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Chemical Alternatives Assessment: Enabling Substitution to Safer Chemicals

EMMA T. LAVOIE*,†
LAUREN G. HEINE§
HELEN HOLDER⊥
MARK S. ROSSI§
ROBERT E. LEE II†
EMILY A. CONNOR‡
MELANIE A. VRABEL†
DAVID M. DIFIORE†
CLIVE L. DAVIES†

Design for the Environment Program, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460, United States, Abt Associates Inc., 4550 Montgomery Avenue, Suite 800 North Bethesda, Maryland 20814, United States, Clean Production Action www.cpa.org, and Hewlett-Packard Company, 1501 Page Mill Road, Palo Alto, California 94304, United States

Introduction

This paper describes the chemical alternatives assessment (CAA) approach to managing chemical risk, its use in practice at the U.S. Environmental Protection Agency (EPA) Design for Environment (DfE) Program, a voluntary partnership program, and its application in industry. DfE, situated in the Office of Chemical Safety and Pollution Prevention (OCSPP)—formerly EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS)—uses CAAs to evaluate the hazards posed by chemicals during relevant phases in the product life cycle and to provide a basis for informed decision-making, through careful comparison of potential human health and environmental hazards.

DfE developed its approach to CAAs in partnership with a broad range of stakeholders. The DfE approach can be applied to a range of chemical substitution circumstances. A common element is use of OCSPP expertise in chemistry, toxicology, and associated modeling; this expertise has developed over the last 30 years through evaluation of more than 50,000 chemicals in EPA's New Chemicals Program under the Toxic Substances Control Act (TSCA).

Alternatives Assessments Can Guide the Choice of Safer Chemicals

Around the world in business and in government, drivers for safer chemicals are increasing. As part of their sustainability programs, product manufacturers like Hewlett-Packard (HP), Dell, Nike, and Bissell have taken steps to go beyond regulatory restrictions in selecting the chemicals used to make their products. Nongovernmental organizations (NGOs), such as Clean Production Action, Environmental Defense Fund, Greenpeace, and ChemSec with their Substitute it Now (SIN) list, are encouraging industry action and raising public awareness. At the same time, governments are taking steps to restrict the use of chemicals and even remove chemicals from commerce. Europe's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulatory list, Canada's Chemicals Management Plan, and EPA's Enhanced Chemical Management Program are driving chemical substitution. Since December 2009, EPA has published action plans for eight chemicals or chemical classes (*1*). The action plans describe steps that EPA intends to take to prevent exposures where risks are likely; and for phthalates, bisphenol A (BPA), nonylphenol ethoxylates (NPEs), decabromodiphenyl ether (decaBDE), and hexabromocyclododecane, proposed actions include CAAs, to inform substitution to safer chemicals.

What are Chemical Alternatives Assessments?

DfE CAAs characterize chemical hazard based on a full range of human health and environmental information, including primary data sources and expert predictive models. The outcome of a CAA provides industry and other stakeholders with the information they need to choose safer chemicals and minimize the potential for unintended consequences, like those that result from switching to a poorly understood

* Corresponding author e-mail: lavoie.emma@epa.gov.
† Design for the Environment Program, U.S. Environmental Protection Agency.
‡ Abt Associates Inc.
§ Clean Production Action.
⊥ Hewlett-Packard Company.

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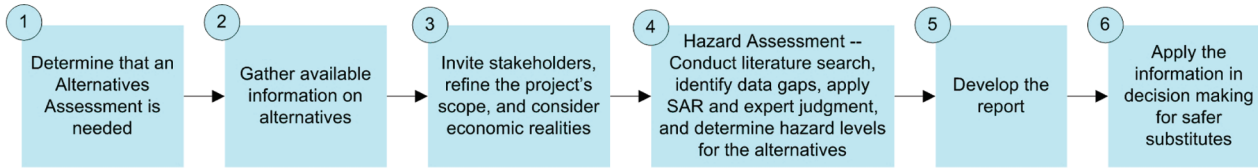

FIGURE 1. Six broad steps in conducting an alternatives assessment.

