Alternatives Assessment in Regulatory Policy: History and Future Directions

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ABSTRACT

As the use of alternatives assessment as a tool to support the adoption of safer chemicals continues to evolve, the role of government in forming successful policies and initiatives needs thoughtful analysis. Although many chemical policies restricting or phasing out chemicals exist, very few mandate alternatives assessment or have adequate frameworks or tools to support successful implementation while avoiding regrettable substitutions. This chapter explores the justification and rationale for requiring alternatives assessment in the formation of chemical policies that support ‘informed substitution.’ A historical and current overview of chemical restriction and alternatives assessment policies is then provided and also a typology of current policies and initiatives that require or incentivize alternatives assessments. Five case studies highlighting regulatory policies requiring alternatives assessments, along with other examples, are used to support several lessons learned for future government policies that support informed substitution. Taken together, these policies illustrate that (1) there is a need for policies that require alternatives assessment, (2) carefully designed incentives and disincentives can encourage adoption of safer alternatives, (3) alternatives assessment requirements should be tied to initiatives that incentivize adoption of safer alternatives and (4) there is a need for clear, yet flexible guidance and criteria for alternatives assessment.

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†The views expressed in this chapter are the personal views of the authors and do not purport to reflect the official views or positions of the Occupational Safety and Health Administration (OSHA) or the US Department of Labor.
assessment processes. Although alternatives assessment requirements are necessary, it is critical that they not become overly prescriptive, burdensome or scientized in a way that inhibits their ability to achieve the goal of safer chemistry.

### 11.1 Introduction

Alternatives assessment is a critical tool in advancing the informed substitution of hazardous chemicals. However, alternatives assessment is rarely required or incentivized in policy. The purpose of this chapter is to characterize government policies that incentivize or mandate alternatives assessment as part of requirements to reduce, phase out or substitute chemicals of concern. Whereas other chapters in this volume have focused on particular alternatives assessment frameworks, tools and case studies, this chapter evaluates the role of policy in stimulating the informed quest for safer chemistries. For the purpose of this chapter, we define alternatives assessment as a process for identifying and comparing potential chemical and non-chemical alternatives that could replace chemicals or technologies of concern on the basis of their hazards, performance and economic viability. The goal of alternatives assessment processes is to support informed substitution, or ‘a considered transition from a chemical of particular concern to safer chemical or non-chemical alternatives.’

Government efforts to drive chemical substitution (including mandated chemical phase outs, reductions and restrictions that lead to substitutions) are not new, but with the adoption of the European Union (EU)’s Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program and several European and US state initiatives, there is greater government attention to policies that support the informed transition to safer chemicals. In this chapter, we argue that to achieve informed substitution, there is a need for policies that not only provide incentives to substitute, but also require an adequately flexible evaluation of alternatives and provide structures to support the informed transition to safer chemicals. We explore the rationale for integrating alternatives assessment in policies that drive substitution. We then provide a historical overview of government policies that support chemicals restrictions and alternatives assessment and characterize the range of current policies and programs that include alternatives assessment elements, mainly in North America and Europe. Following this overview, we outline five case examples of regulatory policies that require assessment of alternatives and lessons learned from them.

### 11.2 Rationale for Informed Substitution

Substitution requirements can play an important role in promoting a solutions-oriented approach to toxic chemical problems. Rather than focusing on
establishing ‘acceptable levels of exposure,’ as many risk-based policies do, chemical reduction, restriction and substitution requirements focus attention on risk prevention and opportunities to identify and adopt more sustainable chemistries.\textsuperscript{2,3}

Efforts to reduce or eliminate problematic chemical use through chemical substitution or process redesign can lead to changes to production processes (along a whole supply chain), products, or work practices and use patterns that can enhance ecosystems and human health. However, reducing or eliminating the use of chemicals – even relatively dangerous ones – can also result in unintended adverse consequences, or trade-offs. Examples abound where well-intentioned efforts (government or otherwise) to restrict a chemical of concern without a clear plan, information, processes, or requirements to evaluate substitutes or the implications of substitution processes has resulted in risk trade-offs. Some notable examples include the following:

- **Flame retardants.** Global concern has been raised about the class of flame-retardant chemicals polybrominated diphenyl ethers (PBDEs). These chemicals are now subject to government restrictions throughout the world. Most of these policies have directed little attention toward potential substitutes. However, manufacturers are still required to comply with flame retardancy (performance) requirements for materials. Some manufacturers have switched to substitutes that are functionally similar and technically and economically feasible, such as brominated phthalates, without undertaking broad evaluations of alternative materials. This has resulted in increased levels of these substitutes in the environment due to the persistence and/or bio-accumulation of some of the alternatives or their breakdown products.\textsuperscript{4,5} Some evidence indicates that these alternatives may also be toxic.\textsuperscript{6}

- **Bisphenol A.** Consumer pressure on bisphenol A (BPA) in baby bottles and water containers led manufacturers and retailers to replace polycarbonate plastics containing BPA. Although policies restricting BPA use in bottles have now emerged in many places, none has required a review of the substitutes. Research indicates that a number of plastic materials that could serve as replacements for BPA may also be toxic and exhibit estrogenic activity, a health endpoint of concern for BPA.\textsuperscript{7,8}

- **Solvents.** Air quality regulations in various jurisdictions have forced the substitution of hazardous air pollutants. In some cases, this has led to substitution with chemicals that are more hazardous to workers, as such hazards were not considered in the substitution decision process, nor were changes in work practices that might occur from a chemical substitution. For example, restrictions on the use of perchloroethylene led to a number of problematic substitutions, including \textit{n}-hexane in vehicle repair applications and \textit{n}-propyl bromide in dry-cleaning and degreasing. Although these chemicals were relatively easy to implement as ‘drop-in’ substitutes (important for small businesses without technical resources to redesign production processes), both pose neurotoxicological risks to workers.\textsuperscript{9,10}
These examples of ‘uninformed substitution’ illustrate important shortcomings of chemical substitution efforts that do not adequately consider safer alternatives. These include:

- Policies to restrict a chemical of concern to a particular population or media may result in substitutions that shift the risks to another population or media, including ones at different phases of a chemical or product life-cycle. This occurs in part because chemical restrictions are often implemented by government agencies or divisions representing a particular population, life-cycle stage, or medium. Assessments of substitutes, if undertaken at all, may fail to consider other populations or media.
- Chemical restriction policies generally fail to consider how chemical changes may change process chemistries, work practices or exposure patterns.
- Efforts focused only on eliminating chemicals of concern fail to consider the ‘functional use’ of the chemical, instead focusing on the chemical and not the service it provides. By focusing on functional use, an agency or manufacturer may be able to identify non-chemical or process options to fulfill the function or determine that the function is not even necessary.
- Chemical restriction policies often focus on the creation of lists of ‘chemicals of concern.’ Given the large percentage of chemicals lacking hazard data and the detailed processes often required to establish ‘authoritative’ lists for some chemical endpoints (such as carcinogens), these lists may miss many chemicals of concern and lead to manufacturers or consumers assuming that chemicals not on these lists (or that are not regulated) are therefore ‘safer.’

Ultimately, unintended consequences of chemical restrictions can undermine efforts to transition to safer chemistries, diverting attention away from encouraging solutions. If the goal of chemical restriction policies is to promote the identification and adoption of safer chemicals, there is a clear need to ensure that these types of chemicals management efforts are integrally tied to policies, guidance and support that ensure a thoughtful evaluation of and transition to safer alternatives.

11.3 Evolution of Alternatives Assessment Elements in Government Chemicals Reduction Policies

Government policies to restrict or limit chemicals of concern are not new. Nor are policies that require proponents of potentially harmful activities to consider a range of alternatives to reduce harm from those activities. What is relatively new is the integration of these two concepts in different policy contexts.

