Society of Environmental Toxicology and Chemistry

Technical Issue Paper

Chemical Alternatives Assessment

What Is Chemical Alternatives Assessment?

An increasing number of chemicals used in the making of materials and products for industrial or consumer purposes have been associated with negative impacts to human health and the environment. Over the last two decades, a combination of scientific data, regulatory measures and consumer interest to promote safer environments have resulted in greater pressures to phase out and replace some substances. Unfortunately, some efforts to replace certain chemicals with less-studied or regulated alternatives, thought to be less toxic, have resulted in "regrettable substitutions," where the replacement chemicals were found to have equally severe, if different, hazard and toxicity potential than the original chemical, or where the negative impacts were simply shifted from one group to another (e.g., from workers to aquatic organisms).

Alternatives assessment is "a process for identifying and comparing potential chemical and non-chemical alternatives that could replace chemicals of concern on the basis of their hazards, performance, and economic viability." (2014 National Research Council [NRC] Framework).

Alternatives assessment was developed as a tool for the informed substitution of toxic chemicals. Alternatives assessment considers several factors, including hazard, performance and economic viability at its core. Other relevant factors may include exposure potential, material recoverability, lifecycle impacts, and social impacts, as well as other factors that contribute to decisions that strive to minimize the potential for unintended consequences so that the resulting substitution is indeed safer and more sustainable, while fulfilling the function of the incumbent chemical.

The Commons Principles for Alternatives Assessment:

- Reduce hazard – Alternatives should be less hazardous (i.e., carcinogenicity, persistence, reactivity, etc.)
- Minimize exposure – The use patterns and exposure pathways for the alternative should contribute to lower risk
- Use best available information – Decisions should be made using the best information available (i.e., hazards, performance, cost, etc.) to avoid unintended consequences
- Require disclosure and transparency – Stakeholders should be engaged throughout the assessment process to promote information sharing
- Resolve trade-offs – Use available information, organizational goals, and other societal values to guide decisions and acceptable trade-offs
- Take action – Choose a safer and feasible alternative, reviewing the decision when new information or other alternatives become available

Importantly, alternative solutions are not limited to drop-in chemical substitutions; rather, they may involve product reformulation or upstream process changes that either negate the need for the chemical or fulfil the function of the chemical in another way.

Alternatives Assessment Differs from Safety Assessment

As quoted in the 2014 NRC framework, alternatives assessment "is different from a safety assessment, where the primary goal is to ensure that exposure is below a prescribed standard; different from risk assessment, where risk associated with a given level of exposure is calculated; and different from a sustainability assessment, which considers all aspects of a chemical's life cycle, including energy and material use." While alternatives assessment is different from these fields, it is aligned with them, utilizing them to answer a different question: Is the alternative safer and feasible with regard to cost and performance to support substitution?

In the context of chemicals management, there has been significant debate regarding a "hazard" versus "risk"-based approach. Consistent with the principles of green chemistry and pollution prevention, alternatives assessment focuses on comparing options that reduce the intrinsic hazard and exposure properties (persistence, toxicity, etc.) associated with an alternative compared to the chemical of concern. In this way, alternatives assessment feeds into risk management decisions but focuses on safer alternatives instead of exposure controls, though alternatives assessment does not obviate the need for exposure considerations to ensure even safer alternatives do not result in problematic exposures. One key aspect of alternatives assessment is that it not only characterizes the candidate alternatives but sets up a framework for comparing the tradeoffs associated with each option to support decision-making and implementation.

Alternatives assessment rarely reveals a standout solution that has eluded the marketplace. Rather, alternatives assessments outline the key tradeoffs to consider for each potential alternative solution during the decision-making process.

The Alternatives Assessment Framework

Over the years, several alternatives assessment frameworks, or guidance documents, have been developed to support both regulatory and voluntary substitution initiatives. In the U.S., the two most commonly used frameworks include those published by the NRC and the Interstate Chemicals Clearinghouse (IC2). Both feature a multistep iterative and increasingly data-dependent assessment process that includes scoping and problem formulation in the beginning, through to decision-making and adoption of a solution at the end.

