Assessment of Chemical and Non-Chemical Alternatives: Focusing on Solutions

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Report Highlights

There are increasing drivers for removing chemicals of concern from manufacturing processes and products. These drivers tend to be at the market level (retailers and global brands); and regulatory (European Union and the United States) and tend to be focused on a small number of countries (Europe, Canada, United States) and brands that are global in nature. Global treaties have had some impact, particularly the Montreal, Stockholm and Rotterdam Conventions.

Informed substitution is expanding conventional risk management efforts. Against the backdrop of market and regulatory pressures to reduce the health and ecosystem risks associated with chemicals in products and manufacturing processes, there is increasing attention to the identification, assessment and adoption of safer chemical and non-chemical alternatives. Informed substitution is a critical chemical risk management approach, particularly in countries where emissions controls and safety infrastructure is limited. Substituting hazardous chemicals with safer alternatives reduces the need for complex engineering controls, safety systems, personal protective equipment, and collection and monitoring schemes that can be costly and can fail.

Alternatives assessment has emerged as the preferred approach to support informed substitution. Alternatives assessment is an iterative, step-defined and solutions-oriented process "*for identifying and comparing potential chemical and non-chemical alternatives that could replace chemicals of concern on the basis of their hazards, performance, and economic viability*". The focus of the assessment is not on the replacement of the individual chemical of concern, but rather on addressing the function that the chemical provides. Alternatives assessment can be less or more complex, depending on the technical capacity of the user. Being solutions and action oriented (e.g., evidence exists to substitute a chemical), alternatives assessment should not be onerous for users, nor should users wait for perfect information to support informed substitution decisions, but rather identify safer and feasible options based on the best information available. Informed substitution is a continuous improvement process with the goal of progressively transitioning to safer alternatives; hence action should not be stalled waiting for the perfect solution. Research on safer alternatives is a critical supplement to the alternatives assessment process.

Alternatives assessment frameworks, methods and tools are available though some differences exist. Current approaches to alternatives assessment suffer from gaps in data and methods that can hinder substitution actions, including gaps in: toxicological data, particularly on mixtures; information on performance and costs of alternatives; data on exposure and lifecycle impacts; and knowledge on available alternatives. Methods and tools are most developed for the hazard assessment component of an alternatives assessment. Consideration of life cycle impacts and comparative exposure characterization are recent additions to the alternatives assessment approach and thus methods and tools available are less developed. Consistent methods and data requirements will help support transferability of assessments from one region to another as well as strengthen alternatives assessment practice. No two alternatives assessments are exactly the same, and situations in which alternatives assessments are conducted can vary greatly, depending on country or region, chemical or chemical class involved, or place on the supply chain. The Commons Principles for Alternatives Assessment are a set of guiding principles meant to align the practice of alternatives assessment.

Globally there are few national or regional chemicals management/restriction policies that include detailed alternatives assessment requirements or support for informed substitution. Few substitution policies exist outside of Europe and North America. These policies are rarely supplemented with

government programs to support the transition to safer chemicals, including technical support, demonstration projects, etc. A mix of regulatory and non-regulatory policies is needed to support the informed substitution to safer chemicals.

Efforts to advance informed substitution and alternatives assessment should focus on international alignment and greater technical support and resources for developing countries/countries in economic transition. The actions required to advance alternatives assessment and informed substitution will differ according to region, industry and use. At the global level, developing consistent guidance on alternatives assessment and informed substitution, including outlining steps in the assessment, minimum and preferred data, and attributes to consider would be an important step in strengthening alternatives assessment and informed substitution across regions. Developing countries and countries with economies in transition often have limited resources to evaluate chemical hazards of replacements, to collect and properly dispose of the toxic materials that were replaced, and to support or enforce substitution requirements. To remove these barriers, there is a need for technical support, capacity building and case examples of successful substitutions as well as collaboration between research institutions, governments, employers, and international agencies.

Governments should focus on establishing policy mandates, building best practices, building capacity, and effectively engaging stakeholders to advance alternatives assessment and informed substitution. Government has an important role to play in establishing the mandates for alternatives assessment and substitution, including: developing criteria for chemicals and materials to avoid in substitution processes (e.g., less-safe and safer chemicals), establishing clear guidance and requirements for the alternatives assessment process, and developing metrics to monitor the substitution process. Governments can also establish non-regulatory mechanisms that help achieve program goals and accountability, including: providing technical capacity, and networking support to companies and other stakeholders; undertaking or funding alternatives assessments to support industry actions; collecting and compiling relevant case examples and lessons learned; and sharing information and knowledge on best practices.

The private sector should focus on enhancing supply chain communication, engaging stakeholders and advancing collaboration and partnerships that advance the evaluation and adoption of safer chemistries. Companies are responsible for understanding the chemicals they are using (function/uses, toxicity, potential exposures) through their supply chains; establishing processes to systematically and thoughtfully evaluate and adopt alternatives, involving workers, communities, and supply chain stakeholders, as necessary; evaluating implementation for potential trade-offs and improvement opportunities; and transparently presenting results and decisions. Stakeholder engagement (both inside and outside of firms) can help ensure critical questions are asked during the assessment and that implementation of substitutes occurs in an efficient manner, guaranteeing greater adoption.

The academic community should focus on research, methods development, and education that supports alternatives assessment and informed substitution. The academic community can focus research on critical alternatives assessment and substitution needs, including: development of methods and data to more rapidly evaluate chemical hazards, compare exposure trade-offs, make informed multi-criteria decisions, and compare chemical and non-chemical alterantives. Academic research on safer chemicals, materials, manufacturing processes, and practices can be better linked to government and scientific substitution priorities. Academic institutions can be more proactive in delivering multi-disciplinary education of chemists, engineers, and health scientists so that future professionals understand how to integrate substitution thinking into design and investigation.

1. Introduction and Objectives

Scientific, policy and consumer concerns regarding the health and environmental impacts of toxic substances have resulted in increased pressures to restrict them in manufacturing processes and products. However, selecting chemical alternatives without thoughtful consideration of their hazard profiles or other trade-offs can have regrettable consequences when substitutes are as toxic or even more toxic as the chemical they replace or have lower performance. These mistakes occur, in part, because chemical performance and cost are often considered a priority over health, safety and environment in chemical selection decisions. As a result, informed substitution has emerged as a critical strategy to effectively manage and reduce the risks from chemicals of concern to human health and safety and the health of the environment.

