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ISSUE BRIEF

THE ESSENTIAL-USE APPROACH:
A POLICY TOOL FOR REDUCING EXPOSURES TO TOXIC CHEMICALS

Exposure to chemicals of concern in consumer and industrial products and the environment puts people at increased risk of disease and death.[1] In light of this, uses of chemicals of concern that are not necessary for health, safety, or the functioning of society should be removed from consumer and industrial products and processes. This policy brief outlines a practical approach known as the "essential-use approach" to reduce the use of chemicals of concern and more efficiently use regulatory resources to manage hazardous chemicals while transitioning to safer alternatives.

A NEW, MORE HEALTH-PROTECTIVE REGULATORY APPROACH IS NEEDED

Current regulatory methods—including risk assessments—for managing chemicals of concern have failed to protect people and the environment from widespread pollution and exposure to harmful chemicals.[2] Operating under the prevailing chemicals-management approach—that chemicals are safe until proven otherwise—has led to widespread contamination of air, water, and soil as well as the bodies of humans and wildlife.[3]

Meanwhile, regulatory agencies continue to apply inefficient and ineffective risk assessment methods.[4] Regulatory risk assessments of chemicals already in the marketplace typically take years or even decades to finalize, leading to relatively few existing chemicals being assessed for toxicity. Assessments of new chemicals are sometimes burdened by a lack of specific requirements, limited resources, and insufficient time frames for review, leading to many potentially harmful chemicals being approved by default.[5] Compounding these issues, the financial interests of the regulated community often have undue influence on how policies are made and executed.[6] Further, most assessments address only a single chemical or a small group of chemicals, leaving large chemical classes of concern such as PFAS (per- and polyfluoroalkyl substances) mostly unevaluated.

Soaps are great at removing germs, without the need for added toxic chemicals.

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WHAT ARE CHEMICALS OF CONCERN?

Chemicals of concern are any chemicals, or class of chemicals, that have confirmed or suspected hazard traits, such as:[7]

- Human health risks, such as cancer, or reproductive or developmental harms
- Risks to wildlife, domesticated animals, plants, or biodiversity
- Environmental risks such as accumulation, persistence, mobility, ozone depletion, or climate change
- Physical threats such as combustion facilitation, explosivity, or flammability

Chemicals with similar characteristics (such as similar structures, environmental properties, or biological hazards) should be evaluated and managed as a class wherever possible. This would decrease regrettable substitution—the replacement of a chemical of concern with a chemical with unknown but likely similar hazards—and more efficiently reduce the use of chemicals of concern.

THE ESSENTIAL-USE APPROACH IS MORE EFFICIENT AND HEALTH-PROTECTIVE

The essential-use approach is a policy strategy to reduce exposures to hazardous chemicals by **eliminating all nonessential uses**. The approach was first applied in 1987 under the Montreal Protocol to phase out ozone-depleting chlorofluorocarbons.[8] The Montreal Protocol states that uses of chlorofluorocarbons may continue only if they are determined to be "necessary for health, safety, or critical for the functioning of society" and if "there are no available technically and economically feasible alternatives."[9]

The essential-use approach is based on this belief that the use of chemicals of concern is not warranted in products or processes where they are not critical for health, safety, or the function of society.[a] That is, chemicals of concern should not be used in products that are not critical for these purposes, for nonessential functions within products, or when there are safer alternatives. The goal of this approach is not to ban products but to discontinue the use of toxic chemicals when not needed.

FRAMEWORK FOR APPLYING THE ESSENTIAL-USE APPROACH TO CHEMICALS OF CONCERN MORE BROADLY

The essential-use approach offers a way to address unnecessary uses of confirmed or suspected chemicals of concern, including large classes of chemicals, without having to engage in lengthy and resource-intensive assessments. Aspects of the essential-use approach are already being adopted by governments and businesses committed to reducing the use of harmful chemicals as quickly as possible.[10] However, there is currently no clear framework for its policy application beyond the Montreal Protocol.

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Chemicals of concern should not be used in products that are not critical for health, safety, or the function of society.

Here we outline an actionable approach for determining essential use through three related true/false statements. This framework, adapted from the work of Bălan et al., can streamline the process and avoid lengthy timelines with a particular focus on facilitating policy application.