(and potentially more hazardous) substitute. DfE develops a conceptual framework for each CAA based on two key factors: life-cycle thinking and the chemical's functional use (see below for definition of "functionality" in DfE context).

DfE has applied its CAA methodology to guide the transition to safer alternatives for chemicals that include flame retardants (including pentabromodiphenyl ethers [pentaBDEs] in furniture foam) and ingredients such as solvents, surfactants, and fragrances used in cleaning products. CAAs can take various forms—depending, for example, on the scope of end points included in the analysis—and provide a range of outcomes—depending largely on the degree to which toxicological thresholds and categories of preferability are established. CAAs are a useful tool because they are broader than some screening and prioritization models (e.g., the Scoring and Ranking Assessment Model [SCRAM] (*2*)) but more focused than a full life-cycle assessment (LCA). The latter typically do not address chemicals used in small concentrations; nor do they delve into the comprehensive details of fate and toxicity. In contrast to risk assessments, which evaluate the nature and magnitude of both hazard and exposure, CAAs provide a comparative assessment of chemicals across a suite of hazard end points to inform the selection of safer alternatives. Some CAAs provide information to allow others to make decisions about substitution, such as the DfE Furniture Flame Retardancy Partnership. Others actually define and point to safer substitutes, such as Clean Production Action's (CPA) Green Screen for Safer Chemicals and the criteria for the DfE Safer Product Labeling Program (SPLP).

Life-Cycle Thinking. DfE uses life-cycle thinking to help focus the CAA on hazard at critical exposure points along the chain, from chemical manufacture through product manufacture, use, and disposal. Incorporating life-cycle thinking into chemical decision making results in a more comprehensive consideration of consumer, worker, and environmental exposure pathways. A full LCA is often unnecessary and too costly. For many chemicals and use scenarios, in addition to the points of direct chemical exposure, DfE considers likely fate and transport pathways, and end-of-life transformation products. For chemicals in consumer products, the exposure associated with the use phase is critically important. For down-the-drain products and products with potential impacts at end-of-life, chemical hazards associated with the use and end-of-life phases are included.

Functional Use Approach. In designing and conducting a CAA, DfE focuses on functional use. DfE applies the functional use concept in two ways: first and foremost, to characterize the purpose a chemical ingredient serves in—or the properties it imparts to—a product or process (*3*) and second, to evaluate the whole product and how its use may influence the assessment of alternatives. For example, a chemical may function as a solvent or surfactant in cleaning products, or as a flame retardant or plasticizer in a polymer for electronic products. Properties like physical form, if the chemical is a liquid, solid, or powder, and reactivity, (e.g. if the chemical is an additive flame retardant versus reacted into a polymer), may drive functionality and change the potential for chemical exposures, especially in the use phase. Where relevant, such properties become part of the alternatives assessment.

In DfE projects, the review of potential alternatives is focused on those providing the desired functionality. Further, the functional use approach is valuable in simplifying the assessment and avoiding the need for a full risk assessment on each alternative. Where similar product and chemical use patterns are expected, exposure can be considered a constant. As a result, risk (defined as hazard multiplied by exposure) can be reduced through a reduction in chemical hazard.

CAAs are a methodology for informed substitution. This approach enables the move from chemicals of concern to safer chemicals, while minimizing the likelihood of unintended consequences. Informed substitution analysis evaluates the hazards of alternative chemicals, during the relevant phases in the product life cycle, to ensure that substitutes are safer based on their health and environmental profiles.

The DfE Approach to Conducting a Chemical Alternatives Assessment

In this section we present six broad steps to conducting a CAA (Figure 1) and principles that should be considered throughout. These approaches and considerations draw from a number of experiences at EPA and CPA in evaluating alternatives and at HP in using CAAs in decision-making for their products. The outlined approach might serve as a basis for future CAAs in a broad range of domestic and international contexts.

