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Perspective

# Optimizing Chemicals Management in the United States and Canada through the Essential-Use Approach

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**ABSTRACT:** Chemicals have improved the functionality and convenience of industrial and consumer products, but sometimes at the expense of human or ecological health. Existing regulatory systems have proven to be inadequate for assessing and managing the tens of thousands of chemicals in commerce. A different approach is urgently needed to minimize ongoing production, use, and exposures to hazardous chemicals. The premise of the essential-use approach is that chemicals of concern should be used only in cases in which their function in specific products is necessary for health, safety, or the functioning of society and when feasible alternatives are unavailable. To optimize the essential-use approach for broader implementation in the United States and Canada, we recommend that governments and businesses (1) identify chemicals of concern for essentiality assessments based on a broad range of hazard traits, going beyond toxicity; (2) expedite decision-making by avoiding unnecessary assessments and strategically asking up to three questions to determine whether the use of the chemical in the product is essential; (3) apply the essential-use approach as early as possible in the process of developing and assessing chemicals; and (4) engage diverse experts in identifying chemical uses and functions, assessing alternatives, and making essentiality determinations and share such information broadly. If optimized and expanded into regulatory systems in the United States and Canada, other policymaking bodies, and businesses, the essential-use approach can improve chemicals management and shift the market toward safer chemistries that benefit human and ecological health.

**KEYWORDS:** *chemicals of concern, risk assessment, chemicals management, alternatives assessment, chemical regulation, environmental social and corporate governance, PFAS*



## ■ INTRODUCTION

Over the past century, human invention in the field of chemistry has delivered functionality and convenience in industrial and consumer products. However, ample scientific evidence has revealed significant adverse health effects in human and wildlife populations from exposure to chemicals at concentrations currently found in the environment [e.g., polybrominated diphenyl ethers, per- and polyfluoroalkyl substances (PFAS), lead, and organophosphate pesticides].[1−5] Product development and chemical usage have been largely driven by internal company decisions regarding cost and performance, with limited regulatory oversight and incomplete information disclosure.[5] Unchecked production, use, and disposal, combined with inadequate consideration of human and ecological health impacts of some of these chemicals, have resulted in polluted air, water, soil, and indoor environments.[5]

Consumers, while favoring products offering convenience through diverse functionalities, are typically unaware of the potential exposure to hazardous chemicals in such products or of the broader environmental consequences. For most products, there is currently no requirement for companies to disclose the identity of chemicals in products.[6] However, with increasing awareness, there is often increasing demand that hazardous chemicals be eliminated from consumer products, yet current regulatory systems have proven to be unable to effectively assess risk from the tens of thousands of chemicals in commerce or to adequately control the extensive and growing contamination and its accompanying harmful effects.[6−9] Therefore, innovative approaches to chemicals management are urgently needed to minimize ongoing production, use, and exposure to hazardous chemicals.

In this paper, we discuss key limitations with the current approaches to chemicals management systems in the United States and Canada and then describe the essential-use

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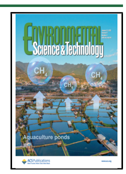





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approach that holds promise for reducing the use and widespread distribution of chemicals of concern. We define chemicals of concern broadly, without reference to any specific jurisdictional definition, as based on the presence of one or more confirmed or reasonably anticipated health or environmental hazard traits. We provide several recommendations for how to optimize the essential-use approach in the United States and Canada for both governments and businesses.

## WHY A NEW APPROACH TO CHEMICALS MANAGEMENT IS NEEDED

Beginning in the late 1960s, the United States, Canada, and several other jurisdictions established regulatory frameworks to assess and manage chemical safety.[10] Many such frameworks are based on the use of risk assessment, in which the hazard of a chemical (often narrowly defined as toxicity) and the likelihood of exposure at sufficiently high concentrations to cause harm must be demonstrated to trigger risk management actions. In some jurisdictions, this process can take ≥10 years to complete for a given chemical already on the market.[11−13]

The lack of chemical-use and toxicity data for the vast majority of chemicals used in consumer products or industrial processes[5,14] and the often-unjustified assumption that a chemical poses a low risk in the absence of data to the contrary further limit current regulatory systems. This inability to accurately assess risk is even more pronounced for the tens of thousands of chemicals that were already in use when the laws were enacted in the 1970s and were exempted from review.