This paper provides a state of the art review of substitution and alternatives assessment approaches to advance chemicals management efforts globally. The paper provides:

- an overview of informed substitution and alternatives assessment
- a review of current alternatives frameworks, methods and tools as well as current challenges and associated needs to advance the science and practice of alternatives assessment
- a landscape of substitution and alternatives assessment provisions in existing international and national policies and an outline of considerations for future policy design to support the transition to safer chemicals and technologies
- lessons learned from substitution case examples
- options for actions for a range of stakeholders including scientists, government officials and enterprises.

2. Methods

A review of the literature focusing on substitution and alternatives assessment was conducted. The literature review of alternatives assessment frameworks and approaches was based in large measure on a recent paper by Jacobs *et al.* 2016 and a research and practice agenda paper by Tickner *et al*. 2018. Additional literature reviewed included white paper publications, government reports as well as published critiques. Policies and approaches undertaken by authorities internationally were identified using a number of sources, including reports, peer-reviewed literature, and on-line resource and tools, including Subsport (2018) and the State Policy database (2018) – which are compendia of international and U.S.-focused substitution policies, respectively – and the OECD (2018) Substitution and alternatives assessment tool box. Our comparative review focused on the subset of policies that included evaluation of alternatives/alternatives assessment/substitution provisions. Strengths and limitations related to each policy approach were characterized based on the project team's chemical management policy and alternatives assessment expertise. Where more information was needed for such characterizations, additional policy research was conducted.

Case examples presented in this report were selected based on a series of criteria, including industry sector, countries impacted, international treaty involved, and global importance of the chemical of concern. Document reviews and interviews were used to develop each case example. Lessons learned were extracted for each case study to help inform needs and opportunities to enhance informed substitution efforts globally.

3. Understanding Informed Substitution and Alternatives Assessment

Momentum is increasing to remove chemicals of concern from processes and products

Both regulatory and market drivers are providing signals for the removal of chemicals of concern from manufacturing processes and products. For example, non-governmental organization (NGO) actions, such as Greenpeace's global Detox campaign, which is focused on toxic chemicals in the textile industry, are stimulating market demand for the removal of toxic chemicals in a variety of consumer product sectors (Grappi *et al.* 2017; Greenpeace International 2018; Harlman and Klaschka 2017). In developed countries, such as the U.S., major retailers including Walmart, Target, and Home Depot have launched safer chemicals management policies and programs. These programs aim to restrict the sale of consumer products containing priority chemicals of concern in household products with high human exposure potential, such as household cleaners and cosmetics (Bomgardner 2014; Brown-West 2017; Ley 2017; Natural Resources Defense Council 2018; Walmart 2018).

A number of regulatory programs, including those in the European Union (E.U.) and the U.S. state of California, require that assessments of alternatives be conducted for chemicals of high concern (European Parliament and Council 2006; California Code of Regulations 2013). Other policies in the E.U., U.S. States and some countries, restrict chemicals of concern for specific uses. At the international level, treaties such as the Montreal Protocol on Substances that Deplete the Ozone Layer and the Stockholm Convention on Persistent Organic Pollutants have specific provisions for the analysis of potential alternatives. These treaties provide critical stimuli for substitution by regions, countries and global corporations.

From conventional risk management to informed substitution

Against the backdrop of market and regulatory pressures to reduce the health and environmental risks associated with chemicals in products and manufacturing processes, there is a heightened attention to the identification, assessment and adoption of safer chemical and non-chemical alternatives as the focus of risk management efforts. Conventional chemicals risk management strategies typically assume that the use of a toxic chemical is a given. Consequently, these strategies often focus on controlling exposure to an acceptable level, as informed by risk assessments. By contrast, the focus of informed substitution is to replace a chemical with a functional match (one which is safer for humans and the environment) through chemical replacement or a process or technological change. Informed Substitution is different than chemical restrictions, bans, or a de-selection approach, where chemicals may be eliminated without consideration of what may replace them. It involves a considered transition from chemicals of higher concern to health and environment to chemicals, processes, and products of lower concern.

Informed substitution is part of a strategy aimed at reducing chemical risks at the product or process design or selection stage by eliminating the hazards associated with a chemical of concern, rather than relying on exposure control strategies that may fail or shift risks. It assumes that the function of a toxic chemical can be replaced by a safer option, which could be a different chemical or a completely different technology. In a given application it is the function provided by a chemical that is needed, not necessarily the chemical itself. In some cases, the function may not even be necessary. When significantly safer options are not available, research can be undertaken to investigate the use of safer chemistries (i.e., green or sustainable chemistry) or to develop engineering or design solutions to eliminate or mitigate the risk posed by using a hazardous chemical. This is consistent with the precautionary principle and the

source reduction approach inherent in cleaner production and the industrial hygiene hierarchy of controls – concepts that evolved in the 1990s (O'Brien 2000; Ashford 2013). Considering chemical function, rather than simply comparing the risks of drop-in chemical alternatives, offers a means of identifying a broad range of options to meet a particular functional need. This is referred to as "functional substitution" (see table 1). In essence, the process of functional substitution also re-orients chemicals management approaches from time-intensive risk assessment and risk management based on single chemical substances, to comparative evaluations of the best options to fulfil a specific function (Tickner *et al.* 2015).

Table 1: A functional substitution approach for chemicals in products and processes (Tickner et al. 2015)

Functional Substitution Level	**Chemical in Product** Bisphenol-a in Thermal Paper	**Chemical in Process** Methylene Chloride in Degreasing Metal Parts
Chemical Function (Chemical Change)	Is there a functionally equivalent chemical substitute (i.e., chemical developer)? **Result: Drop-in chemical replacement**	Is there a functionally equivalent chemical substitute (i.e., chlorinated solvent degreaser)? **Result: Drop-in chemical replacement**
End Use Function (Material, Product, Process Change)	Is there another means to achieve the function of the chemical in the product (i.e., creation of printed image)? **Result: Redesign of thermal paper, material changes**	Is there another means to achieve the function of the process (i.e., degreasing)? **Result: Redesign of the process** (e.g., ultrasonic, aqueous)
Function As Service (System Change)	Are cash register receipts necessary? Are there alternatives that could achieve the same purpose (i.e. providing a record of sale to a consumer)? **Result: Alternative printing systems** (e.g., electronic receipts)	Is degreasing metal parts necessary? Are there other alternatives that could achieve the same purpose (i.e., providing metal parts free of contaminants for other end uses)? **Result: Alternative metal cutting methods**

Substitution as an innovation driver

Framing substitution as an innovation strategy rather than compliance one could help to scale substitution approaches (ECHA 2018). Chemical substitution efforts often focus on removing the chemical of concern but not on the transition to safer chemistry or technologies. Redefining substitution in terms of its potential for innovation, rather than as a tool for removing and replacing problem chemicals in response to regulatory or market demands, is critical to the development of technologies that will help mitigate the current problem of toxic chemicals in the global chemical supply chain (see Box 1 for a case example).