11.3.1 Chemical Restriction and Phase-out Policy Development

Government policies in the USA and Europe that restrict or require reduction or substitution of chemicals of concern date back to the 1950s, such as the
Delaney Clause of the US Federal Food, Drug and Cosmetic Act prohibiting the inclusion of carcinogenic additives in processed foods. The philosophy behind such policies is that the most effective way to address chemical risks is not through exposure controls but elimination of the chemical. Restrictive policies give clear signals to the marketplace that can also push innovation towards safer substitutes.\textsuperscript{11,12} They are also seemingly easy to implement in practice. However, these policies have remained largely silent on the issue of what will replace the chemical of concern or how alternatives should be evaluated. For example, government initiatives in the 1970s called for phase outs of discharges of chemicals of concern to critical aquatic ecosystems. The 1977 Great Lakes Water Quality Agreement called for ‘the virtual elimination,’ the reduction of the concentration of the substance to below detectable levels, of discharges of persistent and bio-accumulative chemicals in the Great Lakes basin.\textsuperscript{13} The US–Canada International Joint Commission, a bi-national body dedicated to protecting boundary waters, issued numerous reports calling for precautionary policies that lead to substitution of chemicals of concern in the region but mentioning little about evaluating those alternatives.\textsuperscript{14}

Similarly, regional agreements in Europe for the protection of the Baltic and North Seas also included goals for substitution of chemicals of concern in these ecosystems with little guidance as to the nature of the substitutes. In fact, Greenpeace commissioned a report which noted that to implement these precautionary goals, a focus on achieving safer alternatives through clean production methods was necessary.\textsuperscript{15}

US and European governments have undertaken chemical restriction efforts on specific chemicals of concern, such as lead, polychlorinated biphenyls (PCBs) and organochlorine pesticides, since the 1970s. Much of the focus of restrictions was on chemicals that ended up in various media – air, water, waste – from manufacturing processes or at the end of life of products. For example, the European Union Limitations Directive, passed in 1976 (now part of the EU’s REACH regulation), authorized the EU to restrict or ban chemicals of concern across Member States. More than 900 chemicals have been restricted under this authority; many of these are petroleum products restricted as carcinogens, mutagens and reproductive toxicants in consumer-available preparations.\textsuperscript{16}

Similar types of chemical restrictions increased in the late 1990s and early 2000s as concerns about the links between chemical exposures and human health impacts grew.\textsuperscript{17,18} European and US governments initiated policies to restrict individual chemicals of concern (often called bans or phase outs), such as mercury, PBDEs, phthalates, BPA, short-chain chlorinated paraffins, and formaldehyde. For example, 32 US States have some type of policy on mercury in products.\textsuperscript{19} In the 2009–2010 legislative session, 19 US States proposed restrictions on BPA, 12 proposed restrictions on PBDEs and 24 proposed restrictions on chemicals of concern (phthalates, BPA, lead, \textit{etc.}) in children’s products.\textsuperscript{20}

Various European countries (Sweden, Denmark, Norway) and US States (Washington, Maine, Minnesota) also developed lists of ‘chemicals of concern’
to provide clear signals to the marketplace of the types of chemicals that were of concern to regulators, providing a driver for substitution. An early example of this is the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop 65), which establishes a list of chemicals known to cause cancer, reproductive toxicity, or developmental toxicity. While the Swedish Observation List and the Danish List of Undesirable Substances listed only several hundred chemicals of concern, the more recent US State lists, built from authoritative lists of chemicals of concern for specific endpoints (carcinogens, persistent chemicals, reproductive toxicants, etc.), contain more than 1000 chemicals.\textsuperscript{16,21}

These chemicals policies have had an impact in moving manufacturers away from chemicals of concern and reducing quantities of the chemicals in the environment.\textsuperscript{22,23} However, the question remains as to whether they have stimulated the adoption of safer alternatives, as evidenced in the case of PBDE replacements. Nonetheless, more recent policies, such as some State-level chemical restrictions in the USA (PBDEs in Washington and Minnesota) and some European restrictions (flame retardants in Sweden and phthalates in Denmark) have explicitly linked restrictive policies to research on alternatives.

\subsection{11.3.2 Alternatives Assessment Policy Development}

The evolution of alternatives assessment in government policy parallels that of chemical restrictions. An early example of a policy that requires alternatives assessment is the Environmental Impact Statement (EIS) process under the 1970 National Environmental Policy Act (NEPA) and similar state programs. Under NEPA, major federal actions affecting the quality of the human environment must undergo an EIS process. The goal of NEPA is to foster better decisions and ‘excellent action’ through the identification of reasonable alternatives that will avoid or minimize adverse impacts.\textsuperscript{24} NEPA regulations specify an environmental impact assessment process that proponents must follow before initiating an activity. Through an interdisciplinary approach, proponents must (1) comprehensively identify and examine environmental effects and values, (2) rigorously study, develop and describe appropriate (reasonable) alternatives in comparative form, including not moving ahead with an activity, and (3) recommended courses of action. Proponents are instructed to undergo a ‘scoping process’ to broadly define potential impacts and to examine them in detail including direct and indirect impacts, cumulative effects, effects on historical and cultural resources, impacts of alternatives and options to mitigate potential impacts.

In the chemicals area, the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer represents the first global effort to restrict and evaluate substitutes for a group of chemicals of concern. The Montreal Protocol Chemical Technical Options Committees review alternatives for ozone depleting substances and some national programs, such as the US Environmental Protection Agency (EPA)’s Significant New Alternatives Policy (SNAP) Program, require evaluation of alternatives to ozone-depleting substances.
The principle of informed substitution for dangerous chemicals was codified in EU Member State policies in the 1980s and 1990s (most notably in Sweden). For example, the amended 1990 Swedish Act on Chemical Products states that:

Anyone handling or importing a chemical product shall take such steps and otherwise observe such precautions as are necessary to prevent or minimize harm to human beings or to the environment. This includes avoiding chemical products for which less hazardous substitutes are available.

In applying the substitution principle, the Swedish government called for a progressive elimination of chemicals of concern, a process called ‘sunsetting,’ whereby the government would provide generic criteria for undesirable chemicals and substitutes and also ambitious but long-term targets and lead times to develop new processes and products.

The passage of State-level pollution prevention requirements in the USA and cleaner production initiatives and the Integrated Pollution Prevention and Control Directive in Europe in the 1990s sparked the development of facility planning processes to support waste, chemical and emissions reduction policies. Facility planning (also known as cleaner production, pollution prevention, or source reduction planning) involves characterizing and understanding why and how chemicals are used in a particular production process and evaluating options for reducing use, waste, or emissions. Geiser characterized such facility plans as documents ‘describing the means and timing by which corporations will reduce the risks of toxic chemicals in production.’ The goal of the plan is ‘to serve as a guide for raising the level of attention about toxic chemicals, increasing motivation to change, presenting alternatives, guiding decision-making, advocating for resources and providing information to evaluate the consequences of change.’ The passage of pollution prevention and cleaner production policies in the USA and Europe sparked the development of dozens of new tools for chemical ranking and scoring to support reduction and substitution efforts, case studies of safer alternatives, such as those developed by the Massachusetts Toxics Use Reduction Program’s Office of Technical Assistance, voluntary demonstration projects and challenges, such as the US EPA’s Project XL and European Initiatives such as the PRISMA Project and frameworks for alternatives assessment, such as the US EPA’s Cleaner Technologies Substitutes Assessments and Use Cluster Scoring System.

Beginning in the late 1990s, initiatives in EU Member States, such as those in Germany, The Netherlands, Sweden and Denmark, and discussions leading up to the EU’s REACH proposal reinvigorated the development of policies and tools for chemical alternatives assessment. For example, the Swedish government developed the PRIO chemical assessment tool to provide chemical users with an ability to evaluate chemicals of concern and safer alternatives. The Danish government developed chemical action plans for several chemicals of concern (such as phthalates) that outline problems with the substance, goals for reducing hazards, evaluation of alternatives and costs of implementation.
As part of the Dutch government’s Strategy on Management of Substances, the Ministry of Housing, Spatial Planning and the Environment developed the Quick Scan rapid hazard assessment method to provide decision guidance to support voluntary chemical substitution efforts by firms.\(^{16}\) The European Commission developed several reports and a guidance document outlining decision frameworks and tools for advancing informed substitution of chemicals.\(^{31}\) The European Commission and German government funded the development of the SUBSPORT project, a database of tools, guidance and case studies of safer alternatives.\(^{32}\)

Similarly, occupational policies in Europe addressing chemicals in the workplace, such as the Chemical Agents Directive, led to the development of detailed alternatives assessment regulations for substitution in Germany. The Spanish Trade Union Confederation Institute for Health, Work and Environment has worked with Spanish authorities to establish its RiscTox database, designed to provide workers with tools and information to evaluate chemical hazards and substitutes.

In the USA, the European Restrictions on Hazardous Substances (RoHS) in Electronic and Electrical Products Directive and some State chemical restrictions led to the establishment of a variety of State and federal initiatives around alternatives assessment for chemicals of concern in products. New policies, such as Maine’s Toxic Chemicals in Children’s Products Law, require the evaluation of alternatives to chemicals of concern to children. In 2005, the Massachusetts legislature requested that the Toxics Use Reduction Institute (a State-funded research institute based at the University of Massachusetts Lowell) undertake an alternatives assessment of five chemicals of concern used in products: lead, formaldehyde, diethylhexyl phthalate, perchloroethylene and chromium(VI). The Institute developed the Five Chemicals Alternatives Assessment methodology for the assessment (adapted from its pollution prevention planning guidance), engaging stakeholders in reviewing potential alternatives for priority uses of those chemicals in the state on the basis of health and safety, economic and technical feasibility considerations.\(^{33}\) The US EPA’s Design for the Environment (DfE) program established its Alternatives Assessment and Safer Product Labeling programs to evaluate alternatives for chemicals of concern and provide recognition for product formulations containing safer chemical ingredients. The EPA developed guidance on comparative chemical hazard assessment, a process for comparing chemicals on the basis of their intrinsic hazards in 2011,\(^{34}\) and also a list of chemicals that meet the DfE criteria for safer chemistry for use in chemical cleaning formulations in 2012.\(^{35}\) In 2008, the California legislature passed its Safer Consumer Products legislation, requiring the evaluation of alternatives to chemicals of concern in products.