In addition, an inordinately high degree of proof of risk is required to enact regulatory controls once a chemical is in use, much higher than any proof of safety required before a chemical is allowed to enter into commerce or for expanded usage.[8] The sheer number of new chemicals being produced and the frequent changes in the use or production of existing substances, which may or may not be disclosed, have prevented government agencies with limited funding from maintaining surveillance and completing risk assessments in a timely manner.[7]

In the absence of sufficient regulatory oversight, very little incentive exists for companies to determine or disclose the chemicals or complex chemical mixtures in the products they sell. When disclosure is required, chemical manufacturers often claim that the structural identities of their compounds, production and import volumes, and even health and safety testing data qualify as confidential business information (CBI).[9] Thus, regulators, the greater scientific community, and the public often do not know which substances are widely used, emitted, and dispersed in the environment, nor what the adverse health effects of these compounds might be.[8]

In the United States and Canada, only a small percentage of chemicals (excluding pesticides and pharmaceuticals) have undergone thorough risk assessment and even fewer have ever been restricted. Most of the restrictions enacted include exemptions that allow certain uses to continue.[15] In addition, when one chemical is restricted, manufacturers often replace it with a chemical with similar structural, functional, and other characteristics.[16−18] In most cases, little, if any, evidence for a chemical's safety is required before such "drop-in" replacements enter the marketplace. When hazards are suspected, years or even decades can pass before sufficient data are acquired to assess risks of the replacements and take regulatory action. During this time, the use of a chemical may increase, applications may diversify, and supply and demand may become locked in.[19] Such regrettable substitutions increase the potential for combined exposures to chemicals with similar adverse effects on human and ecological health. Persistent chemicals are especially problematic because they will accumulate, thereby increasing risk to humans and other species.[20] They are also much more expensive to remediate (if technically feasible) because they do not naturally decay in the environment.[20]

To address these issues, an approach called "essential use" could be optimized and effectively incorporated into current regulatory systems in the United States and Canada for both new and existing uses of chemicals (i.e., pre- and postmarket).[21,22] Chemical and product manufacturers, as well as retailers, can also leverage this approach to complement regulatory action and help move the market toward safer products and processes while continuing to deliver essential functions.

## ORIGINS OF THE ESSENTIAL-USE APPROACH

The essential-use approach states that chemicals of concern should be used only in cases in which their function in a product is "necessary for health, safety or is critical for the functioning of society" and where feasible alternatives are not available. Here "use" means a function provided by the chemical within a product or system. This includes chemicals used during manufacturing processes such as processing aids, degreasers, or solvents that may or may not end up in the final product.[23] If a particular use of a chemical of concern is "essential", that specific use would be approved, but on a time-limited basis. Internationally, this idea was first introduced in the Montreal Protocol, which addresses environmental harms caused by ozone-depleting substances such as chlorofluorocarbons by setting a timetable for phasing them out, with exemptions for essential uses.[24]

More recently, an adapted version of the essential-use approach has gained attention worldwide, due in large part to the work of an international collaboration of scientists.[22] Notably, Cousins et al.[22] proposed to apply the essential-use approach to the large class of PFAS, identifying three categories of uses: (1) non-essential uses, (2) substitutable uses, which are, in effect, non-essential because they have viable alternatives, and (3) essential uses. In 2020, the EU released its Chemicals Strategy for Sustainability, calling for phasing out use of the most harmful chemicals such as PFAS and endocrine disruptors, except for uses that are determined to be essential for society.[25] The U.S. state of Maine took a similar approach in 2021, banning the use of PFAS in all products by 2030, except where the state determines a use is "currently unavoidable".[26] Other U.S. states have used a similar framework to ban the use of PFAS in specific applications.[27−31]

## RECOMMENDATIONS FOR OPTIMIZING THE ESSENTIAL-USE APPROACH

As the essential-use approach gains broader acceptance among governments and businesses, several issues require careful consideration. Below we provide recommendations, specifically with respect to optimizing implementation of the approach in the United States and Canada.

**Identify Chemicals of Concern Based on a Broad Range of Hazard Traits.** The essential-use approach begins with defining "chemicals of concern", the scope of which will


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vary depending on which decision-making authority is applying the approach. For example, the U.S. Environmental Protection Agency (EPA) may define chemicals of concern as those identified under the Toxic Substances Control Act, while the California Department of Toxic Substances Control might define them on the basis of factors outlined in the California Safer Consumer Products Regulations. In the realm of business, a product manufacturer could apply the approach to their "Red List" of chemicals to avoid. Because the scope will vary, it should in all cases be clearly communicated.