In this approach, a use of a chemical should be deemed temporarily essential only if all of the following are true:

- There are no safer alternatives to the chemical available; **and**
- the function of the chemical is necessary for the product to work; **and**
- the chemical is being used in a product that is critical for health, safety, or the function of society.

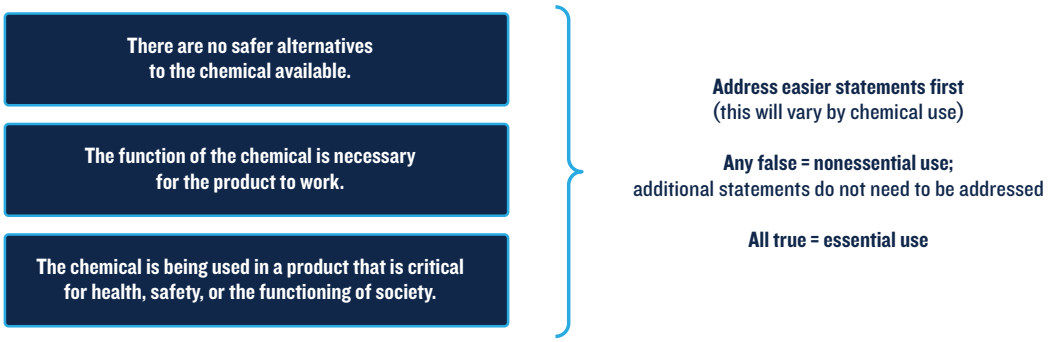
Importantly, not all three of the true/false statements necessarily need to be addressed. If any of the statements is false, that use is nonessential. So, addressing the statement that is most easily answered can alleviate the need to address the remaining statements. Statements that are more difficult to evaluate need to be evaluated only if answers to the easier-to-evaluate statements are true. Only if all three statements are true should decision makers deem the chemical use essential and initiate a plan to develop safer alternatives and mitigate harms from continued use. Any determination that a chemical use is essential is inherently temporary and will change as safer alternatives are developed.

WHAT IS A SAFER ALTERNATIVE?

A safer alternative could be a safer chemical (a drop-in replacement); another option is to eliminate the need to use a chemical of concern by changing the design of the materials, products, or processes. For example, in the thermal paper used for shopping receipts, harmful bisphenols could be eliminated by redesigning the paper itself or providing electronic receipts.[11] Importantly, the drawbacks of proposed alternatives must be carefully considered and addressed (e.g., not everyone has access to electronic receipts).

a *Use*, in this context, means a function provided by a chemical within a product or process.

FIGURE 1: TRIAGE APPROACH TO ESSENTIAL-USE DETERMINATIONS*



*Adapted from Simona A. Bălan et al., "Optimizing Chemicals Management in the US and Canada Through the Essential-Use Approach," *Environmental Science and Technology,* (January 19, 2022) in order to facilitate policy application; and based on the definition of *essential-use* by the United Nations Environment Programme, *Handbook for the Montreal Protocol on Substances that Deplete the Ozone Layer,* 13th ed. (Nairobi: Ozone Secretariat, 2019). That definition states that an essential use is one that is "necessary for health, safety or critical for the functioning of society" and "there are no available technically and economically feasible alternatives."

EXAMPLES OF THE ESSENTIAL-USE APPROACH

The following examples illustrate how the essential-use approach can be applied. While it may be difficult to come to a consensus on every statement, there will often be clear agreement on at least one of the statements, which can lead to a quick conclusion of the process (see examples marked with an asterisk). Additionally, in some cases, performing the assessment identifies specific situations within a use category that are essential, while other uses can be removed as nonessential (see the last example).

