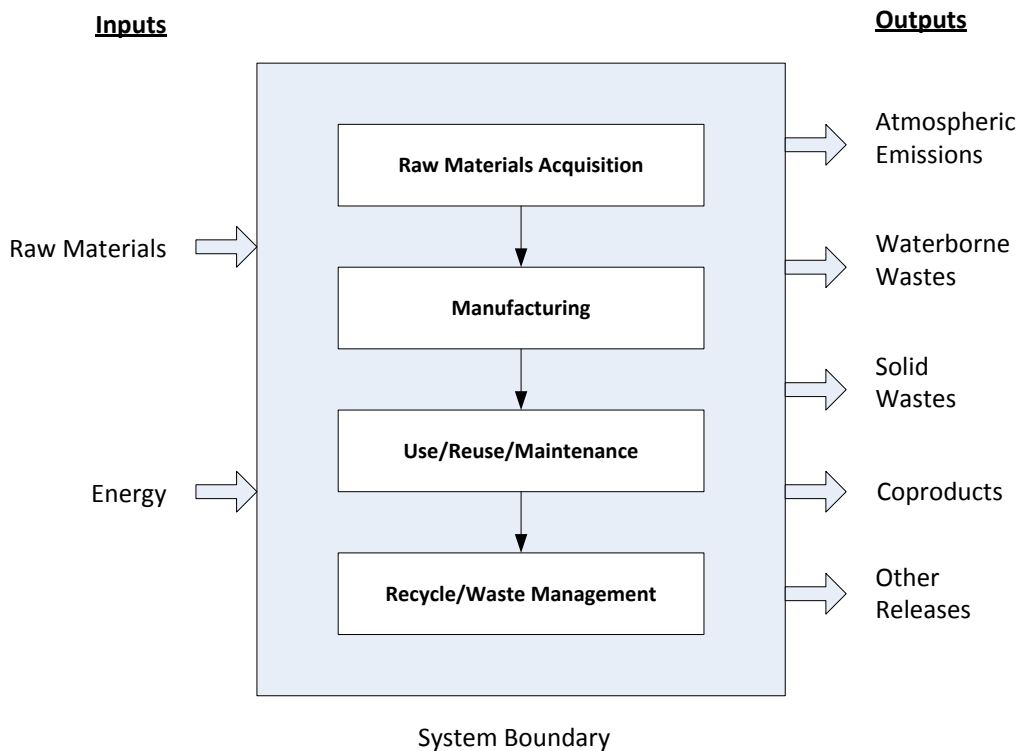
⁵⁸ United Nations Environmental Programme, *Life Cycle Management: A Business Guide to Sustainability*, 2007, 52 pages.

substances. LCT contributes to sustainable production, consumption, and sustainable materials management by going beyond a limited focus on a single production stage or narrow social or economic concerns to consider impacts across the entire life cycle of a product. When considering alternatives, businesses should include the human health and environmental impacts of each product design, in addition to social and economic impacts throughout the full life cycle. By considering potential impacts across all life cycle stages, businesses can strive for choices in product design and development that have benefits for their business, the environment, and society.

LCT may also include taking action to mitigate negative impacts. LCT is an essential component of an AA because it can lead to lessening the negative and improving the positive impacts of products and services by informing the design and decision-making process and helping to further discriminate between alternatives identified as favorable using other attribute 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.” 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, from the extraction of natural resources for raw materials to production, storage, and use of the product, to recycling, recovery, reuse, and/or disposal of wastes, and inclusive of transportation requirements along the way. 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. [Figure 19](#) provides a schematic to account for material and energy inputs and outputs.