In the absence of a predefined scope, we recommend using a broad definition of hazard traits to be protective. For example, in addition to human and ecological toxicity, California's Green Chemistry Hazard Traits developed by the Office of Environmental Health Hazard Assessment include chemical persistence, mobility, (bio)accumulation, lactational and transplacental transfer, among others (Cal Code Regs Title 22, Division 4.5, Chapter 54).[32] Life-cycle considerations such as impediments to material circularity (e.g., the presence of organohalogens in electronic enclosures and carbon black in plastic food containers that impede plastic sorting and recycling) may be other reasons to identify a substance as a chemical of concern.[33] Human and ecosystem exposure can occur throughout a chemical's life cycle, including through occupational exposure. Notably, time-consuming exposure assessments need not be conducted to identify chemicals of concern. More rapid methods that estimate toxicity and exposure on the basis of, for example, physical properties, chemical functional use, or biological activity may prove to be useful in the future.[34−39]

To improve upon the current approach to chemicals management, it is important to increase the number of chemicals of concern being assessed concurrently, thereby reducing human and ecological harm more quickly. Considering chemicals that have similar physicochemical, health, or environmental traits together as a class is one way to do this.[18,40−44] This approach also reduces the likelihood of regrettable substitution by avoiding substitution within a class of concern. For example, for PFAS, which are already on the market in myriad uses, addressing the entire class together is the most efficient path to reducing exposures and potential adverse impacts.[45,46] Many approaches are available to group chemicals, and the decision-making authority will need to decide on its method, depending on the circumstances and conditions.[40]

**Expedite Decision-Making by Avoiding Unnecessary Assessments.** We recommend a process for implementing the essential-use approach in which decisions about the necessity of a chemical in a specific product or process are triaged for maximum efficiency (Figure 1). This can help avoid a lengthy assessment of every use of a chemical of concern (which can lead to paralysis by analysis). Once a chemical, group, or class of chemicals of concern is identified, a government agency or business can start by asking any of the three questions listed in Table 1:

If the response to any question is no, then this is not an essential use and the chemical of concern can be substituted, discontinued, or denied approval.[47] Only if the answer to all three questions is yes is this considered an essential use of the chemical. The most efficient approach is to start with the question that can be most easily answered no, as this eliminates the need to ask the other two questions and concludes the process. Policies should specify that essential uses are given time-limited (temporary) approval with a substitution plan for developing safer alternatives. To be clear, the essential-use approach is about expediting phase-out of chemicals of concern in products or processes, not about removing products. Another way to expedite decisions is for regulators and businesses to assume that all uses of chemicals of concern, or all uses of chemicals of concern in certain product categories, are non-essential and request justification for those uses considered essential.

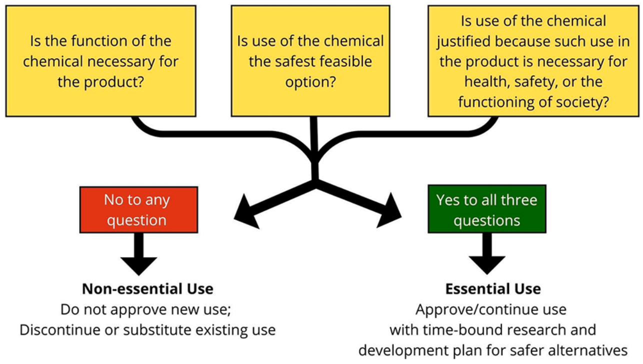


**Figure 1.** Essential-use questions for chemicals of concern. This figure shows a process for implementing the essential-use approach by triaging decisions about the necessity of chemicals of concern in specific consumer products and industrial processes. Once any question is answered no, the process concludes.

To illustrate how the process depicted in Figure 1 could be applied, consider when PFAS are used to provide water and oil resistance in textile products.[48] For general clothing (e.g., fast fashion), neither water nor oil resistance is necessary, and thus, this use can be discontinued. For outdoor apparel, people may disagree about whether the water-resistance function is necessary, but the chemical is not necessary for the function, because safer alternatives are available for most such products.[49] So again, PFAS can be discontinued for that use, avoiding debate over necessity. In some personal protective equipment, PFAS are considered necessary for the function of the equipment, which protects the health and safety of the workers, and currently no safer alternatives are available. Thus, the latter are currently essential uses of PFAS until safer alternatives are available.

