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A Framework to Guide Selection of Chemical Alternatives

CONCERNS ABOUT THE HEALTH AND ENVIRONMENTAL IMPACTS associated with some chemical products and processes have motivated a growing number of national, state, and local governments, manufacturers, and retailers to develop assessments and approaches for finding safer chemical substitutes. These existing assessment frameworks reflect a range of different priorities, whether the focus is on protecting workers, the environment, the end users of products, or other interests. This report builds on those frameworks to develop a more universally-applicable decision framework for evaluating potentially safer chemical alternatives.

Over the past 20 years, increasing scientific, regulatory, and marketplace concerns about the health and environmental impacts of certain chemicals has fueled interest in chemical substitution. There also has been growing interest in approaches and policies that help avoid "regrettable substitutions"— when a substituted chemical is later proven unsuitable. These concerns have led a number of organizations to develop alternatives assessment frameworks that consider potential adverse effects of chemicals to human health and the environment and other factors—leading to a range of frameworks designed for different purposes. A more unified approach to chemical alternatives assessment would benefit a wide range of alternative assessment users, including regulatory agencies at the international, federal, state, and local level; manufacturers; and organizations encouraging the adoption of less harmful chemicals. At the request of the Environmental Protection Agency (EPA), this report develops a decision framework for evaluating potentially safer substitute chemicals, and demonstrates the use of the framework with two case studies.

EXISTING ALTERNATIVES ASSESSMENTS

The report's authoring committee considered a set of publicly available frameworks and tools used to conduct alternatives assessments. The committee did not critically review each framework, but did note some elements that tended to be missing in existing frameworks. For example, despite the known importance of exposure level to the toxicity of many chemicals, many frameworks focus on the inherent hazards of chemicals, and assume that all chemical alternatives would have similar levels of exposure to people, to animals, or to the environment.

Further, many frameworks are not transparent and explicit about the judgments and trade-offs that underlie decisions. The committee identified no "ideal" framework from the existing approaches, but each helped to inform the development of the framework presented in this report.

THE COMMITTEE'S FRAMEWORK

The committee's framework is structured to provide flexibility to its users and some steps or substeps are considered optional depending on the type of decision to be made. The committee's framework builds on existing approaches and also includes several important advancements, such as:

-An Increased Emphasis on Comparing Exposure

Many alternatives assessment frameworks focus on reducing inherent hazards, with only minor considerations of the level of exposure to the chemical. This can streamline assessments, but should only be used when a comparative exposure assessment indicates that the expected routes and amount of exposure are

Box 1. What is an Alternatives Assessment?

An alternatives assessment is:

- a process for identifying, comparing, and selecting safer alternatives to chemicals of concern.
- intended to facilitate an informed consideration of the advantages and disadvantages of alternatives to a chemical of concern.

An alternatives assessment is not:

- a safety assessment, where the primary goal is to ensure that exposure is below a prescribed standard,
- a risk assessment, where risk associated with a given level of exposure is calculated
- a sustainability assessment, that considers all aspects of a chemical's life cycle, including energy and material use.

Box 2. The Committee's Alternatives Assessment Framework

The report's authoring committee developed a 13-step framework to support decision making about chemical and non-chemical alternatives.

Step 1: Identify the Chemical of Concern. The entry point of the framework; identification or prioritization of chemicals of concern was beyond the scope of this report.

Step 2: Scoping and Problem Formulation. Determine stakeholder engagement needs; identify goals, principles, and decision rules; gather information on the chemical of concern including how and why is it is used; gather information on the function of the chemical of concern; and determine assessment methods—the steps of the framework to include, tools to use, the strategies to address uncertainty and tradeoffs.

Step 3: Identify Potential Alternatives. Identify chemical, material, and design alternatives on the basis of requirements established in Step 2.

Step 4. Refer Cases with Limited or No Alternatives to Research and Development.

Step 5. Assess Physicochemical Properties. Gather readily-available information on physicochemical properties to facilitate steps that evaluate hazard and exposure.

Step 6. Assess Human Health and Ecological Hazards, and Assess Comparative Exposure.

Step 7. Integration of Information on Safer Alternatives. Identify safer alternatives based on the information compiled in previous steps.

Step 8. Life Cycle Thinking. Determine whether risks to human health, the environment, or society exist at a place or time beyond the point of use or application, and if those risks are expected to differ between the chemical of concern and proposed alternatives.

Step 9. Optional Assessments: Additional Life Cycle Assessment, Performance Assessment, and Economic Assessment.