Figure 19: [Life Cycle Assessment Stages and Inputs/Outputs](#)⁵⁹



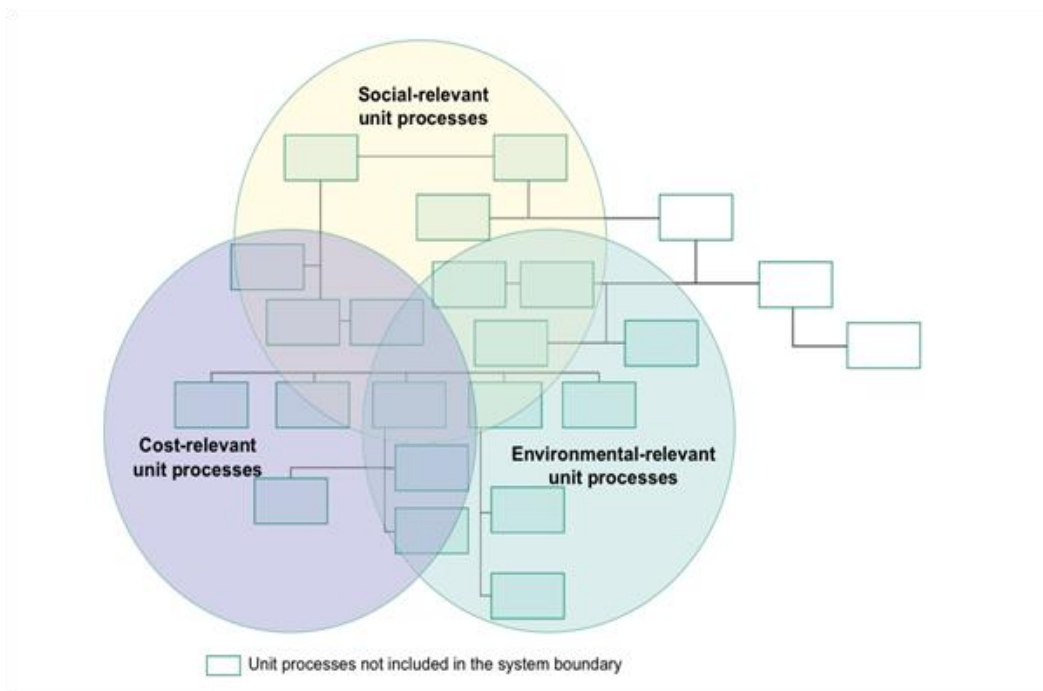
The impacts associated with the inputs and outputs for the processes at each life cycle stage are then measured and compared for the baseline product and the alternative(s). Examples of impact categories commonly used in LCA include:

- 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 20](#)). Because LCT addresses impacts in the product “system” there is unavoidable overlap at times between environmental, economic, and social impacts. For example, negative impacts on freshwater might have social impacts on access to fresh water and associated economic impacts to provide fresh water through the need for additional treatment. This LC module will guide the assessor to determine if social, economic, and environmental impacts are likely to occur with the baseline product and/or the alternative(s) and to guide the assessor in further assessment.

⁵⁹ US EPA, *Life cycle Assessment: Inventory Guidelines and Principles*, February 1993, EPA/600/SR-92/245, Figure 1, page 2.

Figure 20: [Applying Life Cycle to Environmentally, Socially, and Cost Relevant Unit Processes](#)⁶⁰



Assessment is not needed for every process at every life cycle stage for every alternative under consideration because, for any set of alternatives, many of the unit processes will be the same. Focus should be placed on the processes that are different and discriminating. For example, different formulations of a cleaning product may be developed but the packaging might remain the same. Therefore, packaging is not discriminating. Where the life cycle differences are most discriminating they are referred to as life cycle “hotspots.”

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 are judged to be very undesirable and cannot be mitigated. Some life cycle impacts can be mitigated by readily available technologies. For example, discriminating impacts from differences in transportation between two alternatives might be addressed by changing the mode of transportation or by switching to a supplier or distributor who is geographically closer.

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. 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

⁶⁰ United Nations Environmental Programme, *Towards a Life Cycle Sustainability Assessment*, Figure 14, page 35, accessed 2/2013.

the final products are compared. The relative nature of LC comparisons is inherent to the approach and it can be difficult to clearly define “significant differences.” Consistently applying LCT at the product level helps provide some standardization.

Applying the Life Cycle Module

The LC module involves several steps to narrow down LC differences to those that discriminate between options ([Table 16](#)). The Preliminary Steps guide the assessor to first determine if there are likely to be discriminating life cycle differences between the baseline product and the alternative(s). Level 1 guides the assessor to inventory possible life cycle impacts associated with the differences and begin to assess their magnitude. Level 2 measures the magnitude of the impacts by collecting key data. Level 3 determines if any of the impacts can be mitigated. If mitigation is possible, then the optimized alternatives should be reassessed using the LC module to confirm the benefits anticipated.