### 11.3.3 Convergence of Chemical Restriction and Alternatives Assessment Policies

Both policies that require the phase out of chemicals of concern and those that require evaluation of alternatives initially focused on chemicals used in
manufacturing. As information on the dispersive nature of chemicals in products and chemical hazards, particularly concerns about exposures to children, has increased, the direction of these two policy types has evolved to emphasize substitution of chemicals in products. Similarly, there has been increased government and industrial attention to ‘integrated product policy,’ with policies and tools designed to address product life-cycles, including energy, materials use and chemical toxicity. With the focus on products, there is an increasing convergence of chemicals restrictions linked to alternatives assessment requirements. There are various reasons for this convergence, including (1) greater awareness of the negative impacts caused by uninformed substitutions, due to notable failures of substitution, (2) a greater understanding of and support for the application of ‘green chemistry,’ the design of less hazardous chemicals throughout their life-cycles, (3) the increased attention to evaluating alternatives to reduce life-cycle impacts, particularly energy and material use, and (4) increasing marketplace pressure for safer chemicals and products.  

An interesting result of this convergence is the establishment of new structures for government agencies to collaborate and share information on chemicals and alternatives and develop consistent approaches. For example, 11 US States have formed the Interstate Chemicals Clearinghouse (IC2) to share information on chemical hazards and priorities, chemical use in products and safer alternatives, and also to develop consistent frameworks for alternatives assessment. Similarly, EU Member States and other stakeholders have collaborated to develop guidance for alternatives assessment under REACH and to implement substitution requirements in occupational health directives. The Organization for Economic Co-operation and Development (OECD) established an *ad hoc* working group on chemicals alternatives assessment to identify common tools and frameworks for alternatives assessment. 

Despite this convergence, as previously noted, most chemical restriction policies still do not include alternatives assessment elements. A review of the Interstate Chemicals Clearinghouse state chemicals policy database (a database of over 1200 proposed and enacted State chemicals policies) shows that from 1997 to 2012 more than 400 individual chemical restrictions have been proposed but less than 100 of those proposed policies contained alternatives assessment elements. The establishment of alternatives assessment in restriction policies is still in its infancy, with varied application and emerging decision-frameworks and tools.

### 11.4 Alternatives Assessment in Government Chemicals Policies: a Categorization

When they have formed part of government chemicals reduction policies, alternatives assessment elements have been integrated in a variety of different ways. It is instructive to understand the various types of alternatives assessment
policies and how these, on their own or together, can support informed substitution of chemicals of concern. A summary of European, North American and global government regulatory and non-regulatory policies and initiatives that support informed substitution is provided in Table 11.1.

The table is not meant to be exhaustive but rather to provide an instructive sample of some of the most prominent policies and to characterize the range and types of efforts that have been initiated. The table outlines the focus and key elements of the policies and identifies what tools or guidance may have been developed to support informed substitution in their application. The policies or initiatives are summarized below and can be categorized using the following typology. In some cases, policies or initiatives can fit multiple sub-categories:

- **Non-regulatory** – Voluntary policies that support the evaluation and adoption of safer alternatives without requirements on regulated entities. There are two main types of non-regulatory informed substitution policies:
  - **Evaluative.** These policies and efforts are designed to review or designate safer alternatives to chemicals of concern or provide tools for companies to evaluate substitutes. Such efforts include those (1) where governments conduct evaluations of alternatives to support informed substitution, such as the EPA DfE’s alternatives assessment on PBDEs in furniture foam; (2) where governments identify safer substitutes for chemicals in specific applications, such as the EPA’s Safer Consumer Labeling Program or alternatives assessments for ozone-depleting substances under the Montreal Protocol Technical Options Committees; (3) where governments categorize chemicals in commerce and potential alternatives by their hazards, such as the Danish government’s effort to categorize its existing substance list by hazard classification using quantitative structure–activity relationship analysis; (4) where governments provide criteria for evaluating safer materials, such as the German Federal Environment Agency’s Sustainable Chemistry Guidance, which provides a framework for developing safer chemicals; or (5) where governments provide tools for chemical users to evaluate and categorize alternatives, such as PRIO or the Quick Scan.
  - **Supportive.** These policies and efforts support decision-making processes and adoption of safer chemicals. They include: (1) development of guidance documents, such as the REACH authorization substitution guidance, developed by the European Chemicals Agency or the guidance documents being developed by the Washington Department of Ecology, which provide detailed guidance – tailored to smaller and larger enterprises – for the various steps of alternatives assessment; (2) technical support such as pollution prevention research and engineering support provided by the New York Pollution Prevention Institute; (3) case studies and demonstration projects of safer alternatives, such as the wire and cable partnership of the Massachusetts Toxics Use Reduction
Table 11.1 Policies and initiatives supporting informed substitution.

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Name</th>
<th>Date</th>
<th>AA/substitution Elements</th>
<th>Guidance/tools Developed</th>
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<tbody>
<tr>
<td><strong>Non-regulatory – Evaluative</strong></td>
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<tr>
<td>United Nations</td>
<td>Montreal Protocol on Substances that Deplete the Ozone (Article 9)</td>
<td>1987</td>
<td>Supports international research and information exchange on alternatives to ozone-depleting substances. Ratification by countries may include regulatory elements</td>
<td>No guidance, but Technology and Economic Assessment Panel addresses issues concerning alternative technologies</td>
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<tr>
<td></td>
<td>(signed)</td>
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<tr>
<td>Denmark</td>
<td>Chemicals Action Plan 2010–2013</td>
<td>2010</td>
<td>Includes an initiative focusing on the continued development of (Q)SARs to prioritize chemicals and evaluate substitutes. Includes chemical action plans for substitution of chemicals of concern</td>
<td>Oversees (Q)SAR database that can be used by industry to identify substitutes. Also hosts the Catsub database, which includes case studies for successful substitutions of hazardous chemicals (mostly in the occupational health arena)</td>
</tr>
<tr>
<td>United States</td>
<td>US EPA – Design for the Environment (DfE)</td>
<td>Ongoing</td>
<td>Alternatives assessments are conducted for Action Plan chemicals for either broad or specific end uses. Assessment focuses on comparative hazard screening. Identifies safer substitutes for chemicals in specific applications in its Safer Product Labeling Program</td>
<td>Developed hazard assessment criteria incorporating persistence, bioaccumulation, ecotoxicity and human health endpoints</td>
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<tr>
<td>Germany</td>
<td>German Federal Environment Agency – Sustainable Chemistry Activities</td>
<td>2011</td>
<td>Promotes the systematic identification and adoption of sustainable chemicals by businesses</td>
<td>Published Guide on Sustainable Chemicals, which provides a framework and criteria to evaluate and compare chemicals</td>
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Non-regulatory – Supportive

United Nations

Stockholm Convention on Persistent Organic Pollutants (POPs) (Articles 5, 9 and 11)\textsuperscript{76}

2001 (signed)

Aimed at global reduction of priority POPs. Intersestional workgroups develop alternative assessment and substitution policy. Created POPs Free initiative to assist substitution efforts in developing nations.\textsuperscript{77} Ratification by countries may include regulatory elements.

General guidance for review of alternatives to potential POPs\textsuperscript{78}

The Netherlands

Strategy on Management of Substances (SOMS)\textsuperscript{79}

2002–2003

Main purpose of this program was not AAs. It included nine pilot case studies in various industrial sectors aimed at identifying, prioritizing and managing hazardous substances. It was discontinued after the adoption of REACH.

QuickScan was used as a screening prioritization tool that takes into account the potential risks and hazards at each life-cycle stage. The analysis is based mostly on EU risk phrases\textsuperscript{80}

Sweden

Environmental Quality Objectives\textsuperscript{81}

1999

One of the 16 environmental quality objectives includes a ‘non-toxic environment.’ Includes interim targets that may involve regulatory measures.

Hosts a Restricted Substances database.\textsuperscript{82} Published a 2007 report on the Substitution Principle, providing broad overview of the elements of the principle.\textsuperscript{83} Developed PRIO, a web-based tool for chemical risk reduction that is available to the public.\textsuperscript{84}

United Kingdom

UK Chemicals Stakeholder Forum (UKCSF)\textsuperscript{85}

Ongoing

Composed of representatives from government, industry, trade organizations and NGOs. It is an effort that aims to advise the UK government on how industry should reduce risks from hazardous chemicals.