Aspects of the process described in Figure 1 are already being implemented in nonregulatory and regulatory decision-making. For example, the Toxics Use Reduction Act in Massachusetts requires manufacturers within the state to report the usage of chemicals of concern and evaluate options for reducing unnecessary uses.[50] Some furniture and housewares retailers have implemented an internal strategy for managing chemicals of concern that considers the need for a product or substance along with the availability of alternatives.[51] The State of Washington Department of Ecology recently conducted an alternatives assessment and subsequently banned PFAS in several types of food packaging on the basis of being substitutable by safer grease-proofing alternatives.[52,53] Under the California Safer Consumer Products Regulations, if manufacturers claim that a chemical of concern in a regulated consumer product is essential and there are no available safer alternatives, the state requires them to invest in the development of green chemistry or engineering solutions and to inform the public that they are currently using the chemical of concern.[54,55]


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Table 1. Three Questions to Ask for Essential-Use Determinations and Their Rationale

| question | rationale |
|---|---|
| Is the function of the chemical necessary for the product? | Some functions are nice to have but not essential to the product and can thus be removed relatively easily.[a] |
| Is use of the chemical the safest feasible option? | Sometimes safer alternatives are already available, which could be safer chemicals, materials, products, or processes.[b,c] To be clear, identifying the "safest" option is not required to answer "no" to this question; one only needs to identify an alternative that is safer than the chemical of concern. |
| Is use of the chemical justified because such use in the product is necessary for health, safety, or the functioning of society? | This question addresses the combination of function, chemical, and product to assess whether the use is necessary. It is not intended to address the essentiality of the product by itself. |

[a]From ref 22. [b]From ref 68. [c]From ref 47.

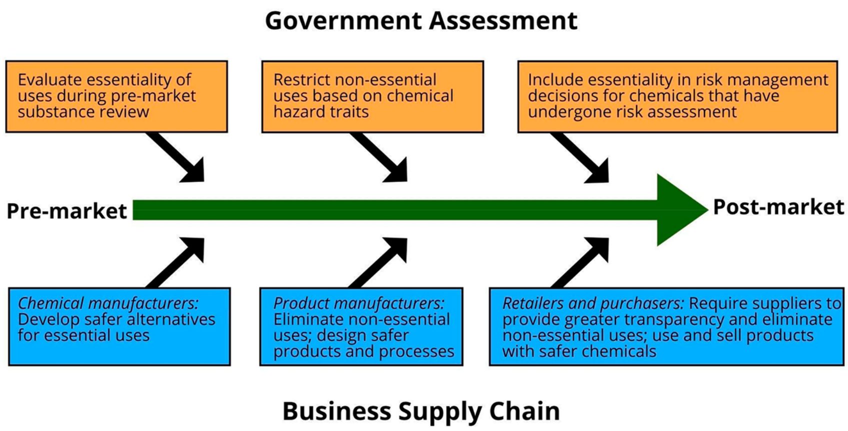


**Figure 2.** Opportunities to apply the essential-use approach to chemicals of concern. This figure shows a simplified view of pre- and postmarket opportunities for governments and businesses to apply the essential-use approach. In reality, the process is not linear; for instance, retailers and purchasers can also influence premarket decisions. Applying the approach earlier can result in fewer people harmed, fewer regrettable substitutions, reduced externalized costs to health and the environment, reduced loss of investment, increased investment in safer chemicals, and fewer uses to be assessed.

**Apply the Essential-Use Approach as Early as Possible.** Governments and businesses managing their product lines can apply the essential-use approach at several points during chemical evaluations (Figure 2). Early application of the essential-use approach (e.g., premarket or at the beginning of the supply chain) is the most effective. Preventing harmful chemicals from ever entering the marketplace minimizes the potential for harm, reduces the risk of regrettable substitution, lowers externalized costs to health and the environment (e.g., medical treatment and environmental cleanup costs), and prevents the "lock-in" effect.[19] Chemical and product manufacturers benefit from a premarket assessment through reduced loss of investment if a chemical is later regulated, fewer public relations risks, and the opportunity for increased investment in safer chemicals. Government agencies can avoid evaluating a myriad of uses and exposures that have already proliferated. While earlier application of the framework is more likely to prevent proliferation of harmful chemicals and the costs associated with them, using the framework at any stage will likely lead to better results than not using it at all.