Most alternatives assessment frameworks begin with an initial evaluation to determine the function of the chemical and if that function is necessary or required. A scoping process is also conducted in the beginning to determine what component evaluations (also called "modules", i.e., hazard assessment, performance assessment, cost assessment, etc.) will be conducted, decision rules (e.g., no option can be a carcinogen or a specific technical performance is needed), the type of information that will need to be gathered, and which stakeholders should be involved at particular stages of the alternatives assessment. The way in which alternatives are evaluated (including pre-screening some non-viable options based on decision-rules) will also need to be decided – whether component evaluations will be conducted one at a time, with only successful candidates moving on to the next component evaluation, or whether information on all the alternatives will be collected for each component evaluation and compared at the end. Once potential alternatives are identified and the component evaluations are carried out, the results of the evaluations need to be compared and a decision made about which alternative solution(s) to implement or whether innovation or a new solution is needed.

Figure 1 shows a sample alternatives assessment framework, adapted and modified with permission from frameworks outlined in the IC2.

The assessment relies on the incorporation of stakeholder engagement throughout the process to focus the assessment, determine the decision rules, select the alternatives to consider, and share data resources to inform the assessment.

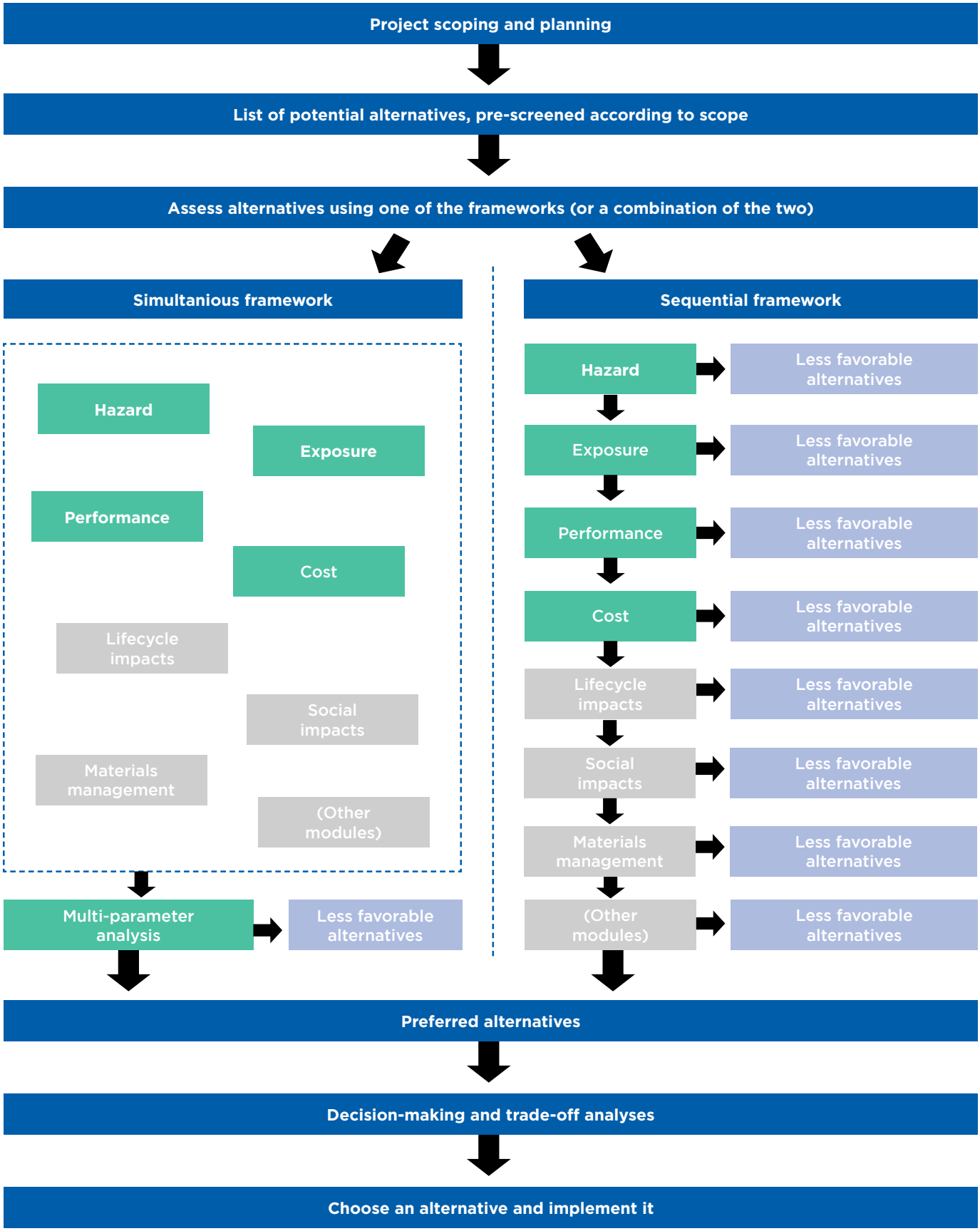

Figure 1: A sample alternatives assessment framework (Grey boxes indicate optional component evaluations).

Challenges

One of the biggest challenges in alternatives assessment is the scope of resources needed to conduct a thorough assessment. Depending upon the context, each of the component evaluations individually can be a tremendous task, depending on the depth of each component evaluation and the number of alternatives undergoing assessment. Another major challenge is data availability. If data do not already exist on an alternative for a component evaluation (or are classified as confidential), then data will have to be generated. In order to fill data gaps for hazard evaluations, new approach methodologies could be used; however, this is still a developing area. The best alternatives assessments engage a range of stakeholders, and that too, is time and resource intensive.