Published a general guide to substitution in 2010\textsuperscript{86}

United States

2009–2011

Multi-stakeholder discussion forum recommending

No guidance
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<tr>
<th>Jurisdiction</th>
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<th>Date</th>
<th>AA/substitution Elements</th>
<th>Guidance/tools Developed</th>
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<tbody>
<tr>
<td>Centers for Disease Control (CDC) – National Conversation on Public Health and Chemical Exposures</td>
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<td>governments and organizations work towards substituting hazardous chemicals with safer alternatives. Also, calls for enhancement of research and development in this area</td>
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<tr>
<td>United States – Washington</td>
<td>Reducing Toxic Threats Initiative</td>
<td>2011</td>
<td>Focuses on preventing the use of toxic substances by encouraging safer alternatives and promoting green chemistry</td>
<td>AA guidance document is currently under development. Endorses GreenScreen and QCAT for conducting hazard assessments</td>
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<tr>
<td><strong>Regulatory – Classification-based Substitution Requirements</strong></td>
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<tr>
<td>France</td>
<td>Labor Code Article R4412</td>
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<td>Requires employers to replace CMR substances, to the extent technically feasible, with a substance, preparation or process which is less hazardous to health</td>
<td>Substitution-CMR database containing an inventory of CMR substances, alternatives and case studies</td>
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<tr>
<td>Country</td>
<td>Ordinance/Regulation</td>
<td>Year</td>
<td>Description</td>
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<td>Germany</td>
<td>Hazardous Substances Ordinance (GefStoff V)</td>
<td>2008</td>
<td>Requires substitution analysis for hazardous substances in the workplace.</td>
<td>TRGS 600 Guidance covers the full scope of substitution from determination of potential substitutes through technical suitability. Developed the Column Model, a tool for simple comparison of hazards and risks of identified alternatives.</td>
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<td>United Kingdom</td>
<td>Control of Substances Hazardous to Health (COSHH) Regulations</td>
<td>2002</td>
<td>Requires that, where reasonably practical, employers prevent the exposure of employees to substances hazardous to health through substitution.</td>
<td>Developed COSHH Essentials web tool designed to help companies implement COSHH regulations, although it focuses mostly on chemical management activities.</td>
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<td><strong>Regulatory – Pollution Prevention Planning Requirements</strong></td>
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<tr>
<td>United States –</td>
<td>Toxic Use Reduction Act</td>
<td>1989</td>
<td>Calls for a 50% reduction in the use of hazardous byproducts within the State. Companies must create a reduction plan and are encouraged to substitute with less hazardous substances. Created the Toxic Use Reduction Institute to provide resources and education.</td>
<td>Conducted the Five Chemicals Study in 2006, which analyzed alternatives for five hazardous chemicals. P2OASyS is a comparative hazard assessment tool developed by TURI. Supports the development of demonstration projects, case studies and research efforts on safer alternatives.</td>
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<td>Massachusetts</td>
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<tr>
<td>Canada – Ontario</td>
<td>Toxics Reduction Act (TRA), Ontario Regulation 455/09</td>
<td>2009</td>
<td>Requires regulated facilities to track, quantify and develop plans to reduce the use of toxic chemicals.</td>
<td>Published AA guidance which covers topics such as hazard assessment, life-cycle, technical feasibility and cost–benefit.</td>
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### Table 11.1  Continued.

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<th>Jurisdiction</th>
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<th>AA/substitution Elements</th>
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<tr>
<td><strong>Regulatory – Alternatives Assessment to Support Regulatory Decision-making</strong></td>
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<tr>
<td>European Union</td>
<td>Biocidal products (EU 528/2012, replaces 98/8/EC)</td>
<td>2012</td>
<td>Prohibits CMRs, sensitizers and bio-accumulative chemicals from use as active ingredients in biocidal products. Requires evaluation of alternatives for active ingredients under review for approval</td>
<td>No guidance</td>
</tr>
<tr>
<td>United States – California</td>
<td>Safer Consumer Products Regulations [Draft]</td>
<td>2012</td>
<td>Companies are required to conduct alternatives analysis of any chemical of concern in priority products</td>
<td>Guidance is currently under development</td>
</tr>
<tr>
<td>United States – Minnesota</td>
<td>Toxic Free Kids Act</td>
<td>2009</td>
<td>Requires Agencies to evaluate alternatives for chemicals of high concern used in children’s products. Published a report in 2010 concerning options for reducing and phasing out chemicals</td>
<td>No guidance</td>
</tr>
<tr>
<td><strong>Regulatory – Single or Multiple Chemical Restrictions with Alternatives Assessment Requirements</strong></td>
<td></td>
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</tr>
<tr>
<td>European Union</td>
<td>VOC Directive (1999/13/EC), Article 7</td>
<td>1999</td>
<td>Calls for substitution of VOCs at specific installations that operate above consumption thresholds</td>
<td>Provides guidance documents and resources for substitutes in various VOC-containing products</td>
</tr>
<tr>
<td>Region</td>
<td>Policy</td>
<td>Initiative</td>
<td>Status</td>
<td></td>
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<tr>
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<td></td>
</tr>
<tr>
<td>European Union</td>
<td>Restrictions of Hazardous Substances in Electrical and Electronic Equipment (RoHS) (2002/95/EC)</td>
<td>2002 Eliminates cadmium, lead, mercury, PBDEs and PBBs in electronic products and encourages substitution with safer substance where technically feasible(^{112})</td>
<td>No guidance</td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td>Consumer Product Safety Commission (CPSC) – Consumer Product Safety Improvement Act (CPSIA) (S.108)(^{113})</td>
<td>2008 CPSC is required to assess health effects of all phthalate alternatives used in toys and other childcare products. Activities are conducted through the Chronic Hazard Advisory Panel (CHAP)(^{114})</td>
<td>No guidance</td>
<td></td>
</tr>
<tr>
<td>China</td>
<td>Administration on the Control of Pollution Caused by Electronic Information Products (Joint Ministerial Decree No. 39) (China RoHS)(^{115})</td>
<td>2007 Calls for producers of electronics to substitute safer alternatives</td>
<td>Unknown</td>
<td></td>
</tr>
<tr>
<td>United States – Minnesota</td>
<td>Products Containing Polybrominated Diphenyl Ethers(^{116})</td>
<td>2007 Requires the State to conduct assessment for deca-BDE to identify safer alternatives</td>
<td>No guidance</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory – Requirements for use of Acceptable Substitutes**

<table>
<thead>
<tr>
<th>Region</th>
<th>Initiative</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>US EPA – Significant New Alternatives Policy (SNAP) Program (Clean Air Act §612(c))(^{117})</td>
<td>1990 SNAP identifies chemical substitutes that reduce risk compared with Class I and Class II ODS for multiple industries. Rules and regulations are promulgated based on results of the substitution analysis</td>
</tr>
</tbody>
</table>

**Regulatory – Requirements for use of Safer Alternatives in Procurement**

<table>
<thead>
<tr>
<th>Region</th>
<th>Initiative</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States – New York</td>
<td>Establishing a State Green Procurement and Agency Sustainability Program (Executive Order No. 4)(^{119})</td>
<td>2008 Establishes processes for identifying preferred products, and also a list of chemicals to avoid in purchasing</td>
</tr>
</tbody>
</table>
Institute designed to support firms in substituting lead in electronics applications; (4) databases of alternatives such as the Danish Catsub database providing information on safer chemicals in specific applications or the French Ministry of Environment’s Substitution CMR database of alternatives to chemicals that may cause cancer or reproductive impacts in the workplace; and (5) stakeholder dialogues designed to identify challenges to safer chemicals and opportunities for advancing adoption, such as the UK Stakeholder Forum and the US Centers for Disease Control National Conversation on Chemical Exposures.

• Regulatory – Policies that require chemical substitution and alternatives assessment for chemicals used in manufacturing processes or products. There are several types of identified regulatory informed substitution policies:
  o Classification-based substitution requirements. Several European Directives on chemicals (such as the Chemical Agents Directive, the Cosmetics Directive and the Toys Directive) derive from European and now Globally Harmonized System of Classification and Labeling (GHS) classifications, particularly for carcinogens, mutagens and reproductive toxicants. These policies require evaluation of alternatives for continued use of such substances.
  o Pollution prevention planning requirements. These policies require manufacturing firms to characterize chemical use in processes and evaluate alternatives to reduce or eliminate toxics use and waste. The Massachusetts Toxics Use Reduction Act and Ontario Toxics Reduction Act both require manufacturers to characterize chemical use and evaluate alternatives to chemicals of concern in manufacturing processes.
  o Alternatives assessment to support regulatory decision-making. Under these policies, alternatives assessments are required prior to regulatory decisions either to permit continued use of a chemical of concern or to undertake regulatory restrictions. For example, REACH requires that firms seeking authorization undertake an alternatives assessment to demonstrate the need for authorization and their processes to adopt safer alternatives.
  o Single or multiple chemical restrictions, with alternatives assessment requirement. These are policies that restrict a particular chemical or class of chemicals, but also require either government agencies or regulated companies to evaluate alternatives to demonstrate availability or lack of availability of alternatives or to avoid regrettable substitutions. For example, the Minnesota Act on Products Containing Polybrominated Diphenyl Ethers (and other State policies restricting PBDEs, phthalates and lead), requires the state Pollution Control Agency to undertake an evaluation of alternatives prior to finalizing the restrictions process.
- **Requirements for use of acceptable substitutes.** These represent policies where manufacturers are required to use safer (or approved) substitutes to a chemical of concern with mandated requirements to list a substance as acceptable. The EPA SNAP Program requires companies to seek approval for substitution of ozone-depleting substances.