Governments can ask the essential-use questions during premarket substance review or during assessment of new uses (Figure 2). An example of premarket application can be found in the newest version of China's chemical registration law, which requires proof of necessity of use for all highly hazardous chemical substances and an analysis of socio-economic benefits, including "environmental friendliness".[56] Unfortunately, a premarket approach cannot be used for the tens of thousands of chemicals currently in commerce (e.g., on the Domestic Substances List in Canada).[53] In addition, some government agencies, for example at the U.S. state level, do not evaluate chemicals premarket and thus are able to apply the essential-use approach only postmarket. To balance the drawbacks of the postmarket approach, regulatory agencies may employ the essential-use approach without conducting a full risk assessment (e.g., after hazard assessment only, or with limited assessment of potential exposure). For chemicals that have already undergone risk assessment, the essential-use approach can be incorporated into risk management decisions with an emphasis on time-limited exemptions and incentivizing the development and use of alternatives.

Businesses have many opportunities to apply the essential-use approach to managing chemicals in their products and processes (Figure 2). The earliest opportunity is during chemical development, where businesses can invest in safer alternatives to chemicals of concern. For the many chemicals already in commerce, product manufacturers can develop programs to eliminate non-essential uses of chemicals of concern, as well as design safer chemicals, products, and processes. Retailers and other institutional purchasers can require supply chains to provide greater transparency of chemical uses and eliminate non-essential uses of chemicals of concern. Businesses can also make policy decisions to use and sell products with safer chemistries. For example, a footwear manufacturer determined that 70% of the more than 100 uses of PFAS in their products were not necessary for product function and removed them. The company then concentrated their resources on finding safer substitutes for the remaining uses and eventually removed all PFAS from their products.[57]

**Support Decision-Making by Engaging Diverse Experts and Sharing Information.** Essential-use determinations are made by the government agency or business


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conducting the assessment. However, answering the three questions in Figure 1 may require knowledge and expertise from many different stakeholders, and sharing of information is critical. Relevant stakeholders include government agencies, chemical and product manufacturers, retailers, technical experts, relevant private and nongovernmental organizations, and the public.

Product manufacturers may be best equipped to identify which products and processes use chemicals of concern and list the functions those chemicals provide. However, complex supply chains may impede transparency, resulting in retailers and product manufacturers not knowing the identity of specific chemicals in their products or the function they provide.[58,59] While companies along the supply chain understandably want to protect CBI, this may not be appropriate for chemicals of concern. In fact, the recent cleaning product law in California stipulates that a statutorily defined list of chemicals of concern cannot be protected by CBI.[55,60] The Principles for Chemical Ingredient Disclosure[61] describes good practices for full transparency recommended by key stakeholders in businesses, civil society, and government. In addition, greater transparency is needed regarding the identities of polymers and complex mixtures such as substances of unknown or variable composition, complex reaction products, or biological materials (UVCBs), which constitute a vast number of substances on the global market.[62,63]

A number of systems for sharing chemical information within and outside supply chains have been established in multiple industrial sectors, as reviewed by the United Nations Environment Programme.[5] In many cases, government agencies may need to require transparency. For example, the United States recently began such an effort by proposing one-time reporting requirements for uses of PFAS.[64] In addition, the U.S. EPA regularly collects chemical-use information for many existing chemicals through the Chemical Data Reporting rule.[65] This program could be updated to collect information about the necessity of a chemical use. In Canada, sections 46, 70, and 71 of the Canadian Environmental Protection Act can be but are not often used to gather information for decision-making (e.g., screening or risk assessment).[66]

If safer alternatives are not readily known, governments or businesses may conduct a formal alternatives assessment to identify alternative technologies, processes, systems, or chemicals with fewer or no health or environmental concerns. Third-party technical experts may be hired, or governments may stipulate that manufacturers conduct and pay for the alternatives assessment. Governments can also play an important role by identifying criteria for safer alternatives (and re-evaluating them on a regular basis) so that companies have clear direction for research and development and can avoid regrettable substitutes.[67] In addition, governments can stipulate timed phase-outs of chemicals of concern, together with policies that incentivize innovation in developing alternatives. In some cases, formal assessments of alternatives will not be needed, such as where feasible substitutes with sufficient performance are already available. In addition, thinking more broadly about the needed function may lead to previously overlooked solutions.[68] For example, instead of replacing the developer function of bisphenol A in register receipts with another harmful bisphenol, electronic receipts can provide a record of sale without a printed receipt.[69] Importantly, the drawbacks of proposed alternatives must be carefully considered and addressed (e.g., not everyone has access to electronic receipts).