If you have already applied the Cost and Availability, Social Impact, or Materials Management modules, you can refine identified potential social, economic, raw material, or waste related impacts using the LC Module.

Table 16: Life Cycle Thinking Evaluation Levels

<p>Preliminary Steps</p>	<p><i>Preliminary Steps.</i> Identifying potential differences between unit processes at each life cycle stage that could result in discriminating differences between the baseline product and the alternative(s).</p> <p>The Preliminary Steps determines whether a deeper analysis is needed or if no further analysis is necessary. A series of questions help assess whether the life cycle differences are social, economic or related to raw materials and wastes. If so, assessors are referred to other modules where those impacts are addressed.</p>
<p>Level 1</p>	<p><i>Basic Life Cycle Evaluation.</i> Assessing the life cycle impacts based on readily available data and identifying what further information is needed to assess the impacts sufficiently to inform decision making.</p> <p>Level 1 assesses potential impacts associated with inputs and outputs and process differences across the life cycle between the baseline product and the alternative(s) using readily available information. Identification of life cycle “hot spots” associated with the baseline product and the alternative(s) also support efforts to mitigate negative impacts.</p>
<p>Level 2</p>	<p><i>Extended Life Cycle Evaluation.</i> Conducting a more detailed LCT analysis in</p>

	<p>order to better inform decision making concentrating solely on those factors identified in Preliminary Steps as discriminating for chemical, product or process under evaluation. Determining extent to which impacts can be mitigated and the product design optimized for life cycle benefits.</p> <p>If information gathered in Level 1 is deemed insufficient for decision making, Level 2 evaluates a broader scope and conducts more detailed and quantitative data gathering and LCA informed by best practices and ISO 14040 guidelines. Completing Level 2 should result in sufficient information to compare baseline product and alternative(s) to inform decision making. It may also result in data gaps that cannot be reasonably filled.</p>
Level 3	<p><i>Detailed Life Cycle Evaluation.</i> Conduct a life cycle evaluation of the chemical, product or process using standard ISO 14040 and social life cycle assessment (SLCA), cost benefit analysis (CBA) and materials management evaluations. Better understanding of life cycle “hot spots” can support more informed mitigation and optimization of products and determine what is relevant to the comparison using a complete evaluation of the chemical, product or process.</p>

Preliminary Steps

The Preliminary Steps to LCT determines which LC attributes are important for evaluation by comparing the unit processes associated with each LCT stage for the baseline product and the alternative(s). These [preliminary steps](#) are roughly analogous to the goal definition and scoping phase of a traditional LCA.⁶¹ Differences between products and processes at each LC stage may be societal, economic, or environmental. The Preliminary Steps will guide assessors to:

1. Use the Social Impact Module to address social LC impacts.
2. Use the Cost and Availability Module to address economic LC impacts.
3. Use the Materials Management Module to address LC impacts associated with the supply of raw materials and the generation of wastes.

⁶¹ US Environmental Protection Agency, *Life Cycle Assessment: Principles and Practices* aka *Life Cycle 101*, accessed 2/2013.