DfE's approach to CAAs was developed from the following sources: EPA's TSCA New Chemicals Program, DfE's Cleaner Technology Substitutes Assessments, the Lowell Center for Sustainable Products (LCSP) Framework for Alternatives Assessments, and nearly two decades of experience in defining safer chemistry. The LCSP Framework (*4*) points out that establishing criteria for comparing chemicals, including toxicity comparisons, is especially challenging; DfE has since developed specific Criteria for Hazard Evaluation that define low, moderate, and high hazard designations for CAAs (*6*).

Key Principles. DfE uses seven principles to ensure the value and utility of any CAA.

First, alternatives must be commercially available or likely to become available. Second, their use must be technologically feasible. Under these two principles, an alternative would satisfy the same functional use as the chemical it is replacing. If alternatives are not "drop-in" substitutes, the assessment would have to consider the significance of the changes needed in engineering processes or manufacturing equipment. DfE realizes that, in some cases, the best alternative may not be a chemical substitution. For example, an alternative such as an inherently flame retardant material or a barrier may be better than an alternative flame retardant chemical.

Third, the alternatives should deliver the same or better value in cost and performance as the replaced material. Fourth, alternatives should have an improved health and environmental profile, as demonstrated by the CAA, to enable confident substitution. Fifth, as alternatives are included, the analysis should consider economic and social factors. Sixth, stakeholders must be interested in participating in the process with DfE. Finally, the alternatives should have the

potential to result in lasting change. These principles are integrated into the steps that describe how to implement a CAA and the examples that follow.

Steps in Implementing a Chemical Alternatives Assessment. *Step One: Determine Needs.* CAAs to find safer alternatives to chemicals of concern have been initiated by industry or consumer requests and by policy or regulatory drivers. Examples include: concern for pentaBDE used in furniture foam which was found in human tissues and the environment leading to a voluntary phase-out by the U.S. manufacturer and the need for evaluating alternatives; the need for rapidly degradable surfactants in cleaning products was tied to EPA water quality criteria and environmentally preferable purchasing; and strong stakeholder interest through the supply chain prompted evaluation of safer flame retardants for electronics in both the use and end of life stages. Currently, Existing Chemical Action Plans (*1*) are the primary source for identifying chemical candidates for risk management and are driving the use of DfE CAAs as the tool to find safer substitutes when success is likely for this type of assessment.

Step Two: Gather Information. DfE investigates the functional use of and previous work done on identifying alternatives for the chemical of concern. DfE develops an understanding of how well alternatives are characterized; how the alternatives compare on structural, functional, and physical properties; the respective chemical manufacturing process, including feedstocks and contaminants or residuals from production; and the range of product functional uses.

Via informal consultation with stakeholders, DfE considers the scope and availability of alternatives, the product functional uses that may pose the highest level of concern, and the life-cycle elements critical to the assessment.

Step Three: Involve Stakeholders. Stakeholder participation is critical to the success of DfE projects. Stakeholders help to design the methodology, monitor its implementation, and use the outcome to move to safer chemicals. Involvement throughout the project helps to ensure that stakeholders understand and support the outcome, enhancing credibility and promoting adoption of the safer alternative(s).

Stakeholder participation should include organizations involved throughout the life cycle: chemical manufacturers, product manufacturers (throughout the supply chain), retailers, NGOs, government agencies, academics, end users, and waste management entities. Those developing new technologies in the area of the CAA are critical members of the group. Early in each CAA, DfE contacts and informs potential stakeholders of the project, methodology, and potential benefits to gain representation of the broadest-possible points of view.

In view of the background and expertise of stakeholders, and mindful of new technologies and future uses, DfE further defines the scope of the assessment. DfE considers the role that economic and social realities might play and how they intersect with the human health and ecological impacts of the alternative. Then, with stakeholders, DfE makes the final decision on the functional use(s) to be addressed and identifies alternatives for evaluation.