Additional barriers in alternatives assessment involve time constraints in meeting either an internal company or regulatory deadline given the potential resource intensity of the assessment process. For each of the component evaluations, expertise is also needed in conducting the evaluations and understanding and interpreting data from evaluations conducted by others on the hazards, exposure, lifecycle, etc., for each alternative. Engaging necessary experts and other stakeholders in these component evaluations can take time. Regulatory constraints may also impact the ability to consider certain alternatives or affect the ability to deviate from the incumbent chemical of concern. However, alternatives assessment can be conducted in an iterative and increasingly data-dependent way, where it is possible to discriminate between options by focusing on the most important and relevant components for a particular project.

Implementation of the chosen alternative is often the biggest challenge in alternatives assessment. Despite a safer and preferable alternative being identified, there may be barriers, whether in the resources needed to implement it or changes in product formulation, equipment, processes, training of personnel, marketing, etc. Additionally, there may be a promising alternative solution on the horizon that appears preferable to the existing options but is not yet at the market stage or available in sufficient quantity and for which further investments in infrastructure and research may be needed to make it a truly viable solution. Other challenges to implementing an alternative could involve company or regulatory policies, consumer pressure, image and the uncertainty of making decisions amidst existing data gaps or uncertainty.

Despite these challenges, there are many enabling factors and market drivers that support informed substitution efforts. Advances in predictive toxicology and quantitative structure–use relationship (QSUR) software has allowed for better product formation and earlier screening of alternatives. Free access to information databases on consumer product ingredients and their toxicological information has allowed the public to become more informed. Businesses have also invested in ways to transition to safer alternatives as a way to reduce costs associated with hazardous chemical management and to increase their competitiveness by lowering their chemical footprint. Likewise, governments have invested in regulatory measures and other types of recognition programs and incentives to transition the economy to safer chemicals to benefit public health and reduce burden on the health care system from diseases associated with exposure to hazardous chemicals. For all of these scenarios, alternatives assessment is a critical tool for this transition.

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