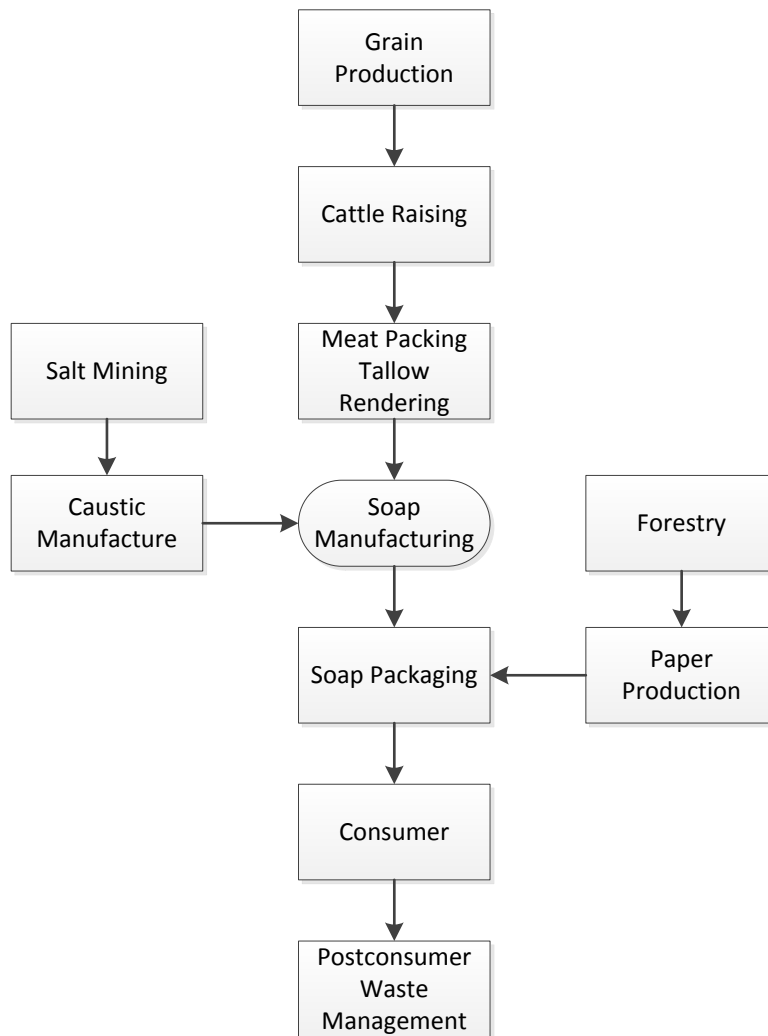
For environmental impacts not considered by the other modules, the Preliminary Steps will serve as the first step to higher levels of the LC module where impacts based on material and energy inputs and outputs can be assessed. The Preliminary Steps help define the boundaries of the system that requires further investigation to compare the baseline product to each of the alternatives. While LCA scoring review may be quantitative, it is based on many assumptions about how products are used and the boundaries of the processes identified that can have a profound effect on the outcome of the analysis.

The Preliminary Steps begin by developing a diagram of the major processes that take place in each of the product's LC 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 LC of the product, the major sources of each material, the production processes, use(s), and end-of-life disposition. An example is provided in [Figure 21](#).

Due to supply chain challenges, it may be difficult to have good knowledge of all LC segments. Therefore, the first steps are to capture what is known and not known about the product LC. Once a basic diagram has been drawn, the assessor uses the information in the diagram to determine what changes, if any, might be introduced by using the alternative(s) being evaluated.

The initial flow diagram is qualitatively assessed to establish the similarities and differences between the baseline product and the alternative(s), and areas where changes and no changes are expected. For example, for the hypothetical bar soap system (Figure 21), a chemical may be substituted into the soap's fragrance but the all other processes will remain unchanged. Therefore, there is no need to compare the baseline product and the alternative(s) for those processes that do not discriminate between the products. At the completion of these preliminary steps, the assessor can determine whether additional data gathering and analysis are necessary to inform the AA.

Figure 21: [Flow Diagram of a Hypothetical Bar Soap System](#)⁶²



The following questions are intended to assist in the scoping process.

1. How does the baseline product compare to the alternative(s) for material inputs and outputs and processes at each stage of the LC?
 - 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 LC assessment may not be necessary

⁶² For more information, see LCA 101, EPA, 2006, accessed 7/2013

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- If yes, then further consideration should be given to possible differences in social, economic or environmental impacts associated with those changes.
2. At which LC stage(s) are the material inputs and outputs and/or process flows expected to be different between the baseline product and the alternative(s)?
 - 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 LC impacts, whether environmental, economic, or social might be associated with the differences noted above for the baseline product and the alternative(s)?
 - For each of the differences noted, are increased cost impacts likely to result?
 - If yes, address LC costing impacts using the Cost and Availability Module.
 - If no, continue with the LCA.
 - For each of the differences noted, are increased social impacts likely to result?
 - If yes, assess social LC 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 likely to result? 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 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 LC. This assessment may be limited to just those

areas where there are differences. Differences that appear to be discriminating may be referred to as LC “hot spots.”

5. What type of information do I need to gather in order 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 noted in the Initial Screen between the baseline product and the alternative(s) using readily available information. Readily available information is used to evaluate the life cycle impacts and determine if that information is sufficient to make an informed decision or if additional data and analysis are needed. Additional information may be needed for only some of the differences noted between the baseline product and the alternative(s). If so, 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 alternative(s) for the impacts of interest?
 - If no, continue with the Level 1 assessment.
 - If yes, is there sufficient information to compare the baseline product to the alternative(s) for the impact(s) 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 alternative(s) 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.