Step Four: Assess Hazard. Much of the work in a CAA centers on selecting and populating the suite of comparative hazard end points. For every chemical, DfE assigns a value of high, moderate, or low for each end point based on hazard thresholds. The most valuable end points are those that reveal significant variation in toxicity among alternatives; these end points are "distinguishing" and make it possible to differentiate "safer" from "less safe." DfE has developed the Criteria for Safer Chemical Ingredients (*5*) and criteria for hazard assessment (*6*) to transparently define low-hazard chemicals. DfE will continue to refine these criteria and "raise the bar", when appropriate, based on scientific discovery and new information.

Literature searches for alternatives information should be sufficiently comprehensive to give confidence that hazard is characterized based on available data. DfE's assessments combine information from five sources, in this order: (1) publicly available empirical data; (2) confidential empirical data received at EPA under TSCA regulations; (3) structure–activity relationship (SAR)-based estimations from EPA's Pollution Prevention Framework and Sustainable Futures predictive methods (*7*); (4) professional judgment of EPA staff, often predicated on experimental data for chemical analogues; and, (5) confidential empirical data on experimental studies supplied by the chemical manufacturers for the alternatives assessment. Throughout the process, DfE utilizes EPA information and expertise to inform the comparison of alternatives.

Where measured data do not satisfy an end point, DfE assigns concern for the hazard based on SAR and expert judgment to ensure that end points without measured data are considered. This is implemented at four levels: expert-acquired data from estimation models when available, such as EPI Suite (*8*) for fate, bioaccumulation, and aquatic toxicity or Oncologic (*9*) for structural alerts of concern for carcinogenicity; measured data from chemical analogs; review of estimated data and analog data by a subject area expert at EPA; and a discussion of the hazard conclusion in an expert group. SAR tools or expert knowledge are limited for some end points or chemical classes.

Step Five: Report Information. Once the hazards have been fully profiled, DfE prepares a report to communicate hazard and other information to decision makers. The report provides data on each alternative so that those with a role in choosing safer chemicals can make informed substitution decisions. The report may also contain information on alternative technologies that might influence manufacturing practices.

Step Six: Apply Information. Although DfE CAAs do not specify a favored alternative, when combined with cost, performance, and other factors, they inform stakeholders' decisions about alternatives. Also, CAAs may complement regulatory action with regard to chemicals of concern. CAAs may show that safer, highly functioning alternatives are available, aiding environmentally preferable product formulation or adding weight to the argument for phase-out of a chemical. CAAs might also show that viable alternatives are not available for certain uses of a chemical of concern and could spur innovation and safer chemical design.

Stakeholders involved in the process, especially those choosing safer chemicals, have developed and implemented complementary approaches to guide chemical selection. CPA created the *Green Screen for Safer Chemicals* (Green Screen) (*10*) to assist manufacturers in selecting safer substitutes. This tool is broadly intended to help move society toward the use of more sustainable chemical-intensive products. The Green Screen focuses on hazard reduction and assigns a value for each chemical, based on hazard determinations from the CAA. The resulting data provide those choosing chemicals with a calibrated tool to weigh the health and environmental trade-offs among alternatives.

Following are examples of how this methodology can be applied in real-world situations. The methodology is tailored to each situation, but the steps described above are very useful in ensuring a comprehensive approach, and for communicating with partners.

Implementation of Chemical Alternatives Assessments in the DfE Program

Example 1: DfE Furniture Flame Retardancy Partnership. Step 1: DfE began the partnership in response to stakeholder

concerns over the presence of pentaBDE in the environment and human tissues. PentaBDE was the primary flame retardant used in the manufacture of low-density, flexible polyurethane foam for furniture. The project coincided with a voluntary phase-out of pentaBDE at the end of 2004, requiring a move toward alternatives in a matter of months.

Step 2: Information on all alternatives was not readily available, but chemical manufacturers indicated that alternatives were under development and could be evaluated in the partnership time frame.