Box 1: Proactive substitution by frontrunners: safer alternatives for brominated flame retardants in the electronics sector (source: Chemical Watch 2015; Wendschlag 2015)

Hewlett Packard (HP) is among dozens of companies in the electronics sector that face continued regulatory and consumer pressure to remove hazardous substances of concern from electronic and electrical products. Brominated flame retardants are one class of toxic chemicals in electronics that carries risk across all product life cycle stages – during production, use and disposal. They are among the six substances restricted under E.U. RoHS (Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment) Directive and also regulated under the Stockholm Convention. The increasing number of regulations and standards around the world that cover the electronic industry stimulated HP to evolve its chemical substitution approach.

To identify safer alternatives, HP created its Integrated Alternatives Assessment Protocol, which uses tools such as GreenScreen® to comprehensively assess the hazard profile of potential alternatives, as well as life cycle assessment tools to address the broader range of potential life cycle impacts. In its evaluation of 45 potential substitutes, HP identified roughly a dozen safer alternatives and subsequently worked with its suppliers to incorporate these substitutes into its products.

Alternatives assessment – the preferred tool for informed substitution

Alternatives assessment emerged in the late 1990s as a comparative process used by the U.S. Environmental Protection Agency (U.S. EPA), some U.S. states, and European countries to evaluate substitutes to toxic chemicals used in specific industry sectors (U.S. EPA 1996; Lohse *et al.* 2003). Since then, alternatives assessment has evolved as the preferred approach to support informed substitution.

Alternatives assessment is an iterative, step-defined and solutions-oriented process "*for identifying and comparing potential chemical and non-chemical alternatives that could replace chemicals of concern on the basis of their hazards, performance, and economic viability*" (NRC 2014; Geiser *et al*. 2015). O'Brien (2000) notes that in its simplist form, alternatives assessment has three main components: (1) identification of a wide range of alternatives; (2) identification of the pros of alternatives: (3) identification of the cons of alternatives. The focus of the assessment is not on the replacement of the individual chemical of concern, but rather on the function that chemical provides. Alternatives assessment is a systematic approach that provides critical information that is used to inform the transition to safer chemicals, materials, processes, or practices, reducing the potential for regrettable substitutions. The process may include modifications to how a product is engineered or used or may explore non-chemical alternatives, thereby shifting the focus from problem analysis to innovations and solutions (Geiser *et al.* 2015). This is similar to the planning approach that is central to cleaner production and pollution prevention. Six general steps for alternatives assessments are shown in Table 2.

Alternatives assessment can be less or more complex, depending on the technical capacity of the user. For example, the United States Occupational Safety and Health Administration (U.S. OSHA) created a "Transitioning to Safer Chemicals" website and capacity training to support small and medium-sized enterprises (SMEs) in making informed choices about chemical alternatives (U.S. OSHA 2014). The goal was to instil systematic thinking about alternatives at the company level in a relatively simple manner, providing resources for firms to make informed decisions and understand potential trade-offs in choices (U.S. OSHA 2014). This is particularly important for developing countries where resources might be limited. Being solutions and action oriented (e.g., evidence exists to substitute a chemical), alternatives assessment should not be overwhelming for users to implement.

Table 2: Alternatives Assessment – A Snapshot of its Components (Tickner et al. 2018)

Component	What it involves
1. Scoping, problem formulation, identifying alternatives for consideration	Establishes the scope of and plan for assessment. Identifies stakeholders to engage and decision rules that will guide the assessment; gathers data on chemical of concern, its function and application; determines assessment methods and identifies alternatives to be considered
2. Hazard/comparative exposure assessment	Evaluates human health and ecological hazards and assesses comparative exposures
3. Technical feasibility assessment	Assesses the performance of alternatives against the requirements established during the problem formulation step above
4. Economic feasibility assessment	Assesses the economic feasibility of alternatives against the requirements established during the problem formulation step above
5. Other life cycle considerations	Addresses additional factors critical for determining risks to human health and the environment beyond those included in the hazard/exposure assessment component to avoid risk trade-offs (e.g., energy, climate change impacts, etc.)
6. Decision making	Identifies acceptable alternatives on the basis of information compiled in previous steps. Addresses situations where no alternatives are currently viable by initiating R&D to develop new alternatives or improve existing ones and establishes an implementation and adoption plan to identify potential trade-offs during adoption

Alternatives assessments help to avoid regrettable substitutions

Chemical substitution without adequate consideration of the function of the chemical, and the advantages and disadvantages of a range of alternatives to meet that function, can result in a regrettable substitution. A regrettable substitution is one in which the alternative turns out either to have an unexpected hazard that results in similar or worse toxicity than the chemical of concern, involves shifting the burden of a hazard to another entity, or results in lower quality. For example, an alternative may no longer be carcinogenic compared to the chemical of concern, but it may be toxic to aquatic organisms. Alternatives assessments support the transition to safer chemicals and materials in a way that reduces the likelihood of regrettable substitutions by ensuring that hazards and potential exposure trade-offs are considered alongside issues of performance and cost (Hogue 2013). By studying examples of regrettable substitutions, practitioners and policy makers may be able to avoid similar pitfalls in future evaluations. Examples of notable regrettable substitutions are presented in Table 3.