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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.

Level 1 of the LC process is complete.

Level 2: Extended Life Cycle Evaluation

Level 2 scopes and conducts a more detailed and quantitative data gathering and analysis including a partial life cycle assessment (LCA) informed by best practices and ISO 14040 guidelines. Depending upon the level of technical information involved, additional expertise may be warranted. 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 alternative(s).
- All impact assessments results associated with the life cycle inventory.
- A summary of all interpretations of life cycle inventory and impact assessment data.

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.

Completing Level 2 should result in sufficient information to compare the baseline product and the alternative(s) 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.

Level 2 better quantifies and verifies those life cycle impacts that decide whether or not a potential alternative is an improvement. It may inform final LC and LCA decisions and 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 alternative(s)?
 - If yes, summarize metrics used and document interpretation of results. Continue evaluation.

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- If no, summarize metrics used and document interpretation of results. Continue evaluation.
2. Do the discriminating results suggest one alternative may be more or less preferred over another?
 - If yes, document the rationale. Continue evaluation.
 - If no, document the information used to reach the conclusion. Continue evaluation.
 3. For each hot spot associated with the baseline product and/or the alternative(s), 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 LC module after mitigation.
 - If no, use the information to inform decision making and document decisions.

Level 2 of the LC process is complete.

Level 3: Detailed Life Cycle Evaluation

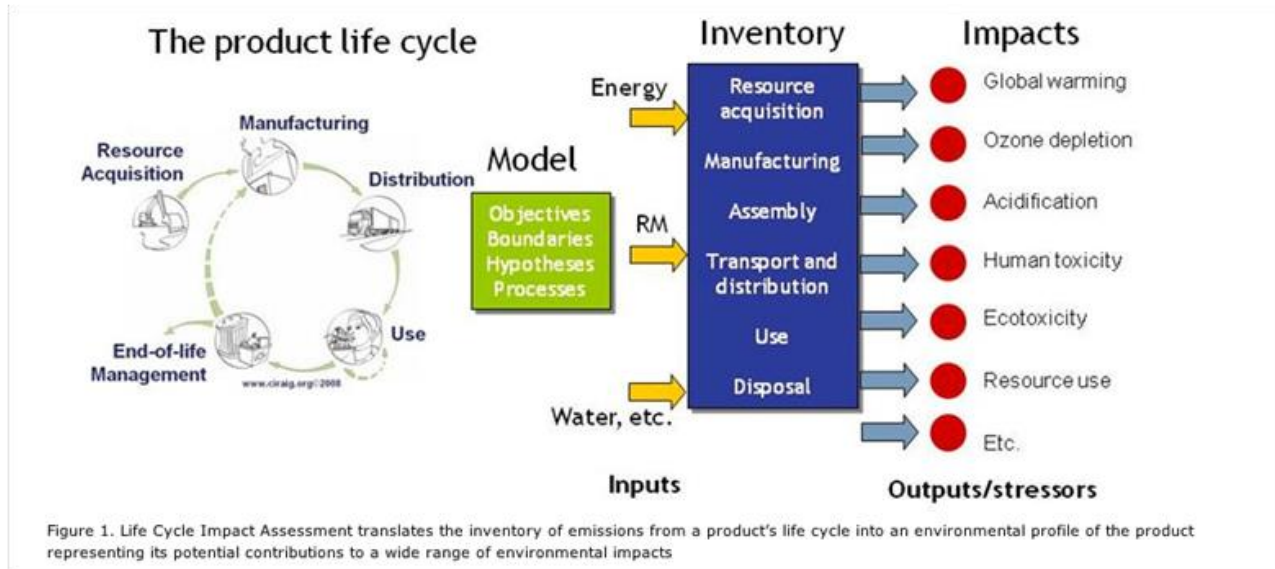
Level 3 consists of a full life cycle assessment that meets ISO 14040 requirements and includes a social life cycle assessment, materials flow analysis, cost benefit analysis, and other pertinent considerations. More information on these techniques is found in the Appendix.

Appendix

Life Cycle Assessment

Among the tools, life cycle assessment represents one of the most thorough and reliable methods. 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 being to quantify all physical exchanges with the environment, whether these are inputs in the form of natural resources, land use, and energy, or outputs in the form of emissions to air, water, and soil.