Step 3: DfE convened a diverse group of stakeholders, including members of the furniture industry, chemical manufacturers, environmental groups, fire safety advocates, and government representatives, to develop a tailored CAA method. The need for cost-effective fire safety led to a focus on alternative retardants, rather than more expensive solutions such as barrier fabrics and inherently fire-safe materials which were feasible for some uses. The project focused on the potential for exposure at the most significant stages of the life-cycle—including the use and disposal phases.

Chemical manufacturers contributed information on potential alternative flame retardant formulations—14 and all commercially available—and partnered with foam manufacturers to demonstrate feasibility and cost-effectiveness. Technical experts agreed that several of the available alternatives functioned well.

Step 4: DfE's assessment combined information from the literature, SAR, and expert judgment. SAR-based estimations from EPA's Pollution Prevention Framework and Sustainable Futures predictive methods played a critical role in filling data gaps. Table S1 (found in Supporting Information (SI)) is an excerpt from the summary table of the report showing how hazard values and supporting data are displayed.

Step 5: The final report (*11*) included a screening-level assessment of the commercially available alternative flame retardant formulations. The report captures the hazard calls and exposure routes (Table S1), including important caveats and footnotes, so that interested readers can easily compare the alternatives and see bottom-line assessment information in less than three pages. The report confirmed that available alternatives were safer than pentaBDE, and enabled decision-makers to consider health and environmental impacts in choosing alternatives.

The report indicated that the alternatives had a lower level of concern for persistence, bioaccumulation, and toxicity compared to pentaBDE; however, each alternative was of concern for at least one of the key hazard end points, and exposure to the alternatives, via at least some routes, was possible. The report also included information on barrier fabrics and higher-density foams that could serve the same functional purpose as pentaBDE for some uses.

Step 6: The partnership achieved a considered move to alternative flame retardant formulations. Without EPA's involvement, market forces may have caused the choice to be based largely on cost and effectiveness. Foam manufacturers used the assessment information to inform their choice of alternatives in the period leading up to the voluntary phase-out of pentaBDE.

The assessment process prepared manufacturers and other stakeholders to accept EPA efforts to regulate the future manufacture or import of pentaBDE. EPA finalized a TSCA Significant New Use Rule (SNUR), a regulatory backstop to the December 2004 voluntary phase-out, effective August 14, 2006.

Participation in the Partnership inspired CPA to develop the Green Screen, which has since been used by Washington state and Maine to evaluate alternatives to decaBDE.

Example 2: Applying Chemical Alternatives Assessment in Industrial Decision Making. This example describes how Step 6 is being implemented by HP.

Regulatory action to eliminate the use of certain chemicals is probably the most important driver for the use of CAAs in industry. One example of substance restriction legislation that broadly affected material selection in an industry is the EU *Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment* (commonly referred to as RoHS), which restricts the use of several substances in electronics products.

When laws such as RoHS impact an industry, the default reaction may be to treat all unrestricted substances as equally viable replacements for restricted substances. Under this scenario, performance and cost would likely govern selection of the alternative. This reaction is understandable because companies want to minimize the transition costs and ensure that the replacements are widely available. Indeed, the recent increase in substance restrictions has led to a growing awareness in industry that eliminating substances from products is very expensive. It can cost companies millions of dollars to eliminate a single substance and generate proof of compliance with regulations.

Treating all unrestricted substances as equally viable greatly increases the risk of unintended consequences; some replacements could be targeted for future restrictions as well. With the increase in restrictions, there is a growing risk of businesses having to do multiple substitutions—and incurring costs multiple times—if some level of a CAA is not used to evaluate potential replacement technologies.

Companies are increasingly recognizing the importance of reducing the risk of multiple substitutions by requiring that replacement technologies have better hazard profiles than the substances that they replace. Progressive companies can go farther and use the differentiation provided by CAAs to select environmentally preferable materials, not just minimally or incrementally better ones, thereby ensuring their long-term freedom from chasing chemical after chemical for elimination.