Conducting an alternatives assessment cannot completely eliminate the potential for adopting alternatives that may negatively affect human or environmental health, given evolving understanding of chemical toxicity and exposure. Nonetheless, concerns about problematic substitutions or missing data, or the quest for perfect information on which to base decisions (leading to “paralysis by analysis”) or the perfect alternative, should not be used as reasons to avoid substitution. And in some countries, especially those with limited scientific resources, action may be needed with less than perfect information but should at least have sufficient information to thoughtfully consider potential trade-offs of alternatives. As in continuous improvement processes, a less than perfect alternative may be sufficient while research is conducted to identify even safer options. In essence, given drivers for substitution, alternatives

assessment processes require the best available information that enables well-informed decisions that support substitution activities.

Taking a broader functional substitution approach that considers both chemical and non-chemical alternatives can provide an important approach to avoid regrettable substitutions that may occur as a result of chemical-by-chemical drop-in replacement approaches. Box 2 provides an example on pesticides, a case where systems practice changes can have a significant benefit over drop-in chemical replacements.

Table 3: Notable examples of regrettable substitutes (Harney et al. 2003; Siddiqi et al. 2003; U.S. U.S. CDC, 2008; Birnbaum 2010; ECHA, 2013; NTP, 2011; Velders et al. 2012; Ichihara et al. 2012; Tomar et al. 2013; Eldak et al. 2015; Rochester and Bolden 2015; CCOHS, 2018)

Chemical of Concern (function)	Hazard	Substitute	Hazard
Bisphenol-A (BPA) (plasticizer)	Endocrine disruption	Bisphenol-S (BPS), Bisphenol-F (BPF)	Endocrine activity
Bis(2-ethylhexyl) phthalate (plasticizer) (DEHP)	Endocrine disruption	Diisononyl phthalate (DiNP)	Carcinogenicity, Possible endocrine disruption
Lead (additive in gasoline)	Neurotoxicity	Methyl tert-butyl ether (MBTE)	Aquatic toxicity
Methylene chloride (solvent carrier in adhesives)	Acute toxicity, carcinogenicity	1-Bromopropane (nPB)	Carcinogenicity, neurotoxicity
Methylene chloride (brake cleaners)	Acute toxicity, carcinogenicity	n-Hexane	neurotoxicity
Poly brominated diphenyl ethers (PBDEs) (flame retardant)	Persistence, neurotoxicity, reproductive toxicity, carcinogen (penta and deca)	Tris (2,3-dibromopropyl) phosphate	Carcinogenicity, aquatic toxicity
Trichloroethylene (TCE) (metal degreasing)	Carcinogenicity	Bromopropane (nPB)	Neurotoxicity, carcinogenicity
Chlorofluorocarbons (CFCs) (refrigerant)	Ozone depletion	Hydroluorocarbons (HFCs)	Greenhouse gas

Box 2. Using non-chemical alternatives: agroecology to replace Endosulfan (source: Food and Agriculture Organization of the United Nations and UNEP 2012; Febles 2016)

Endosulfan is a broad-spectrum organochlorine insecticide employed to control insects and mites. In use since the 1950s, it has been employed on a global scale for vegetable and fruit crops, vineyards, cereals, coffee, tea, tobacco and cotton, among others. Endosulfan causes poisonings that can prove fatal, accumulates in the fatty tissues of humans and animals and in breast milk and is a possible endocrine disruptor. It is included in Annex A (Elimination) of the Stockholm Convention and in the Rotterdam Convention, and is considered a Highly Hazardous Pesticide under the FAO-WHO criteria. Importantly, when Endosulfan was listed under the Stockholm Convention in 2011, the Conference of the particies (COP) asked the Persistent Organic Pollutants Review Committee (POPRC) to assess both chemical and nonchemical alternatives. On the basis of this assessment, POPRC recommended and the following COP (2013) endorsed the recommendation that when replacing endosulfan priority be given to ecosystem-based approaches to pest control.

In Cuba, endosulfan ceased appearing in the phytosanitary strategies planned by the Plant Health Department in 2010 as part of the country's broader policy on pesticide reduction. In 1988 the construction of a network of biological control laboratories began country-wide. This has been the basis of phase-out programmes for several pesticides. Cuba took an agroecological (a variation of IPM) approach, in which eliminating the use of

a pesticide is not seen as a simple substitution of inputs; instead changes in the management of agroecosystems were introduced, including use of biological agents, cultural changes, natural enemies, and finally the focused application of other pesticides.

See Annex 1 for more details

4. Frameworks, Methods and Tools for Alternatives Assessment

Driven by government policies and market demands, researchers and practitioners have developed a variety of alternatives assessment frameworks, methods and tools to assist in evaluating chemical hazards and identifying safer substitutes (Jacobs *et al.* 2016).

A number of frameworks for assessments of alternatives exist and although there are differences, they share a common purpose and main components

Over the last two decades government authorities, academic institutions, and NGOs have developed a variety of alternatives assessment frameworks to aid in identifying, evaluating and implementing safer substitutes. A review by Jacobs *et al.* (2016) indicates a growth in the number of frameworks, demonstrating an increased recognition of the importance of evaluating alternatives to inform a transition towards safer options and to ensure against regrettable substitutes as a key aspect of chemicals management science and policy. A select list of existing alternatives frameworks is outlined in Table 4.

Table 4. Alternatives Assessment Frameworks (Jacobs et al. 2016)

Framework	Source/Developer
Alternatives Analysis Guide, Version 1.0 (regulatory)	CA Department of Toxic Substances and Control
Minimizing Chemical Risk to Workers Health and Safety through Substitution (regulatory)	European Commission, DG Employment
Alternatives Assessment Guide V1.1	Interstate Chemicals Clearinghouse (IC2)
Massachusetts Toxics Use Reduction Institute 2006 and Eliason and Morose 2011	MA Toxics Use Reduction Institute
A Framework to Guide the Selection of Chemical Alternatives	U.S. National Research Council
Assessing Safer Chemical Alternatives (regulatory)	Ontario Toxics Use Reduction Program
Guidance on the Preparation for an Application for Authorization (regulatory)	European Chemicals Agency
Guidance for the Preparation of an Annex XV Dossier for Restrictions (regulatory)	European Chemicals Agency
General Guidance on Considerations Related to Alternatives and Substitutes for Listed Persistent Organic Pollutants and Candidate Chemicals	United Nations Environment Program, Stockholm Convention
TRGS 600 (regulatory)	German Institute for Occupational Safety and Health (BaUA)
Alternatives Assessment Criteria V2.	U.S. EPA Safer Choice Program (formerly Design for Environment Program)
Cleaner Technologies Substitute Assessment: A Methodology and Resource Guide	U.S. Environmental Protection Agency
Instructions for the Significant New Alternatives Policy (SNAP) Program TSCA/SNAP Addendum (regulatory)	U.S. Environmental Protection Agency Significant New Alternatives (SNAP) Policy Program
Transitioning to Safer Chemicals: A Toolkit for Employers and Workers	U.S. Occupational Safety and Health Administration

All alternatives assessment frameworks identified share a common purpose, namely to identify safer alternatives based on a comparative assessment of hazard characteristics as well as technical and economic feasibility (Geiser *et al.* 2015; Jacobs *et al*. 2016). More recent frameworks include provisions for the comparative assessment of intrinsic exposure potential (i.e., without physical or administrative controls) and life cycle considerations.