- **Requirements for use of safer alternatives in procurement.** Many jurisdictions have enacted policies that require government agencies to ‘lead by example’ to choose the least toxic alternatives for particular chemical or product classes. New York Executive Order No. 4, Establishing a State Green Procurement and Agency Sustainability Program, establishes processes for identifying preferred products, for example, cleaning products, and also a list of chemicals to avoid in purchasing.

Table 11.1 demonstrates that there have been a wide range of voluntary and regulatory initiatives to support informed substitution to date. Voluntary government initiatives, often in response to regulatory programs, have focused for the most part on government-initiated alternatives assessments for chemicals of concern to either inform the marketplace or support restrictive policies and action plans; development of substitution guidance documents, tools and criteria for evaluating alternatives; and stakeholder dialogues on substitution methods, examples and policies, engaging a range of chemical users, manufacturers, environmental groups and government agencies. Regulatory policies around informed substitution have generally centered on single chemical restrictions with alternatives assessment requirements prior to substitution and classification-based substitution requirements. There is an increasing focus on requiring alternatives assessment to support the regulation of chemicals of concern, for example, under REACH and the proposed California Safer Consumer Products regulations, which would require chemical manufacturers and users to conduct alternatives assessments for chemicals of concern in specific products of concern prior to government regulation to restrict or control that chemical. Interestingly, these requirements for alternatives assessment, primarily for chemicals in products, build off of the facility planning steps inherent in policies such as the Massachusetts Toxics Use Reduction Act.

### 11.5 Examples of Regulatory Informed Substitution Policies

In this section, we provide five case examples of government regulatory policies that support informed substitution, covering several of the policy categories outlined above. They provide details of how informed substitution requirements are being implemented in different regions and in different contexts. These, along with the evaluation of policies above, provide important lessons as to gaps in current policies and their implementation, and also the strengths and weaknesses of particular policy types.
11.5.1 Pollution Prevention Planning Requirements – Massachusetts Toxics Use Reduction Act

The Massachusetts Toxics Use Reduction Act, passed in 1989, represents a successful example of required alternatives assessment in the context of facility planning. The Act requires that manufacturers producing, processing or using some 1000 chemicals over threshold amounts conduct a materials accounting every year to understand chemical throughputs and undertake a detailed planning process every 2 years to identify options for toxics reduction. About 600 firms in Massachusetts are required to comply with the program. These firms pay a relatively small fee on chemicals that funds both the regulatory program but also a voluntary technical assistance program for firms (the Office of Technical Assistance for Toxics Use Reduction) and a research and education center [the Massachusetts Toxics Use Reduction Institute (TURI)].

The results of the program have been impressive. From 2000 to 2009, Massachusetts companies reduced toxics use by 21% (adjusted for production), toxic byproducts by 38% and emissions by 56%. Since its inception, Massachusetts firms have reduced toxics use by more than 50%, with even greater reductions in some uses, such as trichloroethylene use in surface cleaning, which has been reduced by about 95%. The success of the toxics use reduction/facility planning model is due in part to two main elements: recommended materials accounting and required planning supplemented by technical and research support. The materials accounting process forces firms to understand how chemicals are being used in various production processes and also costs and inefficiencies. The planning process requires that firms carefully identify a wide range of potential alternatives. As noted in the 2011 Program Report, ‘TURA does not require toxics users to stop using a chemical, but instead requires them to examine how they use it and what their alternatives might be. When toxics users are required to evaluate how they use chemicals and to identify alternatives, they often find ways to improve manufacturing and develop safer products and more efficient operations, boosting the competitiveness of Massachusetts firms.’ Educational programs, tools development and required certification by trained planners ensure that manufacturers’ planning processes are as comprehensive and of as high quality as possible. The planning requirements force firms to think about the ‘functional use’ of a chemical in a production process or product, whether that function is indeed necessary and whether safer chemical or process or product design alternatives can technically and economically fulfill that function.

Technical, educational and research support supplements the planning requirements, providing an incentive to innovate. A large challenge to firms, particularly small and medium sized ones, is capacity to innovate. Government partners provide services, demonstration projects and evaluation support to help firms overcome barriers to adoption of safer chemicals. For example, TURI’s Surface Solutions Laboratory tests alternative cleaning agents...
(including water-based systems) to ensure their performance and safety, lowering the technological risk to adoption. Supply chain partnerships, to support substitution of lead in electronics, allow firms to share experiences and resources in solving pre-competitive challenges.

Nonetheless, toxics use reduction has focused primarily on chemicals in manufacturing processes and not on products. For example, there is no planning requirement for chemicals in products manufactured outside the State. Also, firms are not required to adopt alternatives, even if they are technically and economically viable. However, market demands and regulatory requirements outside Massachusetts, such as the RoHS Directive in Europe, are forcing Massachusetts manufacturers to have to evaluate alternatives to chemicals of concern in products they manufacture. As such, the Toxics Use Reduction Institute has adapted its guidance and outreach for alternatives assessment and informed substitution in facility planning to also include product level alternatives assessment.

11.5.2 Alternatives Assessment as a Precursor to Regulation – California Safer Consumer Product Regulations

Through the passage of Assembly Bill (AB) 1879 in 2008, the State of California began an effort to regulate chemicals of concern in products based fundamentally on the thorough evaluation of safer alternatives.

AB 1879 has resulted in extensive discussions, conferences, legal, scientific and technical opinions and the development of multiple iterations of regulations to implement the mandate. The law requires the Department of Toxic Substances Control (DTSC) to develop processes for: (1) evaluating and prioritizing chemicals (Chemicals of Concern) and products of concern (Priority Products) in the State; (2) determining who is required to undertake alternatives assessments; (3) undertaking comprehensive alternatives assessments that consider life-cycle impacts of alternatives and critical exposure pathways; and (4) establishing which regulatory responses to reduce exposure and risks are warranted based on the results of alternatives assessments.

The requirements of the law are fairly simple, yet comprehensive, representing the first regulatory policy explicitly to require consideration of life-cycle impacts in the context of chemical substitution processes. Any manufacturer, distributor or retailer that sells products in California would be subject to the requirements. The goal of the law is to encourage the marketplace to substitute chemicals of concern in products of high concern while avoiding regrettable substitutions that may shift risks through the product life-cycle.

The California DTSC developed proposed regulations to implement the law in 2012. Based on a Priority Product designation (which may focus on a particular component or material in a product), the draft regulations would require manufacturers of the chemical/product to undertake a multi-stage, detailed alternatives assessment. DTSC has indicated that only a few Chemical of Concern–Priority Product combinations would be selected at first to ‘test’ the program and its implementation. DTSC will develop guidance for the
alternatives assessment processes, but expects some level of flexibility provided that the regulatory requirements for evaluation are met. Companies would be allowed to submit previously conducted alternatives assessments or to use different approaches to evaluate alternatives if these meet the minimum requirements of the regulations. As currently proposed, the alternatives assessment process would be overseen by a certified alternatives assessment planner, a trained professional, who would ensure the quality and detail in the plan, much like the planners in Massachusetts. The proposed alternatives assessment process consists of the following two steps:

a. **First stage**: This is an initial alternatives assessment to identify whether options exist that could lead to immediate substitution of the chemical of concern. In this first stage of the alternatives assessment, the ‘responsible entity’ (which may be a consortium of companies), must undertake the following steps:

   i. Identification of Product Requirements and Function of Chemical(s) of Concern. If the function is not necessary, the company may choose to eliminate the chemical altogether.

   ii. Identification of a range of possible alternatives.

   iii. Initial chemical hazard screening, comparing the chemical of concern to possible alternatives.

   iv. Identification of next steps in the full alternatives evaluation. Following completion of a first-stage alternatives assessment, the responsible entity submits the report to DTSC for review.

b. **Second stage.** This is the more detailed alternatives assessment that considers economic and technical feasibility along with life-cycle impacts and potential exposures. In the second-stage alternatives assessment, the responsible entity must identify the life-cycle stages and hazards for comparing alternatives, particularly those where differences might exist between alternatives. Based on the identification of these life-cycle stages, alternatives are compared on their ecological and human health impacts. The comparison of alternatives must also include an evaluation of potential exposures and exposure pathways to the alternatives, including an evaluation of quantities of the alternative chemical used. Finally, the analysis must review economic impacts (jobs, market, costs of manufacturing) of alternatives in addition to technical feasibility. The second-stage alternatives assessment report must identify location of key suppliers of the chemical in the product, a justification of the alternative chosen, and proposed regulatory options based on the results of the alternatives assessment. Based on the assessment reports, DTSC then determines appropriate regulatory responses for the chemical–product combination.