Even when companies have the goal of incorporating a CAA into material selection, applying the findings to products can be challenging, especially in today's complex supply chains. Most products are very complicated assemblies of materials and subsystems that have been procured from a wide range of vendors who specialize in their commodities. Suppliers generally do not have specialized expertise for weighing environmental and human health data in choosing chemicals. Decision makers need simplified tools for integrating health and environmental considerations into supplier interactions and designs.

To confront this complex reality, CPA's Green Screen has an evolving method derived from the DfE CAA that can be applied to the outcome of a DfE CAA or used independently with guidance. A key addition provided by the Green Screen is an algorithm designed to aid decision-making in the selection of safer alternatives. The Green Screen is designed to facilitate commercial adoption via a simplified benchmark score: an integer value from 0 (bad) to 4 (good) is applied for each chemical and is easy to interpret. The Green Screen can be used to communicate product or material targets and even set contractual requirements with suppliers.

The value of the Green Screen to businesses is shown through its adoption at several companies, such as HP, to inform material selection. Like many companies, HP has committed that replacements for restricted materials will not adversely impact human health or the environment. HP has piloted the use of the Green Screen as an alternatives assessment tool for PVC replacements and other substances, and has found it to be extremely useful in identifying preferable options and for communicating materials goals and criteria to suppliers. A key finding of the pilot studies is that alternatives assessments can be structured in ways that are not only compatible with modern business practices,

but also significantly reduce the impact to businesses of future chemical restrictions.

For the electronics industry, widespread adoption of the Green Screen, with its basis in DfE CAA method, would enable broader sharing of information on substances of concern and their potential replacements, as well as faster adoption of environmentally preferable replacement technologies. It would also substantially reduce the collective risk of negative unintended consequences from material substitution choices.

Example 3: DfE Safer Product Labeling Program (SPLP). DfE's SPLP uses a CAA approach closely related to the one used in the Furniture Flame Retardancy Partnership. The most significant difference is that here, DfE leads the work of the CAA through step 6—applying the information in decision-making. The labeling program defines and recommends safer chemicals and allows use of the DfE label on products that use them exclusively. It does so through an informed understanding—grounded in physical properties and toxicology, as well as functional use and life-cycle thinking—of the chemistries in various types of products. DfE assesses a chemical based on its hazard profile and in relation to other chemicals that could be used for the same purpose. The SPLP shares with manufacturers the chemical information it develops, which includes the judgment of EPA technical experts. The assessment provides the basis for DfE's decision on whether to allow a product to carry the label, shown in the opening illustration of this article.

Step 1: DfE opens product sectors to partnership largely based on the extent to which the sector uses chemicals of concern and opportunities exist for safer formulation.

Step 2: Based on product type, DfE develops a knowledge base of the available alternatives for each functional class of chemical used in the product, along with information on human health and environmental characteristics. For cleaning products, the main functional classes are typically surfactants, solvents, chelating agents, builders, colorants, fragrances, and preservatives.

Step 3: DfE convenes stakeholders to refine its understanding of the sector and to help develop or modify DfE component-class criteria (*5*) which must be met to earn the label. Stakeholders help by clarifying the functionality of ingredients, ensuring that the full range of possible alternatives is considered, and providing information on how products formulated with safer ingredients perform. Manufacturers also share economic information on ingredient and product pricing. Cost-effectiveness is critical in ensuring that safer products are marketable and available to all.

Step 4: Working through qualified third parties (hired by product manufacturers), DfE receives available information on each chemical in a candidate formulation and compiles it into hazard profiles. As in the flame retardant assessment, use of SAR estimation methods and expert judgment are important in filling data gaps and completing hazard profiles. Such profiles describe the toxicological characteristics of the ingredient and whether it satisfies DfE's transparent pass/fail component-class and labeling criteria. The DfE Criteria for Safer Chemical Ingredients include data requirements. In some cases, data gaps may be filled through estimation models or suitable analogs; in others, particularly where the end point is key in distinguishing among alternatives, test data may be required.

Step 5: The labeling program provides product manufacturers with a chemical assessment of each ingredient in their product formulation based on DfE's safer chemical criteria and an indication of pass or fail.