Figure 22: Life Cycle Impact Assessment



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 it is often the case that the bulk of impacts occur in ancillary and supply chain processes.

The LCA methodology has been formalized ([ISO 14040 series](#)) and improved for several decades in Europe and the United States. Regulated by the ISO 14040 series standards, LCA consists in four distinct phases:

1. Goal and scope definition (study model which defines the methodological framework).
2. Inventory of all the inputs and outputs related to the product system.
3. Assessment of the potential impacts associated with these inputs and outputs.
4. Interpretation of the inventory data and impact assessment results (as related 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 and coherent requirements derived from LCAs. The [ILCD Handbook](#) aims to improve the compatibility and consistency of data generation and reporting requirements and increase stakeholder acceptance of the tool LCA and its results. The United Nations Environment Programme's

(UNEP) work to promote LC is spearheaded by the UNEP/ Society of Environmental Toxicology and Chemistry (SETAC) Life Cycle Initiative and a [guide to performing LCA](#)).

Material Flow Analysis (MFA)

A Material Flow Analysis 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.

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 (LCI) and then linking it to human health and environmental damage categories. Due to time and cost constraints, variants of the LCA method have been formulated according to the guideline principles established by the SETAC. For example, the boundaries of a system can be limited to certain life cycle stages or to certain impact categories or limited to the main contributors, identified according to expert opinion and experience. An analysis can also be performed using secondary data (generic data from the literature or from databases) or proxy information. Such simplifications can affect the accuracy and applicability of LCA results, but can nevertheless allow for the identification of potential impacts and, to a certain extent, their assessment.

From inventorying to impact assessment to application of results, the LCA framework has been improved, refined, and updated for both general and specific assessment of products, processes, and services. Government environmental entities or non-governmental organizations including academic institutions have created specific guidelines for performing LCA. While some guidelines are general and provide overviews of the LCA framework, others are highly specific to particular aspects. Practitioners can use existing guidelines to complement their understanding and improve their general background needed for specific evaluations related to alternatives analysis.

Life Cycle Costing (LCC)

Similar to LCA, Life Cycle Costing (LCC) is an economic application based on LC. This technique takes into account 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 are also emerging to estimate social impacts and benefits associated with a product's life cycle.

Cost Benefit Analysis (CBA)

Cost-benefit analysis, 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 costs.

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 (NPV) or annualized value.

NPV 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 NPV are preferred while a negative NPV indicates an option that should be generally avoided. CBA encourages a comprehensive enumeration of benefits and costs even when monetization is not possible, ideally using a life cycle lens.

When there is a need for monetization, the appropriate tool for comparing quantified and monetized impacts is CBA. 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. Some costs or benefits do not have a market value, and when attempts have been made, there may be a lack of monetized valuation data available that could be used for a benefit transfer. 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.

This guide suggests using a CBA-type approach, which involves recognizing that not all impacts can be quantified or monetized. As such, it is proposed that 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.

Cost-benefit analysis (CBA) is among the methodologies that, when consistently and completely implemented, can be used to evaluate alternatives. The following information on CBA is copied from [guidance](#) created by the California Environmental Protection Agency for compliance with 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.

The following are references for conducting a full cost benefit analysis.

- [Guidelines for Preparing Economic Analyses](#), EPA, 2010.
- [Towards a Life Cycle Sustainability Assessment](#), United Nations Environment Programme, 2011.
- [Benefit Cost Analysis Center](#) at the University of Washington Evans School of Public Affairs.
 - 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.).

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- 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 (SLCA)

A social life cycle assessment (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'. SLCA concerns can be complicated and examples of social life cycle inventory are shown in [Figure 17](#). A social life cycle inventory is a compilation of a list of possible social interventions caused by the potential alternative.

LCA Tools Matrix

DTSC LC Overview: [Life cycle Assessment Support for California's Green Chemistry Initiative](#) was written in support of California's Green Chemistry Legislation.

European Environment Agency (EEA): [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 as a comprehensive listing of informational sources including newsletters, journals, books, reports, conference proceedings, databases, standards, and software for LCA practitioners.