Although the Safer Consumer Products regulations are not finalized, it is clear that the California proposal will require more comprehensive alternatives assessments than any other policy to date.
11.5.3 Alternatives Assessment as a Precursor to Regulation – REACH

The EU’s REACH Regulation provides an example of a policy that utilizes alternatives assessment to support regulatory decision-making. REACH requires manufacturers, importers and downstream users applying for authorization (i.e., seeking permission to continue to use a chemical on the authorization list) to include ‘an analysis of alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant’ [REACH, Article 62(4)(e)]. Where this analysis demonstrates that suitable alternatives exist, the applicant must also develop a ‘substitution plan including a time table for proposed actions’ [REACH, Article 62(4)(f)], prior to being given authorization for continued use of the chemical. REACH also requires the European Chemicals Agency (ECHA) or EU Member States to present an analysis of alternatives in dossiers for identifying candidate chemicals for authorization and in dossiers for restriction proposals.

The information developed on alternatives is used to make and support various decisions in the authorization and restriction processes. Based on the availability of suitable alternatives, government authorities decide whether an authorization should be granted and, if so, the length of time for which the continued use of a chemical is permitted. For example, where suitable alternatives are available and the substance cannot be adequately controlled, an application for authorization is unlikely to be granted. Where suitable alternatives are available and the substance can be adequately controlled, the decision to grant authorization and the conditions of the authorization are shaped by the required substitution plan. If no suitable alternatives are available and the substance can be adequately controlled, authorization may be granted.

Subsequent information about alternatives plays an important role in the renewal of authorizations or, in some cases, the withdrawal of existing authorizations.

With regard to the restriction process, information on alternatives is required in order to evaluate the effectiveness and practicality of the proposed restriction, identify certain uses that ought to be excluded from restriction, identify other risk management options that ought to be considered and ensure the time for compliance is appropriate.

In order to support its regulatory decision-making with alternatives analyses that are consistent and comprehensive, the ECHA has developed detailed guidance documents outlining the information that must be incorporated into such analyses. For example, according to ECHA’s guidance for developing applications for authorization, an analysis of alternatives involves: identifying possible alternatives for each use; assessing the technical feasibility of possible alternatives identified; assessing possible alternatives for their potential risks to the environment and human health; assessing the economic feasibility of
possible alternatives identified; identifying relevant research and development; assessing the suitability and availability of possible alternatives; and determining the actions and time scales that may be required to make possible alternatives suitable and available for the applicant. A substitution plan includes a description of proposed actions and justifications as to why those actions are required, who will conduct the proposed actions, a timetable for proposed actions that will lead to the transferal to the substitute and justifications as to why the action requires the time allocated and what the uncertainties are in achieving the actions within the time scale and what possible mitigation is to be considered.42

Since the first applications for authorization are not due until 2013 and no dossiers for restriction have been developed to date, the extent to which information on alternatives will be included in these submissions and how the information will be utilized in the decision-making process remain to be seen. While some information on alternatives is included in dossiers prepared by the ECHA and EU Member States for identifying candidate chemicals for authorization, the consistency and comprehensiveness of this information varies widely.

11.5.4 Requirements for Use of Acceptable Substitutes – US EPA SNAP Program

Section 612(c) of the Clean Air Act provides an example of a policy that requires the use of acceptable substitutes where certain chemicals of concern are phased out. Implementation of such a policy involves the development of criteria for acceptability, identification of possible alternatives for particular functional uses, the evaluation of those alternatives based on the criteria developed and the determination that an identified substitute is either ‘acceptable’ or ‘unacceptable.’ This type of regulatory model provides a mechanism for minimizing risk trade-offs and driving the use of safer alternatives to restricted chemicals of concern.

Specifically, Section 612(c) makes it unlawful to replace certain ozone-depleting chemicals with any substitute that the US EPA determines may present adverse effects to human health or the environment when an alternative has been identified that (1) reduces the overall risks to human health and the environment and (2) is currently or potentially available. In order to achieve this mandate, Section 612(c) requires that EPA publish a list of acceptable and unacceptable substitutes for specific uses, and also maintain a public clearinghouse of alternative chemicals, product substitutes and alternative manufacturing processes available for products and manufacturing processes that use ozone-depleting chemicals.44

The EPA established the Significant New Alternatives Policy (SNAP) program to implement these legal requirements. The purpose of the program is to allow a quick, orderly transition away from ozone-depleting compounds by identifying substitutes, evaluating the acceptability of substitutes, promoting
the use of those substitutes believed to present lower overall risks to human
health and the environment, relative to compounds being replaced, and to
other substitutes for the same end use and prohibiting the use of substitutes
found to increase overall risk.\textsuperscript{45}

Manufacturers, formulators and end users introducing a substance, process,
or product for sale, import, export, or use in industrial sectors that historically
have used ozone-depleting substances, including refrigeration and air con-
ditioning, foam blowing, solvent cleaning, fire suppression and explosion
protection, aerosols, sterilants, tobacco expansion and adhesives, coatings and
inks, may be required to submit information to the SNAP program.\textsuperscript{46} Applicants
must submit data on atmospheric effects, exposure assessments, toxicity,
flammability and other environmental impacts (\textit{e.g.}, ecotoxicity, local air
impacts and impacts on aquatic life).

The EPA evaluates identified substitutes within a comparative risk frame-
work, comparing alternative compounds with those of ozone-depleting
compounds and the available alternatives. The environmental risk factors
that are considered include ozone depletion potential, flammability, toxicity,
occupational health and safety, and contributions to global warming and
other environmental factors. Risk factors associated with quality of inform-
ation, uncertainty of data and economic factors, including feasibility
and availability, are also taken into account. Substitutes are also evaluated
by use, as environmental and human health exposures can vary sig-
ificantly depending on the particular application of a substitute. The EPA
has developed specific risk screen methodologies for each industrial sector to
analyze the information and determine the acceptability of a proposed
replacement. When making decisions regarding the acceptability of sub-
stitutes, the EPA does not require that substitutes be risk free to be found
acceptable, restricts only those substitutes that are significantly worse and
defers to other environmental regulations when warranted.\textsuperscript{47} To date, the
EPA has identified hundreds of acceptable substitutes and tens of unac-
ceptable substitutes for 37 end uses in industrial sectors using ozone-depleting
substances.

In some cases, the EPA acknowledges that substances identified as acceptable
alternatives under the SNAP program framework, while reducing the potential
for ozone depletion, can still pose risks to human health and the environment.
For example, the EPA approved methylene chloride as an acceptable alter-
native for its use as a foam blowing agent, a solvent in electronics cleaning,
metals cleaning and precision cleaning, a solvent in adhesives, coatings and inks
and an aerosol solvent, despite the fact that its ‘higher toxicity’ posed a
‘potential risk to workers and residents in nearby communities.’ This decision
was justified by a desire to ‘immediately transition from certain ozone-depleting
substances as well as the belief that the risks to human health and the envir-
onment could be controlled by adhering to existing regulatory standards’ (\textit{i.e.},
State and local restrictions, workplace permissible exposure limits, RCRA
waste disposal requirements, future regulation as a hazardous air pollutant
under the Clean Air Act).\textsuperscript{47}
11.5.5 Classification-based Substitution Requirements – European Union Regulation of Chemicals in the Workplace

The EU Chemical Agents Directive\(^48\) and the Carcinogens and Mutagens Directive\(^49\) provide examples of policies that require substitution for certain classes of chemicals. These regulations place a general duty on employers to replace the use of hazardous chemicals in the workplace with safer substitutes, whenever it is technically possible. As the Member States are responsible for implementing and enforcing these regulations, they have developed in different ways throughout the EU. This type of regulatory model provides a mechanism for the systematic assessment and identification of chemical hazards in the workplace and the continuous transition to less hazardous substances.

The Chemical Agents Directive requires employers to determine whether any hazardous chemical agents are present at the workplace, assess any risk to the safety and health of workers arising from the presence of those chemical agents and take necessary preventive measures where hazardous chemical agents are identified. Specifically, Article 6(2) details that \( '\text{substitution shall be undertaken, whereby the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which, under its condition of use, is not hazardous or less hazardous to workers’ safety and health.}’ \) Similarly, Article 4(1) of the Carcinogens and Mutagens Directive requires employers to \( '\text{reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to workers’ health or safety.}’ \) Both directives utilize EU/GHS classifications to identify hazardous chemicals for which substitution is required.