Principles are available to better guide alternatives assessment practice given the myriad of the framework used, data gaps, and decision contexts

No two alternatives assessments are the same, and situations in which alternatives assessments are conducted can vary greatly, depending on country or region, or chemical or class of chemicals involved. The Commons Principles for Alternatives Assessment (MA TURI 2013) are a set of guiding principles meant to unify the practice of alternatives assessment. This set of principles, which was signed by over 100 orgnizations from academia and the NGO community to industry, aligns alternatives assessment practice across the myriad frameworks, political climates, and socio-economic challenges faced by the practitioners The Commons Principles are: reduce hazard; minimize exposure, use the best available information, require disclosure and transparency, resolve trade-offs, and take action.

Methods and tools for all components of the alternatives assessment are available, but the those for hazard assessment are the most developed

<u>Hazard assessment</u>

Hazard assessment is central to all alternative assessment frameworks. Broadly speaking, hazard assessment involves the evaluation of chemical alternatives based on their intrinsic hazard properties as compared to the chemical of concern. Most frameworks outline specific hazard endpoints to be considered. However, there is no standard set of endpoints and some frameworks are more general than others in terms of the endpoints required. Four general categories of hazard endpoints routinely addressed include: (1) physicochemical properties (i.e., persistence, flammability), (2) human toxicity (3) environmental/ecological toxicity, and (4) additional workplace hazards not captured in the aforementioned characteristics (such as ergonomic strain) (Jacobs *et al*. 2016).

Data and tools used to support hazard assessment can vary. Sources of hazard data/information most referenced in alternatives assessment frameworks include Material Safety Data Sheets (MSDS) or Safety Data Sheets (SDS), authoritative scientific lists (such as the International Agency for Research on Cancer's (IARC) list of carcinogens), regulatory or government priority chemical lists, publicly available substance databases or toxicity databases, and contact with manufacturers or the supply chain. These data are incorporated into comparative chemical evaluation tools, which are designed to explicitly compare alternatives relative to different hazard characteristics. Tools identified in Table 5 utilize a comparative ranking or categorization scheme to determine differences in the levels of severity among the hazard endpoints (e.g,. high, moderate, or low). Metrics for each of the ranks are based on specific data sources, ranging from continuous values (such as an LD_{50}), to presence on an authoritative list, or categorization based on specific decision logic, such as Globally Harmonized System of Classification and Labeling (GHS) classification criteria. GHS criteria and related testing methodologies from the Organization for Economic Cooperation and Development (OECD) are often used help to standardize the data used in the assessment process. Professional judgment is needed to evaluate the merits of specific toxicological studies reviewed in the assessment. Thus, assessments are typically performed by toxicologists or trained analysts. GreenScreen®, a hazard assessment method which is used by a number of government agencies and

companies, is accompanied by a program to certify assessors, including an auditing program to ensure consistency and quality (Clean Production Action 2017).

Data gaps (e.g., on chemical identity in a formulation, toxicity, end-of-life) are a persistent challenge for alternatives assessment (Tickner *et al.* 2018). However, rather than ignoring data gaps, some alternatives assessment methods make data gaps explicit or eliminate data-poor alternatives from consideration, which allows more transparent decisions and helps identify research needs. For example, the GreenScreen® hazard assessment method that is used in multiple alternatives assessment frameworks has a "data gap" classification for endpoints where there is insufficient information to assess the hazard (Clean Production Action 2017). This classification is considered in the overall gradings ("benchmarks" in the GreenScreen® method), often resulting in a lower overall score (i.e. more cautious about hazard). Some frameworks incorporate the use of novel data streams (such as high throughput or in-silico methods) to address data gaps.

As in risk assessment, transparency in the assumptions made and how data gaps are addressed is essential to alternatives assessment, allowing stakeholder discussion about the best means to address a particular chemical function. The iterative process and the continuous improvement nature of alternatives assessment require periodic updating of assessments as new information becomes available.

Table 5. Comparative Chemical Hazard Assessment Tools

Tool	Developer
GreenScreen® for Safer Chemicals	U.S.-based NGO Clean Production Action
Quick Chemical Assessment Tool (QCAT)	Washington State Department of Ecology
P2OASys	Massachusetts Toxics Use Reduction Institute
Column Model	German Institute for Occupational Safety and Health
Chemical Hazard Data Commons	U.S.-based NGO Healthy Building Network

Economic and technical feasibility assessment

For a chemical alternative to be successfully adopted by a manufacturer, it must be economically and technically feasible, which generally means that it performs as well or better than the existing chemical, and is economically viable.

All alternatives assessment frameworks identify the need for an economic assessment of the alternatives, yet not all include specific cost evaluation methods. Some include more holistic cost assessments that encompass a range of direct and tangible indirect production costs, rather than simply a comparison of the alternatives and the chemical of concern in terms of product or chemical purchase price.

Economic tools summarized in Table 5 were primarily developed by pollution prevention/cleaner production programs in the 1990s. These have not been updated for use in alternatives assessment, but remain useful given their focus on total cost assessment. Total cost assessment is: "the process of integrating environmental costs into a capital budgeting analysis and has been defined as the long-term, comprehensive financial analysis of the full range of private costs and savings of an investment" (US EPA 1995). The European Chemicals Agency has developed guidance on preparing a socio-economic analysis as part of an application for authorization under REACH (ECHA 2011b). This type of analysis is complex, requiring specialized expertise and therefore is difficult for small and medium sized businesses to conduct. California Department of Toxic Substance Control's (DTSC) Alternatives Analysis Guidance has put forth

comprehensive economic assessment requirements for evaluating alternatives (including external costs) as part of their the Safer Consumer Products (SCA) regulation. The SCA guidance states that: "The responsible entity shall evaluate, monetize, and compare for the relevant exposure pathways and life cycle segments the following impacts of the Priority Product and the alternatives: (1) Public health and environmental costs; and (2) costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife" (CA DTSC 2017). However, methods and tools to conduct this comprehensive economic assessment in an efficient manner are currently lacking.