European Commission (EC): [International Reference Life cycle Data System \(ILCD\) Handbook: General Guide for Life cycle Assessment](#) is not meant to serve as a training manual for beginners and has a focus on the decision aspects related to LCA. It is heavily focused on the methodological aspects of LCI and LCIA. 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 (EIPRO): [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 ([Life cycle Assessment Support for](#)

[California EPA's Green Chemistry Initiative](#), Page 15 of 30) 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.

U.S. Environmental Protection Agency (EPA): [Life cycle Assessment: Principles and Practice](#) is meant to be an educational tool for those who want to learn the basics of LCA. It discusses the basic stages of LCA (goal and scope definition, LCIs, LCIA, and improvement analysis) and the importance of evaluating processes from cradle-to-grave (raw material acquisition, materials manufacture, production, use/reuse/maintenance, and waste management).

European Union (EU) - Calcas: Coordination Action for Innovation in Life cycle Analysis for Sustainability: [D20 Blue Paper on Life cycle Sustainability Analysis](#). "Life cycle Assessment," as standardized by ISO, is well recognized as the most suitable method for the environmental analysis of products. Nevertheless, the question of sustainability assessment, in particular of complex systems with extended and durable effects on the whole of society, requires a broadened scope of analysis and a deepening of modeling." It was developed for the European Union by LCA researchers at l'Energie l'Environnement (ENEA), Leiden University (CML), and the Swedish Environmental Research Institute (IVL) and presents a roadmap for defining Life cycle Sustainability Analysis (LCSA).

GHG Protocol: [Product Life cycle Accounting and Reporting Standard](#) aims to develop GHG accounting and reporting standards for businesses, governments, NGOs, and academic institutions. It focuses on LCA methodology providing basic information for new LCA practitioners for GHG assessment and was developed by the World Business Council for Sustainable Development and the World Resources Institute.

Hitch Hiker's Guide to LCA: [An Orientation in Life cycle Assessment methodology and Applications](#), Henrikke Bauman and Anne-Marie Tillman, 2004, Student literature AB publishers, 543 pages.

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 LCIA metrics and their evaluation and an excellent resource for those trying to bridge LCIs with LCIA. This document provides step-by-step instructions for performing an LCIA from an LCI including environmental and human health damage characterization factors that can be implemented in LCA software. It was developed by life cycle impact assessment researchers in the Netherlands including PRÉ Consultants, University of Leiden (CML), Radboud University Nijmegen (RUN), and Bilthoven (RIVM).

United Nations Environment Programme (UNEP): [Life cycle Approaches: The Road from Analysis to Practice](#) presents the general background for LCA and Life cycle Management (LCM) principles. It discusses the key steps in performing each analysis but does not provide step-by-step instructions for executing an LCA and was developed by the UNEP and the Society of Environmental Toxicology and Chemistry.

UNEP: [Evaluation of Environmental Impacts in Life cycle Assessment](#) provides a qualitative overview of the LCIA framework for those interested in understanding the importance of performing an LCIA. It does not provide step-by-step instructions for performing an LCIA. It was developed by the UNEP Division of Technology, Industry and Economics, Product and Consumption.

UNEP: [Life cycle Assessment: What it is and how to do it](#) was written early in the development of LCA methodology. The first part discusses what LCA is, why it is used, how an LCA is performed (in general), and how the results can be used. The second part provides information on the basic steps of performing an LCA including goal and scope definition, collecting data, establishing system boundaries, processing data, classification, characterization, valuation, reporting, and improvement analysis. It was developed in conjunction with the University of Leiden (CML) Centre of Environmental Studies, Netherlands Agency for Energy and the Environment (Novem), and the Netherlands National Institute for Public Health and the Environment (RIVM). A. Horvath and M. Chester – Life cycle Assessment Support for California EPA’s Green Chemistry Initiative
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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/TR 14062: 2002 [Environmental management-- Integrating Environmental Aspects into Product Design and Development](#)

ISO 14063: 2006 [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 LCI Data](#)
- [Australian Life cycle Assessment Society and National LCA database](#)
- [American Center for LCA](#)
- [US EPA Life cycle Assessment Research](#)
- [NREL US LCI database](#)
- [Japan Environmental Management Association for Industry \(JEMAI\) and National LCA database](#)
- [China National Institute for Standardization \(CNIS\) and National LCA database](#)
- [Brazilian Institute of Information in Science and Technology \(IBICT\) and National LCA database](#)
- [Thai National Metals and Materials Technology Centre and National LCA database](#)
- [Malaysian National LCA database project](#)

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 conducting scientific studies, 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)⁶³

Bio-monitoring: 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)

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.