The UK and Germany have developed their own regulatory frameworks, guidance documents and tools to support the employer’s duty, as mandated in the EU Directives, to evaluate substitutes to hazardous substances and implement substitution where less hazardous alternatives are identified. For example, the UK has implemented the general duty to substitute under its Control of Substances Hazardous to Health Regulations (COSHH). COSHH requires that, where reasonably practical, employers prevent the exposure of employees to substances hazardous to health through substitution. In order to help employers meet these requirements, the UK Health and Safety Executive produced guidance on the topic of substitution, which describes a process to follow when considering alternatives to hazardous chemicals.\(^50,51\)

In Germany, a regulatory framework, along with detailed guidance and tools to assist small- and medium-sized enterprises, has been developed. To implement the employer’s duty to evaluate substitutes to hazardous substances and implement substitution where less hazardous alternatives are identified, as mandated in the German Hazardous Substances Ordinance,\(^52\) the German Federal Institute for Occupational Safety and Health established guidance, TRGS 600,\(^53\) which includes a framework for identifying and evaluating
substitutes and establishes criteria and decision rules for assessing and comparing the health risks, physico-chemical risks and the technical suitability of identified alternatives. In order to facilitate the application of the TRGS 600 guidance in small and medium enterprises, the Institute for Occupational Safety and Health of the German Federation of Institutions for Statutory Accident Insurance and Prevention developed the Column Model tool. The tool provides a scheme for evaluating and comparing chemicals based on six hazard categories using information obtained from chemical safety data sheets.

Despite the existence of these policies, employers are often not well equipped to compare chemicals and select suitable alternatives. As a result, the extent to which employers are able to implement effectively their duty to substitute and transition their workplaces to safer chemicals is unclear.

11.6 Lessons Learned from Alternatives Assessment in Regulatory Policy

The five case studies and policies outlined above provide some important lessons to guide the development of government alternatives assessment policies in the future. A core lesson is that informed substitution cannot be achieved by a single policy; rather, a mix of policies that require evaluation of alternatives, regulatory incentives and disincentives (such as restrictions) and support structures that facilitate evaluation and adoption of safer alternatives is needed. Nonetheless, two of the policies outlined, the EU’s REACH authorization process and the California Safer Consumer Products regulations, are relatively new and it is yet to be established whether their implementation will or will not drive the adoption of safer alternatives. The REACH authorization process, however, forms part of a broader chemicals management policy overhaul that includes requirements to classify chemicals, characterize uses through the supply chain and develop toxicological data. Some of the main lessons from our analysis of policies and case examples include the following:

- To drive informed substitution, there is a need for policies that require evaluation of alternatives. While there are many regulatory policies requiring the elimination of chemicals of concern, policies that require alternatives assessment are far less common. As noted, alternatives assessment processes have tended to be discretionary in nature, involving research, partnership projects, case studies, guidance development and voluntary technical support databases on chemicals. Such efforts are important and critical to supporting informed substitution but are not sufficient in and of themselves to encourage it. Voluntary initiatives in and of themselves have varied participation which tends to be dominated by leading edge firms, those already with a culture, willingness and interest in sustainability and transitioning to safer products and that see a benefit in participation. While chemical restrictions alone may force laggards to remove a chemical of concern from a production process or product (particularly with drop-in substitutes), they are unlikely to force the investment in
systems and processes to ensure informed substitution. Numerous analysts have documented the importance of regulatory requirements in encouraging innovation in a particular firm or sector. For example, Porter and van der Linde, showed through case studies that stringent but well-designed regulations are a critical component of innovation. Regulation can provide signals about inefficiencies, can increase awareness within the firm, reduce uncertainty and stimulate progress. Geiser suggested that laws requiring alternatives assessment are needed as there is little incentive for firms to plan or reduce toxics otherwise. O’Rourke and Lee reported that facility planning requirements in Massachusetts have not only been instrumental in the success of the Massachusetts program in reducing chemical use and waste, but also led companies to establish structures and procedures that support future innovation, what they call ‘command and innovate policy.’ While the incentives to substitute chemicals of concern are clearly changing, with greater market pressures on manufacturers, government-required substitution planning can help facilitate informed transitions to safer chemicals and improve the knowledge base on which substitution occurs.

- Carefully designed policy incentives and disincentives can encourage the adoption of safer alternatives. Although safer alternatives may be available for a particular chemical, economic viability, technical challenges or lack of markets may inhibit the willingness of some firms to adopt the alternative. As such, alternatives assessment requirements alone may not be sufficient to encourage firms to adopt safer substitutes (and they may not encourage firms to think broadly enough about the range of alternatives available). In the context of Environmental Impact Assessment, Steinemann noted that despite NEPA requirements for broad analysis of impacts and alternatives, such broad evaluations of alternatives do not tend to occur in practice. This may in part be because there is no requirement to adopt the safest alternative for a particular project and the exercise may simply be an effort to justify an already made decision. In an analysis of implementation of the European Chemical Agents Directive, Lissner and Zayzon found that despite a policy mandate to substitute certain chemicals where feasible, such substitution does not occur regularly in practice due to a lack of incentives, guidance and tools for implementation. O’Rourke and Lee found that despite the requirements to plan under the Toxics Use Reduction Act, many firms choose not to implement alternatives identified in their plans, particularly if the payback period is not sufficiently short. This may also be the case where the alternatives are harder to implement and can open the firm to criticism for not acting fast enough. As such, tying alternatives assessment requirements with requirements for substitution of problem chemicals (or other incentives) may facilitate adoption. For example, many firms had undertaken assessment processes to evaluate alternatives to lead in electronics applications but had not adopted alternatives due to technical challenges. The adoption of the EU’s Restrictions on Hazardous Substances, which prohibited the use of lead, provided
the impetus to solve those challenges quickly and effectively in a pre-competitive sector-wide manner. Similarly, governments can recognize or list safer alternatives as an incentive to stimulate the marketplace for safer materials, as demonstrated by the U.S. EPA’s SNAP program and its DfE Safer Product Labeling program. In the latter case, the EPA provides the criteria for defining safer chemicals, an approach that can be used to stimulate the marketplace for alternatives for multiple functional uses of chemicals.

- **To support informed substitution, alternatives assessment requirements should be tied to government initiatives that support the adoption of safer alternatives.** Ashford\textsuperscript{12} and O’Rourke and Lee\textsuperscript{59} noted that technological innovation in safer chemicals requires three elements: motivation, capacity (or facilitation) and opportunities for change. Motivation and opportunity can be addressed through government policies that (1) provide strong incentives and disincentives, (2) establish clear goals and metrics for measuring progress and encouraging accountability and (3) establish mandated yet flexible procedures that require regulated entities to understand the impacts of technology changes. However, the fact that safer alternatives may be available is meaningless if these cannot be adopted in practice by a wide range of firms. While many firms may wish to adopt a safer technology, technical or institutional barriers may inhibit adoption. Capacity can be addressed through government initiatives that provide research, guidance, information, technical assistance, databases and networking of firms that support the adoption of safer chemicals. Massachusetts’ experience with toxics use reduction indicates that carefully designed policies that require understanding chemical use and evaluation of alternatives are more successful when linked to technical support structures to facilitate adoption. Implementation of the European Chemical Agents Directive has been supported at the EU and Member State level with the development of tools, guidance and support for firms to identify safer alternatives to chemicals of concern. Where such support is available, substitution is more successful.\textsuperscript{55}

- **There is a need for clear and consistent, yet flexible, definitions, guidance and criteria for alternatives assessment processes.** Despite the development of numerous policies that require substitution or evaluation of safer alternatives, there has been little consistency in how this process should occur. While the steps of alternatives assessment processes have been fairly consistent (from chemical and functional use prioritization, to product or process characterization to comparative evaluation to implementation), there is much less consistency in how alternatives should be compared. Lack of consistency may make it difficult for alternatives assessments produced in one region to be applicable in other regions. Hence having clear guidance and criteria that define a ‘thorough’ alternatives assessment is important. A key barrier to consistency in approaches is the lack of data on chemical use through supply chains (what chemicals are in what products, particularly for complex supply chains) and also data on chemical
toxicity and hazards. Chemical toxicity data are important to understanding toxicity trade-offs between options. Life-cycle inventory data are important to understanding energy and materials use through product life-cycles. Consistency in the types of data required for alternatives assessment and how data gaps are addressed is important in ensuring compatibility between alternatives assessments conducted from one region to another.