Facility-specific knowledge is needed to conduct a meaningful technical assessment of alternatives. The Massachusetts officials have developed some guidelines for Toxics Use Reduction (TUR) Planners to use in assessing costs and technical feasibility (MA DEP 2018). In addition, the Interstate Chemicals Clearinghouse (IC2) Alternatives Assessment guide provides users with qualitative approaches for considering economic costs and technical feasibility (IC2 2017). Additional tools are outlined in Table 6.

Table 6. Economic and Technical Feasibility Tools

Tool	Developer
Toxics Use Reduction Act (TURA) Planners Guide, Section IVB8: Economic Assessment	Massachusetts Toxics Use Reduction Institute
Cost Calculator	U.S.-based: National Pollution Prevention Roundtable
Cost Analysis for Pollution Prevention	Washington State Department of Ecology
Financial Assessment of Pollution Prevention Investments	Northeast Waste Management Officials' Association (NEWMOA)
TRGS 600	German Institute for Occupational Safety and Health (BaUA)
Safer Consumer Product Analysis of Alternatives Guidance	California Department of Toxics Substances Control
Guidance on preparation of Socioeconomic analysis as part of an application for Authorization	European Chemicals Agency
Toxics Use Reduction Act (TURA) Planners Guide, Section IVB7: Technical Assessment	Massachusetts Toxics Use Reduction Institute

Comparative exposure assessment

Most alternatives assessment frameworks include a minimal evaluation of exposure (i.e., worker, public, and/or environmental). However, the U.S. National Academies of Science (NAS) alternatives assessment framework demonstrates an evolution in the consideration of exposure in alternatives assessment. Comparative exposure (between alternatives) is typically addressed by examining four categories of attributes: physicochemical properties, use characteristics, environmental release, and fate and transport. The NAS framework describes these and other physicochemical properties as intrinsic exposure properties (NRC 2014). The NAS framework differentiates its methods from risk assessment, suggesting that use of available exposure models or critical physicochemical properties is typically sufficient to determine the relative exposure potential of alternatives as compared to the chemical of concern (NRC 2014).

Currently there are no tools for available for comparative exposure considerations in alternatives assessment. However, new methods and tools are expected to emerge in the coming years (Tickner *et al.*

2018). One such example is a paper by Greggs *et al.* (2018) that develops a method for qualitative exposure assessment in an alternatives assessment context.

Life cycle considerations

Alternatives can have trade-offs beyond toxicity, including climate impact, material use, and resource implications. For example, the U.S. EPA has recommended consideration of climate impacts in chemical assessments (US EPA 2014). There are two dominant approaches for addressing life cycle impacts in an alternatives assessment: Life cycle thinking and partial or full life cycle assessment. Both follow the same general principle of more thoroughly considering impacts at different points in the chemical/product life cycle to avoid selecting alternatives that shift risks from one stage of a product life cycle to another. Life cycle assessment (LCA) follows a well-defined quantitative methodology, such as ISO 14040, that quantifies the impacts associated with a standardized set of environmental impacts (i.e., greenhouse gas emissions, resource depletion, energy consumption) of products or processes across their life stages. In contrast, life cycle thinking is less analytical and generally less resource-intensive than LCA. It identifies significant impacts at different life cycle stages but does not normally include quantitative assessment.

The California DTSC requires that LCA tools be taken into account in the evaluation of potential alternatives. Such an evaluation would first include identification of attributes of potential concern at the scoping stage or an assessment. It would then involve evaluating trade-offs and weighing the importance of different attributes (including toxicity, energy, and resource use) in determining the best alternatives (CA DTSC 2009; Sinsheimer 2010).

There are, however, a number of practical challenges related to the application of LCA in alternatives assessment. One challenge is that LCA can miss important toxicological trade-offs by focusing on average emissions through the lifeycle rather than on toxicity to specific vulnerable populations. It can also hide important manufacturing choices that are not inherent to the product – such as energy choices. Another challenge revolves around data gaps and best practices (Fantke and Ernsthoff 2018). Robust, sustainable, and credible use of LCA needs to avoid over-interpretation of results without proper consideration of gaps and limitations. More effective adaptation of LCA methods to alternatives assessment is an impotant research need (Finkbeiner *et al*. 2014). When conducting alternatives assessment, experts have recommended targeting those life cycle stages and impact categories that are comparatively different between the chemical of concern and alternatives being considered in order to streamline and target LCA needs in the assessment (Tickner *et al.* 2018).

Key needs to advance the utility of existing alternatives assessment frameworks, methods, and tools

Moving forward, consistent methods and data requirements will help support transferability of assessments from one region to another, as well as strengthen alternatives assessment as a preferred approach to addressing problem chemicals (Jacobs *et al.* 2016). However, as mentioned above, experts have noted that flexibility in the choice of an alternatives assessment framework is useful, as the context for substitution can vary greatly (Geiser *et al.* 2015). At an international level, governments and other stakeholders could establish clearer, more consistent criteria for safer chemicals and provide guidance on minimum and preferred components, attributes, and data to be included in an alternatives assessment. This would create a means to evaluate the comprehensiveness and quality of assessments.

The field of alternatives assessment is young, and a lack of best practices across regions can hinder global actions towards effective substitution (Tickner *et al.* 2018). As such, there is an urgent need for case

studies of alternatives assessment and informed substitution/adoption experiences in a variety of contexts (e.g., small business, agriculture, institutional settings and large manufacturing companies) to understand challenges and success factors, capacity building needs and best practices.