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.⁶⁴

Environmental monitoring: Continuous or repeated measurement of agents in the environment to evaluate environmental exposure and possible damage by comparison

⁶³ 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.

⁶⁴ Division 4.5, Title 22, California Code of Regulations Chapter 55. Safer Consumer Products, Section 69501.1 (30), accessed 2/2103.

with appropriate reference values based on knowledge of the probable relationship between ambient exposure and resultant adverse effects. (IUPAC)

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 smoke on nonsmokers, increasing the incidence of respiratory distress, and a smokestack which deposits soot on someone's laundry, thereby incurring costs of laundering.⁶⁵

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.⁶⁶

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.⁶⁷

⁶⁵ EPA Design for the Environment Program, *Cleaner Technologies Substitutes Assessment-A Methodology and Resource Guide*, Social Benefits/Cost Assessment, accessed 7/2013.

⁶⁶ IBID.

⁶⁷ Agency for Toxic Substances & Disease Registry (ATSDR), *Glossary of Terms*, accessed 2/2013.

Exposure scenario or exposure profile: The set of conditions, including operational conditions and risk management measures, that describe how a substance is manufactured or used during its life cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures to humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.⁶⁸

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.⁶⁹

Framework: Description of a specific arrangement of assessments and decisions used to conduct an AA. For example, the three frameworks for decision making used in the Guide are Sequential Decision, Simultaneous Decision and Hybrid Decision, 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.

Guide: Description of how to conduct an AA and the overall structure of an AA process. Many organizations such as the European Chemicals Agency, the Interstate Chemicals Clearinghouse, the Toxics Use Reduction Institute, etc. have created documents that describe specific frameworks for conducting an AA.

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.

⁶⁸ British health and Safety Executive, Glossary of REACH definitions, accessed 2/2013.

⁶⁹ 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.

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.”⁷⁰

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.⁷¹

Life Cycle Assessment (LCA): A technique (ISO 14040) to assess the environmental aspects and potential impacts associated with a product, process, or service, by:⁷²

- 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. 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.⁷³

Near field exposure: Indoor, occupational, industrial, and direct exposure pathways from consumer use (e.g., application of personal care products).⁷⁴

⁷⁰ Environment Canada, Section 64, accessed 2/2013.

⁷¹ EPA Design for the Environment Program, *Cleaner Technologies Substitutes Assessment-A Methodology and Resource Guide*, Social Benefits/Cost Assessment, accessed 7/2013.

⁷² Adapted from EPA Life cycle Assessment webpage, accessed 7/2013.

⁷³ Adapted from EPA Life cycle Perspective webpage, accessed 7/2013.

⁷⁴ 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.

Normalization: Normalization is a technique for changing impact indicator values with differing units into a common, unitless format by dividing the value(s) by a selected reference quantity. This process increases the comparability of data among various impact categories.

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 contaminants can be transported long distances and move readily from land to air and water.⁷⁵

Product Flow Diagram: A diagram that identifies all the processes that contribute to the production of a final product emphasizing all 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 bulk material processing, engineered materials 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: Identification of the probability of harm a chemical may have upon human health and the environment. Risk is defined as a function of hazard and exposure and is approximated by the equation: Risk = f (Hazard, Exposure)

Risk assessment: Identification and quantification of the risk resulting from a specific use or occurrence of a chemical or physical agent, taking into account possible harmful effects on individuals or populations exposed to the agent in the amount and manner proposed and all possible routes of exposure. (IUPAC)

⁷⁵ EPA PBT Chemical Program, accessed 2/2013.

Risk reduction process: A process based upon the definition of risk as a function of hazard and exposure. Alternatives to toxic chemicals are selected that pose the lowest possible chemical hazard. These low hazard chemicals are subjected to a further exposure evaluation to identify the chemicals that have both the lowest possible chemical hazard and pose the lowest potential for exposure.

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.

Tools: An approach for assessing a chemical, material and/or process for the purpose of attribute analysis or decision-making within an AA. Tools can be computer programs, paper-based tools, information sources, etc.

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.

Very persistent and toxic (vPT): A substance that exhibits high levels of persistence AND is toxic to human health or the environment.