Perhaps the most challenging decisions are those that determine the essentiality of a chemical's use for health, safety, or the functioning of society. Businesses may make these determinations on their own and remove uses that they deem are not essential. Regulatory decisions may require an expert advisory panel consisting of diverse stakeholders, including scientists, health professionals, and representatives of 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. Such panels must also be convened under a robust conflict-of-interest policy.[8] While chemical and product manufacturers have valuable and necessary expertise and data to contribute, entities with vested interests should not influence regulatory decisions on essentiality. As an example, members of the flame retardant industry were involved in setting numerous flammability standards, including a standard that necessitated the use of harmful flame retardants in household upholstered furniture (California Technical Bulletin 117).[70−72] Although set in California, this flammability standard became the de facto standard in the upholstered furniture industry in the United States and Canada, resulting in the use of large amounts of flame retardants. Decades later, California determined that the standard did not provide meaningful protection against fires, and a new standard (California Technical Bulletin 117−2013) was created and later adopted nationally.[73] Because the use of additive flame retardant chemicals in certain products was deemed unnecessary for fire protection and posed health risks, these chemicals were banned in California from use in several types of products.[74,75] Thus, this example also illustrates how decisions regarding health and safety can be made using the essential-use approach.

Sharing information about chemical uses, safer alternatives, and essential-use determinations can help reduce redundancy, expedite decision-making among other agencies and businesses, promote harmonization, reduce differences in regulations that are difficult for industry to navigate, and provide more equal protections for citizens in different regions and countries. It can also benefit businesses of all types and sizes by creating a more level playing field (e.g., by providing small businesses, imports, exports, and online markets access to the same information). However, efforts to harmonize across regulatory bodies should not delay or otherwise undermine the ability to provide the highest level of protection as quickly as possible.

## ■ SUMMARY

The development, use, and disposal of chemicals in consumer and industrial products have been largely driven by business cost and product performance, with limited chemical disclosure or assessment of environmental and health impacts. Gaps in the current regulatory systems for controlling hazardous chemicals in the United States and Canada have resulted in avoidable health risks, externalized costs, and ongoing degradation of the environment. The essential-use approach has the potential to significantly improve existing chemicals management systems by more quickly and efficiently assessing a greater number of chemicals of concern, ending


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non-essential uses of such chemicals, and promoting innovation by shifting the market toward less hazardous solutions.

We recommend that governments and businesses (1) define chemicals of concern using a broad range of hazard traits and (2) expedite decisions regarding the use of chemicals of concern by asking the easiest of three questions and concluding the process when a no answer is obtained: (a) Is the function of the chemical necessary for the product? (b) Is use of the chemical the safest feasible option? (c) Is use of the chemical in the product justified because such use is necessary for health, safety, or the functioning of society? We also recommend that governments and businesses (3) apply the essential-use approach early in the process of developing, using, and managing chemicals (benefits include fewer people harmed, fewer regrettable substitutions, reduced externalized costs to health and the environment, reduced loss of investment, increased investment in safer chemicals, and fewer uses to be assessed) and (4) support decisions by engaging diverse experts and sharing information (policies that include the essential-use approach should specify who will participate in the evaluations and how financial conflicts of interest will be avoided; chemical-use and -function data, alternatives assessments, and essentiality decisions should be shared publicly whenever possible).

The essential-use approach is already beginning to play a significant role in the management of chemicals by businesses and governments, as shown in the examples we provided. Incorporating the essential-use approach into regulatory systems in the United States and Canada, as well as other policy-making bodies and businesses, provides an opportunity to expeditiously reduce the use of hazardous chemicals, to benefit people and the planet.

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### Author Contributions

All authors contributed their experience and knowledge via group discussions and collaborative editing to the concepts and recommendations provided in this Perspective. In addition, C.F.K. led the discussions and C.F.K. and S.B. contributed substantially to the writing of the manuscript. All authors approved the final manuscript.

### Notes

The authors declare no competing financial interest.

### Biography

Dr. Simona A. Bălan is Chief of the External Communications and Environmental Justice unit in the Safer Consumer Products program at the California Department of Toxic Substances Control. Her work has led to regulatory restrictions on the use of per- and polyfluoroalkyl substances (PFASs) as a class in certain consumer products in California. She earned her Ph.D. in Environmental Science, Policy, and Management from the University of California, Berkeley, where she now lectures in the School of Public Health.

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