The case examples and policies reviewed suggest some important differences in alternatives assessment processes, including:

- **How higher/lower concern is defined to determine a safer alternative.** Some policies, such as REACH and the SNAP program define higher or lower concern based on chemical risk or elimination of a particular risk (without clarity of what level of risk is acceptable for an alternative) whereas others, such as the Massachusetts Toxics Use Reduction program, PRIO and the EPA alternatives assessment program, focus on comparison of key hazard criteria, such as persistence and carcinogenicity. Even these comparative chemical assessment schemes can vary in the criteria used to compare chemicals. The adoption of the Globally Harmonized System of Classification and Labeling may support greater harmonization of processes for comparing chemical alternatives.

- **How economic and technical feasibility should be evaluated.** Alternatives are not viable if they are too costly or do not adequately perform their functions. While many policies require regulated parties to consider economic and technical feasibility in the context of alternatives assessment processes, how these are addressed vary widely. Guidance developed under REACH, German Hazardous Substances Ordinance and the Massachusetts Toxics Use Reduction Act provide details as to how economic and technical feasibility should be addressed, whereas others do not.

- **How exposures should be considered.** Requirements to consider exposures (to consumers, workers, or the environment) vary between policies as to how these should be evaluated. The EPA alternatives assessment approach is primarily ‘hazard based’ (with persistence, bio-accumulation and physical chemistry characteristics serving as a surrogate for exposure), whereas others require a comparison of risks. Some include detailed exposure measures, whereas others evaluate surrogates or indicators for exposure – persistence and bio-accumulation, vapor pressure, use scenario, etc.

- **How impacts along a chemical/product life-cycle should be considered.** The draft California Safer Consumer Products regulation is the first substitution policy to require explicitly consideration of life-cycle impacts. Whereas the EPA SNAP program requires consideration of life-cycle trade-offs, through indicators such as ozone depletion and greenhouse gas emissions, the draft California regulations require the regulated party to evaluate explicitly life-cycle segments that might differ between
alternatives (for example, if one increases worker risks in manufacturing). Although there are extensive life-cycle evaluation methods available, many include limited evaluations of chemical hazards. An EU project, OMNIITOX, was initiated to support consideration of life-cycle impacts in the context of REACH implementation and the State of Washington is working on guidance for integration of life-cycle considerations in alternatives assessment processes.62

While it is important to develop policies that require alternatives assessment and ensure consistency in definitions and approaches, it is equally important that these alternatives assessment processes do not become overly prescriptive or burdensome with more scientific detail than is necessary to accomplish the goal of informing substitution. The history of existing decision-support processes, such as risk assessment and life-cycle assessment, offer some important warnings about the possible pitfalls that may lie ahead in the application of alternatives assessment requirements in policy. Ultimately, although careful consideration of alternatives to chemicals of concern is an important policy goal, alternatives assessment itself is simply a decision-support method or process not unlike risk assessment and life-cycle assessment and how it is used in policy can either promote or limit its promise in making more effective decisions.

We see ahead two potential missteps in the development and use of alternatives assessment in policy that are worth some cautious consideration. These involve the degree to which the methods and uses of alternatives assessment become too heavily weighed down by science or too formally constrained by regulation:

1. The promise of risk assessment particularly in chemical assessment applications has been compromised by the determination of some users and those who contest the decision outcomes to set overly high standards for the scientific evidence that can be used, to rely primarily on variables for which there is extensive research (while largely ignoring the many variables where there is little scientific study) and to discount large amounts of emerging science, novel test methods and thoughtful professional judgment. The calls for ‘sound science’ and ‘rigorous science’ are too often code terms for a narrow, reductionistic approach to using science to constrain decision-making.63 By limiting focus to those variables where there is substantial research and then setting a very high bar for scientific evidence, some risk assessment initiatives have turned a laudable decision-assisting tool into a slow, costly and cumbersome drag on effective decision-making. The recent EPA federal risk assessments on trichloroethylene and dioxin provide telling illustrations of the costs of encumbering such a decision-assisting tool.63 It is important that alternatives assessment policies address the use and misuse of science in conducting alternatives assessments and that agencies and other promoters develop tools that are flexible yet provide sufficient information to make informed decisions. Indeed, the amount of information needed
to compare two alternatives is different to the amount of information needed to determine whether a chemical is definitely safe or dangerous.

2. Overly detailed requirements in alternatives assessment regulations can inhibit the ability to complete such assessments and overburden both the regulated community and regulators themselves. The statutory requirements in California’s Safer Consumer Product Act (AB 1879) requires the use of a life-cycle analysis that includes consideration of 13 specified variables in alternative assessments that will meet regulatory standards. As the regulations mature in California, it is important that they do not become too formulaic, complex and burdensome. Such a ‘locked down’ specification of the design and conduct of alternatives assessments can not only reduce the creative construction of a decision-assisting tool and render it inappropriate to the many and varied conditions that it may need to address, but also tend to convert the tool into a formulistic, compliance-oriented device that encourages a routinized exercise that is neither substantive, innovation generating, nor respected. Overly specifying the logic and applications that must, by mandate, be followed either by statute, government regulation, court dictate or private standard-setting body can drive out the creative, appropriate and accurate uses of the tool. For example, experience with Toxics Use Reduction planning in Massachusetts indicates that if procedures are too narrowly defined and inflexible, firms may complete the required process without necessarily engaging in thoughtful alternatives assessment. The NEPA EIS process provides one model procedure for alternatives assessment, which lays out the components and minimum requirements but does not provide such specificity.

Promoters of alternatives assessment should be wary of efforts to narrow, formalize or routinize the tool too quickly in such a way that limits its flexibility and versatility. Such detailed requirements can also limit the ability of policies and the agencies that implement them to address more than a small number of the thousands of chemicals of concern in commerce. These potential misdevelopments could be advanced with the best of intentions by well-meaning promoters. Scientists might press for tighter scientific foundations and lawyers might press for clear and formulistic standards. If alternatives assessment is to become a truly reliable and effective decision-assistance tool in regulatory policies that supports the transition to safer chemistries, its promoters must work not only to improve its methods and applications, but also to resist these potentially damaging pressures.

11.7 Conclusion

While chemical restrictions and phase outs can lead to the adoption of safer alternatives, they can also lead to regrettable substitutions. As such, carefully designed chemicals policies that require the thorough evaluation of alternatives
can help minimize the potential for such trade-offs and also increase the potential benefits of restrictive policies in supporting innovation in safer materials. If agencies’ actions require or promote the phase out of a specific chemical, this creates a responsibility to oversee and support the transition to safer chemicals.

Alternatives assessment provides an important tool for promoting the informed transition to safer and more sustainable chemicals, materials and products. In its generic form it is nothing more than a logical, transparent and replicable set of methods for evaluating the desirability of one or several alternatives over a currently used chemical, material or product of concern. Alternatives assessment requirements encourage firms to understand the functional uses of chemicals of concern, their role in manufacturing processes and products, a wide range of options to reduce or eliminate a chemical of concern, the pros and cons of reasonable options and the opportunities and challenges to implementation. Combined with policies that provide incentives, disincentives, tools, support and information, these alternatives assessment requirements can move firms from simply examining options to their ultimate adoption.

Nonetheless, in some cases, technologically viable safer alternatives may not be available, may be difficult to implement in a particular process or may present risk trade-offs. In these cases, it may be useful to link alternatives evaluation with policies that support green chemistry research and development. Green chemistry is the design of inherently safer chemicals throughout their life-cycle. For example, the California Safer Consumer Products draft regulations require companies to engage in green chemistry research when safer alternatives are not available. In Massachusetts, the Toxics Use Reduction Institute provides seed research support to academic researchers to investigate alternatives to chemicals of concern across sectors. The German Environmental Protection Agency’s guidance on Sustainable Chemistry supports companies in the development of new molecules.

Although chemical restriction policies have not typically included alternatives assessment requirements, this seems to be changing. This is evident in the policies analyzed – which include various types of alternatives assessment requirements – and the increasing trend towards intergovernmental and industrial collaboration and cooperation in sharing information on alternatives and developing common approaches to alternatives assessment. It is likely that more collaboration will be needed to ensure that alternatives assessment requirements serve the goal of advancing the development, evaluation and adoption of safer chemicals and products without creating overburdensome requirements that inhibit the ability of such policies to be innovation and solutions stimulating. Given the relatively recent history of mandatory alternatives assessment requirements in the context of government chemicals restriction policies, there is a need for metrics in policies and post-implementation evaluation to understand what the most effective policy structures are to ensure that such policies support informed substitution and ultimately live up to their stated goals. Such analyses, which have been done for the
Massachusetts Toxics Use Reduction program\textsuperscript{66} and the European Chemical Agents Directive,\textsuperscript{55} provide the opportunity for authorities to take stock and evaluate the most effective means of integrating alternatives assessment requirements in policy as well as to adapt to new knowledge or changing circumstances.

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