5. Landscape of Requirements for Substitution and Conducting Alternatives Assessment in International and National Policies

Government policies in the U.S., Europe, and Canada that restrict or require reduction or substitution of chemicals of concern date back to the 1950s. For example, the 1958 Food Additives Amendment to the U.S. Food, Drugs and Cosmetic Act included what is known as the Delaney Clause. The Delaney Clause stated that if a substance was found to cause cancer in humans or animals, then it could not be used as a food additive. In 1976, the European Union (EU) Limitations Directive authorized the E.U. to restrict or ban chemicals of concern across Member States. In 1977, the Great Lakes Water Quality Agreement called for 'the virtual elimination' of discharges of persistent and bio-accumulative chemicals in the Great Lakes Basin of the U.S. and Canada (Canadian Environmental Protection Act 1999). The strategy behind such policies is that the most effective way to address chemical risks is not through exposure controls, but through the elimination of the chemical. While these restrictive chemical policies marked important steps forward in recognizing substitution as important chemical management, public health and environmental protection strategy, such policies were largely silent on the issue of what should replace the chemical of concern or how alternatives should be evaluated.

International Treaties

The 1987 Montreal Protocol on Substances that Deplete the Ozone Layer was the first international treaty to specifically recognize the importance of alternatives assessment in chemical management strategies. The Protocol includes provisions that both restrict the use of ozone depleting chemicals and outlines systems for the evaluation of their alternatives. All parties have to elaborate their strategies and plans to comply with the provisions, targets and timetables of the Protocol, while finding and making available safer alternatives. The protocol lacks detailed guidance on the assessment of alternatives/substitution process, but the Montreal Protocol Technology and Economic Assessment Panel addresses issues concerning alternatives, including technical and economic feasibility (UNEP Ozone Secretariat 2018).

The Stockholm Convention on Persistent Organic Pollutants (POPs) is another global treaty that provides specific details regarding how alternatives should be evaluated. The treaty establishes the requirement to use substitute or modified materials, products, and processes to prevent the formation and release of POPs. The Persistent Organic Pollutants Review Committee is charged with conducting risk management evaluations of substances, which includes an evaluation of alternatives. A detailed guidance on steps for the alternatives assessment process under the Stockholm Convention was developed (UNEP 2009). The guidance ncludes broad considerations of hazards, economic feasibility, exposure considerations including use characteristics, emissions and environmental fate, and other socioeconomic factors.

Several additional treaties include substitution requirements to meet treat goals, but do not include details about how the alternatives should be evaluated to avoid regrettable substitutes.

- The Minamata Convention includes provisions for maintaining information on mercury-free alternatives that consider environmental health and safety, cost and technical feasibility, but does not explicitly specify a substitution process or process for the assessment of alternatives (UNEP 2017).

- The Rotterdam Convention outlines the opportunity to take informed risk-based decisions supported by measures to facilitate information exchange regarding hazardous chemicals,

including information on safer alternatives and information on alternatives and their relative risks (UNEP 2011).

- The Aarhus Protocols on heavy metals and POPs, Considers substitution as a primary measure to achieve its goals and targets of controlling emissions of heavy metals of concern (i.e., cadmium, lead, and mercury) and POPs (UNECE 1998a, UNECE 1998b).

Implementation of international treaties drives national program attention to substitution as a chemicals management option, as outlined for example in national implementation plans for the Stockholm Convention (UNEP 2018a).

National and State Policies

A number of regulatory and non-regulatory policies and programs on informed substitution and alternatives assessment exist in Europe and its Member States, the U.S. and its states, and Canada. Specific substitution policies and programs are less common in other countries. For example, the Canadian government is currently exploring how to incorporate alternatives assessment and informed substitution requirements into its post-2020 Chemicals Management Plan and revisions to the Canadian Environmental Protection Act (Government of Canada, 2018)

Policies with specific alternatives assessment requirements

Currently, the E.U. offers the only examples of national policies that include provisions to conduct alternatives assessments as part of substitution requirements. The Registration, Evaluation, and Authorization of Chemicals (REACH) regulation requires companies to seek authorization to continue use of a Substance of Very High Concern (SVHC) (European Parliament and Council 2006). SVHCs include substances with hazard profiles that are classified as carcinogenic, mutagenic or reproductive toxicants (CMRs); persistent, bioaccumulative and toxic (PBTs); or have effects of "equivalent concern", which can include endocrine disruption and neurotoxicity. SVHCs that are subject to authorization require an alternatives assessment (called analysis of alternatives) to ensure that these highly hazardous substances are progressively replaced by safer alternative substances or technologies where economically and technically feasible. To obtain authorization, companies must demonstrate lack of feasibility of alternatives or adequate control in their analysis. Also under REACH, Member State authorities use alternatives assessment in their proposals to restrict SVHCs. These proposals include detailed characterizations of the risk posed by the SVHCs and require examining the availability of safer, feasible alternatives for specific functions/applications to make a determination as to whether specific uses that lack alternatives should be excluded from the proposal.

For both the authorization process and restrictions, The European Chemicals Agency (ECHA) has developed guidance documents outlining the information that must be incorporated into alternatives assessments, including assessments of technical feasibility, economic feasibility and risk (ECHA 2007, ECHA 2011).

The E.U. Biocides Directive requires a similar process to SVHC authorization, but for biocides and pesticides. However, the authorization process for the Biocides Directive is proactive in nature – required to put a product on the market, not to defend its continued use as is the case under REACH. The Directive prohibits CMRs, sensitizers and bioacumulative chemicals from use as active ingredients in biocidal products. Active ingredients in biocidal products identified as candidates for substitution are subject to a

comparative assessment of alternatives at the time of their authorization if safer, feasible products are available, the Directive states that the biocidal product shall not be authorized (European Commission 1998).

Other than the E.U., the U.S. state of California's Safer Consumer Products Regulation also has requirements for alternatives assessments (CA Code of Regulations 2013). Companies must undertake alternatives assessments (called alternatives analysis in the regulation) for Priority Products containing Chemicals of Concern, after which the state's Department of Toxic Substances Control (DTSC) may impose regulatory restrictions. While no alternatives analysis has been conducted under the law as of 2018, DTSC's draft guidance for the alternatives assessment process indicates that the regulation will require a more comprehensive alternatives assessment than any other policy to date. Similar to REACH, the state of Oregon is establishing rules that will require alternatives assessment for the continued use of substances of high concern in children's products (Oregon Health Authority 2018).