Step 6: To become a DfE partner, a manufacturer must use the safest ingredients from each functional group, as well as meet other product-level requirements, such as pH and performance, as described in the DfE Standard (*12*). Product manufacturers must also sign a Partnership Agreement with EPA/DfE that formalizes their commitment to make the recognized product(s) as described to the EPA, with improvements over time as science and innovation advance. Once the agreement is in place, partners may differentiate their products in the marketplace through use of the DfE logo. An audit program verifies partner's product ingredients, good manufacturing practices, and other partnership requirements.

The Criteria for Safer Chemical Ingredients (*5*) and the Standard for Safer Cleaning Products (*12*) have made the program more transparent and encouraged chemical manufacturers to innovate. After DfE established criteria for safer surfactants in cleaning products (*13*), chemical manufacturers synthesized chemicals to meet the criteria. These new surfactants biodegrade rapidly and completely, reducing the potential toxicity to aquatic organisms. Many surfactants and other component-class ingredients that meet the DfE criteria are listed in CleanGredients (*14*), a database of safer chemicals that supports the labeling program.

The marketplace provides incentives for safer product development. Retailers like Wal-Mart and Home Depot consider DfE labeling an important sustainability indicator, and manufacturers who have earned the right to display the logo on a product are rewarded by retailers and subsequently by consumers. Home Depot has designated DfE as the requirement for entry into its Eco Options program (*15*) for healthy homes. State governments are increasingly specifying DfE recognition in their purchasing contracts.

Conclusion

The pace of substituting away from chemicals of concern is accelerating. Industry, NGOs, and governments are all playing roles in identifying safer alternatives. Substitution that is not informed by the best available information and science can lead to unintended and undesired consequences. Alternative chemicals might have human health and environmental profiles that are similar to those of the chemicals of concern or that are different but pose concern for other end points. Uninformed decisions may cause industry to incur costs repeatedly in moving from one alternative to another. CAAs are a proven tool for informing substitution to safer alternatives and minimizing the likelihood of unintended consequences. Their track record has made them a risk management option under EPA's existing chemical action plans. CAAs are in progress for BPA in thermal paper and the flame retardant decaBDE. Even when a CAA does not identify an optimal alternative, the tool proves valuable in clarifying the state of the science among potential alternatives and pointing to the need for chemical research and innovation: effectively posing a focused green chemistry challenge. The DfE CAA methodology outlined here provides a strong foundation for comparing alternatives and informing substitution to safer chemicals in a wide range of industries and applications and may serve as a critical tool for guiding chemical risk management and innovation in the future.

Supporting Information Available

An excerpt of the summary table from the DfE Furniture Flame Retardancy Partnership and a table of resources for alternatives assessments. This information is available free of charge via the Internet at http://pubs.acs.org/.

Clive Davies, David DiFiore, Emma Lavoie, and Melanie Vrabel work in the Design for the Environment (DfE) Program at the U.S. Environmental Protection Agency. Clive Davies is an engineer and Chief of the DfE Branch. David DiFiore is a senior project manager and one of the creative founders of DfE's voluntary approaches to chemical pollution prevention. Dr. Emma Lavoie is an environmental toxicologist. Melanie Vrabel is a chemist specializing in green chemistry. Dr. Robert Lee is Director of the Economics, Exposure and Technology Division (of which the DfE Branch is a part) responsible for science

and engineering analyses for the chemicals program. Emily Connor is an Associate with Abt Associates, Inc. Helen Holder is Corporate Material Selection Manager at Hewlett-Packard where she has introduced environmental criteria to complement traditional requirements for materials selection. Dr. Mark Rossi, Research Director at Clean Production Action is coauthor of the Lowell Alternatives Assessment Framework and chair of the BizNGO Working Group for Safer Chemicals and Sustainable Materials. Dr. Lauren Heine, Science Director at Clean Production Action, serves on the California Green Chemistry Initiative Green Ribbon Science Panel. Rossi and Heine coauthored the Green Screen for Safer Chemicals.

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