Step 10. Identify Acceptable Assessments and Refer Cases With No Alternatives to Research and Development.

Step 11. Compare or Rank Alternatives. Select a single alternative for implementation, or differentiate between acceptable alternatives.

Step 12. Implement Alternatives. Transition to alternatives, including mitigating trade-offs and monitoring for unintended consequences, as needed.

Step 13. Research or De Novo Design of Safer Alternatives. Create chemicals to improve overall safety of chemical products.

not expected to be substantially different between a chemical of concern and its alternatives. Thus, the potential for differential exposure between the chemical of concern and alternatives should be explicitly considered, rather than assuming equivalent exposure. This should not be interpreted as a recommendation for more comprehensive risk assessment—the committee concludes that simplified exposure assessments can meet the needs of many alternatives assessments.

-A Focus on Problem Formulation and Scoping

Many decisions about the selection of alternatives are not purely technical, but rather are value-driven or context dependent—ultimately coming down to trade-offs. The resolution of these trade-offs is shaped by organization's goals and principles, and therefore it is important to explicitly articulate and document assumptions and constraints in advance. The committee recommends that an important scoping step be the documentation of the goals, principles, and decision rules guiding the assessment.

The assessor will need to determine the assessment boundaries and methods in a step called problem formulation. At a minimum, the committee recommends consideration of the chemical of concern's physicochemical properties, comparative exposure, ecotoxicity, human health hazards, and life cycle thinking (methodologies that consider the potential environmental impacts of a product at all stages including production, use, and post-use).

Within problem formulation, the committee found that characterization of function and performance requirements are often undervalued parts of an alternatives assessment process, but are essential for successful prioritization and adoption of alternatives. This shifts focus from simply avoiding hazardous chemicals to identifying the safest, most viable alternative. At the same time, it is important to not define performance requirement criteria too narrowly. This