TABLE 1: EXAMPLES OF ESSENTIAL-USE DETERMINATIONS

Chemical (individual or class) Function Product	There are no safer alternatives to the chemical	The function of the chemical is necessary for the product to work	The chemical is being used in a product that is critical for health, safety, or the functioning of society	Likely determination
Phthalates to extend the duration of fragrance (fixatives) in perfumes[12]	**Depends**; safer fixatives may be available for some uses*	**False**; fragrances do not need to be long lasting, but some people might disagree*	**False**; perfumes are nice to have but not critical	**Nonessential use**
Triclosan and triclocarban to protect against germs in soaps and detergents[13]	**False**; safer alternatives are available, including the surfactant property of soaps and detergents, which can already perform the function of removing germs	**False**; surfactant property of soaps and detergents adequately protects against germs on its own	**True**, in certain cases; though not all uses of soaps and detergents are critical, those used to protect against germs are necessary for health and safety*	**Nonessential use**
TCE as a solvent in metal degreasers[14]	**False**; safer solvents are available	**True**; solvents are needed to break up grease	**Depends**; metal degreasing is needed for numerous industrial operations, some of which are critical for the functioning of society*	**Nonessential use**
Isocyanates to form the chemical structure of polyurethane foam (polymerizing agent) in insulation[15]	**False**; alternative types of insulation are available	**True**; polymerizing agent is needed to form the foam	**True**; building insulation is critical for health	**Nonessential use**
PFAS as surfactants in aqueous firefighting foam[16]	**False**; alternative surfactants are used in fluorine-free foams	**True**; a surfactant is necessary for the foam to spread quickly and suffocate oil-based fires	**True**; the product is needed to fight oil-based fires	**Nonessential use**
PFAS to repel infectious liquids coming in contact with hospital gowns[17]	**True**, specifically for long surgeries; there are no known working alternatives that repel liquids while providing the breathability needed for long surgeries	**True**; hospital gowns are designed to repel liquids	**True**; the product protects medical workers against exposure to infectious liquids	**Essential use for long surgeries**

*Regardless, the statement doesn't need to be conclusively evaluated because at least one other statement is "false."

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Fire fighters can be exposed to many harmful chemicals on the job, including PFAS in firefighting foam.

As is shown in the examples above, making essential-use determinations requires the following:

DATA

Information on where chemicals of concern are used (chemical transparency) is critical to the essential-use approach, and this often requires data from chemical and product manufacturers. Information about the use of chemicals of concern should not be protected by claims that it is "confidential business information" or claims of lack of awareness of their use in supply chains.[18]

EXPERTISE

Decisions about health and safety can be supported by input from individuals with diverse expertise and without financial conflicts of interest, such as scientists, health professionals, and representatives of potentially impacted workers or communities. Creating a plan for stakeholder engagement that includes identification and representation of vulnerable and at-risk populations impacted by the use of the chemicals of concern and the products in question, throughout their life cycle, will help to ensure equitable implementation of this approach. If needed, technical experts can be brought in to conduct an assessment of potential safer alternatives.

CLEARLY DEFINED DECISION MAKERS

Final determinations about essentiality can be made by government bodies at the local, state, and federal levels as well as by businesses that are working to remove chemicals of concern from their product lines. Stakeholders with financial conflicts of interest should not be decision makers in essential-use determinations.

FREQUENTLY ASKED QUESTIONS

Can the essential-use approach be used alongside risk assessment?

In some cases, the essential-use approach may eliminate the need for a traditional, time-consuming risk assessment. For example, during premarket chemical review, nonessential uses can be eliminated prior to the chemical's release into the environment.

However, the essential-use approach can also be applied during the risk assessment process. Nonessential uses can be restricted on the basis of hazard traits (see "What are chemicals of concern?") prior to a full risk assessment, thus avoiding lengthy exposure assessments. Regulatory resources can then focus more efficiently on evaluating and mitigating the risks of essential uses while transitioning to safer alternatives. For chemicals that have undergone a full risk assessment, essentiality determinations can be included in risk management decisions.

How can safer alternatives be identified?

Sometimes safer alternatives are well known and readily available. If not, an alternatives assessment by a technical expert may be needed.[19] Whether a technical expert is required may depend on the level of transparency in a particular market and the amount of available data on the toxicity and other characteristics of alternatives. Note that safer alternatives do not always need to match the function and performance of the chemical they are replacing; they simply need to meet the functional requirements of the product or service.[20] For example, the performance of surfactants in fluorine-free firefighting foams is sufficient for the majority of fire situations, even though they do not perform exactly as the PFAS they replace.[21]

RECOMMENDATIONS

Governments and businesses should implement the essential-use approach described above to:

- Phase out known nonessential uses of chemicals of concern immediately
- Set up programs to systematically assess chemicals of concern with the essential-use approach and phase out other unnecessary uses

To maximize the utility of the essential-use approach, it should be combined with:

- Improved transparency (to gather better data) on where and how chemicals are being used
- Investment in the development of safer alternatives to chemicals of concern
- Conducting more alternatives assessments to identify and characterize safer alternatives
- The class approach to avoid instances of regrettable substitution

ENDNOTES

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