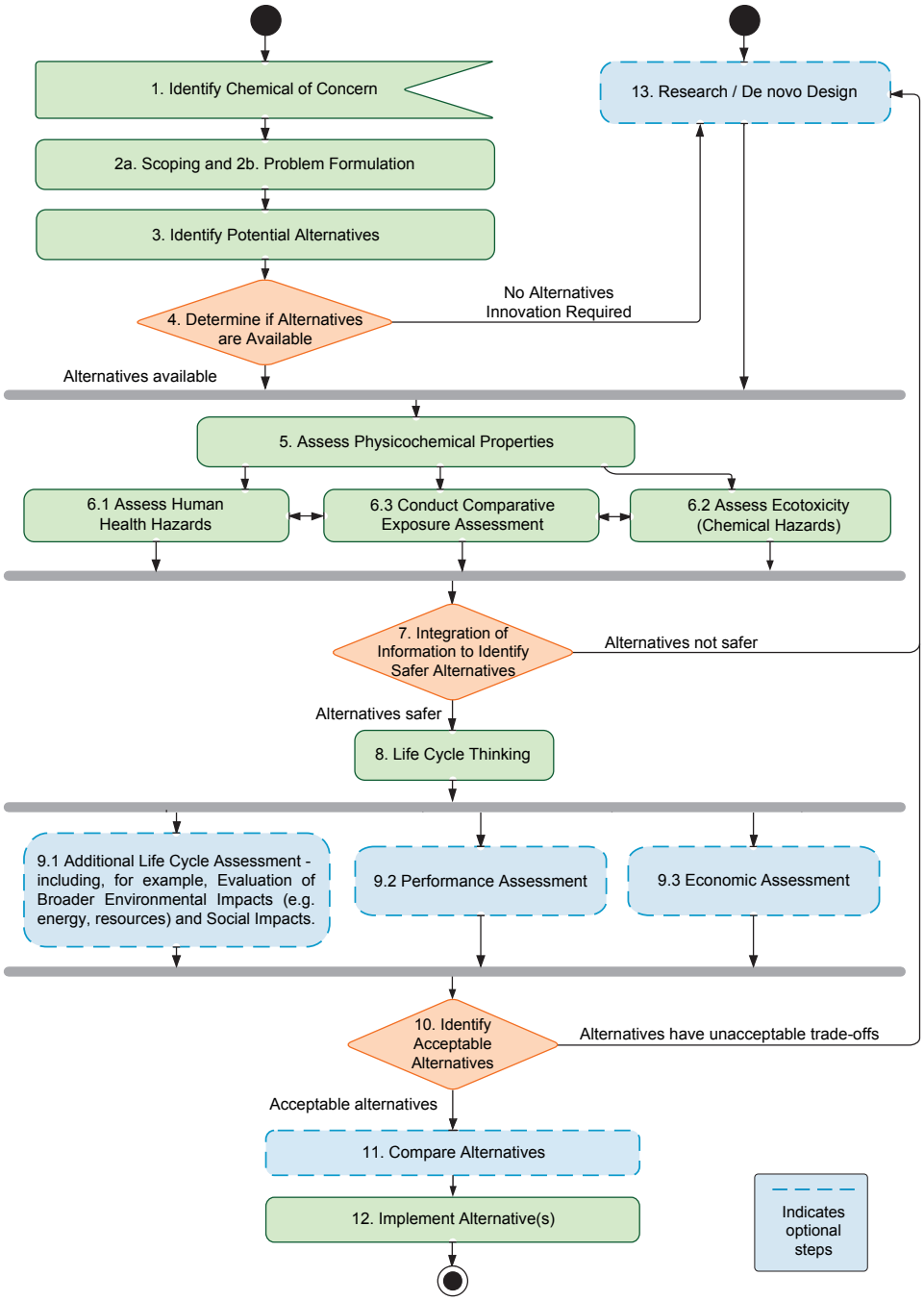

Figure 1. The Committee's Alternatives Assessment Framework

could lead to the rejection of alternatives that have markedly improved human health or environmental performance. These alternatives could be developed as suitable replacements, perhaps through other adjustments in the product, formulation, or process.

-Elevating the Role of Physicochemical Property Evaluation

A growing body of literature shows that a number of physicochemical properties—the physical properties of the chemical, including how it interacts with different media, and the molecular attributes that define its reactivity—can help predict a chemical's ecological and human health hazards. To make broader use of these data, the committee's framework elevates the role of evaluation of physicochemical properties in the alternatives assessment process.

-The Need for Research and Innovation

If the chemical alternatives fail to meet functional requirements, then research and innovation is needed to design new chemical alternatives or identify other

ways to meet the needs of industry and the consumer. In some cases, this provides an opportunity to develop a new chemical that meets functional needs or by developing an innovative concept that solves the problem in a different way. The committee recommends that safety and ecological considerations be an integral part of early chemical design so that the best alternatives can be identified as early as possibly in the design process.

SCIENTIFIC INFORMATION AND TOOLS REQUIRED TO SUPPORT THE COMMITTEE'S FRAMEWORK

Most frameworks rely on traditional toxicology data streams—such as human epidemiologic data and ecotoxicity studies—to assess the human health and environmental hazards of chemical use. Evaluation of these data is often supported by classification tools such as the Globally Harmonized System of Classification and Labelling of Chemicals [GHS]. However, there have been many new developments in toxicity testing over the past 10 years. The 2007 National Research Council report Toxicity Testing in the 21st Century: A Vision and a Strategy, in particular, spurred new approaches and thinking about chemical hazard assessment, and ongoing advances in chemistry, material sciences, and toxicology contribute to this revolution. The current report demonstrates how modern sources of data, such as those generated by high throughput toxicity testing methods and computational approaches, offer new insights to the alternatives assessment process. It is critical that the scientific community embrace the challenge and advantages of using novel data streams in the alternatives assessment process. Future efforts are needed to develop principles or tools that support the benchmarking and integration of high throughput data on chemical effects, especially in the context of different regulatory requirements.

THE COMMITTEE'S FRAMEWORK IN ACTION

The report's authoring committee provides two case studies that demonstrate the use of the framework. The case studies illustrate how product manufacturers could use the framework to seek substitutes for priority or controversial chemicals. The framework also could be used to support efforts by retailers to certify the superior environmental performance of the products they sell, and to support efforts by manufacturers to go beyond regulatory restrictions in selecting the chemicals they use as part of their sustainability programs. Regulatory agencies and other organizations also could benefit from the framework, and its flexible structure may lead to its broad adoption as a decision framework for evaluating potentially safer chemical alternatives.

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The National Academies appointed the above committee of experts to address the specific task requested by the U.S. Environmental Protection Agency. The members volunteered their time for this activity; their report is peer-reviewed and the final product signed off by both the committee members and the National Academies. This report brief was prepared by the National Research Council based on the committee's report.

For more information, contact the Board on Chemical Sciences and Technology at (202) 334-2187 or visit http://dels.nas.edu/bcst. Copies of *A Framework to Guide Selection of Chemical Alternatives* are available from the National Academies Press, 500 Fifth Street, NW, Washington, D.C. 20001; (800) 624-6242; www.nap.edu.