Substitution requirements in classification-based policies

Several European Commission (EC) directives (occupational health and consumer) on chemicals draw from European and now Globally Harmonized System of Classification and Labeling (GHS) classifications particularly for CMRs, and require evaluation of alternatives for continued use of such substances. For example, two directives focused on workplace chemical exposures – the EC Chemical Agents Directive and the EC Carcinogens and Mutagens Directive – include substitution with safer alternatives as the most protective measure at the top of a hierarchy of chemical risk reduction measures (Council Directive 1998, 2004) . These directives are codified in the legislation of EU Member States and each has the authority to develop more detailed guidance and requirements in response to these directives. While the concept of substitution is not directly addressed in harmonized classification and labeling, hazard classifications are directly linked to chemical restrictions and substitution provisions in EU policy and many Member State regulations and provide a strong incentive to industry for substitution.

Requirements for the use of safer alternatives in procurement

Governments have the ability to significantly influence the market place given their large-scale purchasing power (LCSP 2015). Some state and federal executive orders and legislation in the U.S. and policies in other countries require that government agencies "lead by example" regarding the purchase of products that contain the least toxic chemicals/products in specific product classes. These programs tend to focus on particular product categories (e.g., janitorial cleaning products) and single chemicals or classes. However some entities have issued purchasing restrictions for products containing persistent, bioaccumulative and toxic (PBT) chemicals.

Single or multiple chemical restrictions with alternatives assessment requirements

Countries in the EU, U.S., states and elsewhere in the world have issued single and multiple chemical restrictions. Yet these policies most often do not require any evaluation of substitutes. For examples, several EU Member States launced activities in the late 1990s that restricted chemicals and classes of concern through chemicals policies and the use of action plans. At the EU level, the Restrictions on Hazardous Substances (RoHS) regulation and Volatile Organic Compounds (VOC) directives require substitution for particular chemicals, chemical and product types. Legislation modeled on RoHS is now found in other countries, including China, Japan and Korea. In the past ten years, several U.S. states have

passed single chemical restrictions on a number of chemicals of concern (e.g., phthalates, flame retardants, mercury, bisphenol A among others).

More recent state-level legislation in the U.S., such as the state of Washingon's Children's Safe Products Act (Wash RCW 2008) and the state of Minnesota's Toxic Free Kids Act require prioritization of chemicals of concern to children, reporting use of those chemicals in children's products, and for the state agency to evaluate alternatives for such chemicals to demonstrate availability or lack of alternatives and to avoid regrettable substitutions (Minn Stat 2010). In 2018, the state of Washington passed a law to ban the use of perfluorinated chemicals in food packaging should the state's alternatives assessment identify safer substitutes (Wash RCW 2018).

Pollution prevention planning

Several U.S. states and the province of Ontario in Canada have laws requiring materials accounting and toxics use reduction planning for chemicals of concern. These laws generally require manufacturing firms to characterize chemicals used and evaluate alternatives to reduce or eliminate toxics use and waste. Under its Toxics Use Reduction Act, the State of Massachusetts has developed guidance, tools, training, and technical support to assist firms in achieving toxics use reduction, including approaches that adopt safer and feasible alternatives, including specific guidance on the use of alternatives assessment. China is also using its law on Promoting Clean Production to promote research, fiscal and administrative measures to advance substitution strategies.

Non-regulatory policies and programs

Non-regulatory programs can deliver important incentives, guidance, and direction to support informed substitution and alternatives assessment efforts at the firm-level. These programs are most effective when supplemented with a regulatory or market driver (Ashford 2013).

A number of voluntary government initiatives have focused on conducting alternatives assessments for chemicals of concern, such as the U.S. EPA's (2018) Safer Choice Program (formerly the U.S. EPA Design for the Environment program). These alternatives assessments include informed options by firms seeking to voluntarily replace chemicals of concern with safer substitutes in response to consumer demands as well as non-federal regulatory drivers. The Safer Choice program's current efforts focus on stimulating market demand for safer chemicals by recognizing preferred products with its Safer Choice label and promoting the adoption of safer chemistries for specific functional uses through its Safer Chemical Ingredient list (SCIL) (U.S. EPA 2018a). To achieve the label, ingredients are evaluated by a third-party certifier using stringent human health and environmental criteria. Similar in concept to US EPA's SCIL, China's Ministry of Industry and Information Technology has created the Catalogue of Encouraged Substitutes to Toxic and Hazardous Raw Materials. The catalogue identifies recommended chemicals that can serve as alternatives to hazardous chemicals. Although the list is not legally binding, companies that comply may benefit from lower taxes or other incentives. Additional voluntary government initiatives include alternatives assessments conducted by the U.S. state of Massachusetts Toxics Use Reduction Institute and the Toolkit to Guide the Transition to Safer Chemicals and training modules for industry to implement the toolkit developed by the U.S Occupational Safety and Health Administration (U.S. OSHA 2014).

Table 7. Regulatory actions and non-regulatory programs with alternatives assessment or substitution provisions (Tickner et al. 2013; SUBSPORT 2018)

Regulatory actions	Alternatives assessment-specific regulatory provisions – European Commission's 2006 Registration, Evaluation, Authorisation and Restriction of Chemicals – EU Biocidal Products Regulation [(EU)528/2012] Classification-based substitution requirements – European Commission's 2004 Carcinogens or Mutagens at Work Directive – European Commission's 2008 Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation) Requirements for use of safer alternatives in procurement – US Federal Executive Order 13514, 2009 Federal Leadership in Environmental, Energy, and Economic Performance Single or multiple chemical restrictions with alternatives assessment requirements – China's 2006 Management Methods for Controlling Pollution Caused by Electronic Information Products Regulation – European Commission's 2002 Restriction of Hazardous Substances Directive – Japan's 1991 Law for Promotion of Effective Utilization of Resources in Japan and 2008 mandatory industry standard JIS C 0950 the marking for presence of the specific chemical substances for electrical and electronic equipment – Republic of Korea's 2007 Act for Resource Recycling of Electrical and Electronic Equipment and Vehicles (known as Korea RoHS) – Norwegian Environmental Agency's 1976 Norwegian Product Control Act, Section 3A Pollution prevention – China's 2002 Law of the People's Republic of China on the Promotion of Clean Production – European Commission's 2008 Integrated Pollution Prevention Control Directive – European Commission's 2000 End-of-Life Vehicles Directive
Non-regulatory programmes	– China's State Recommended Catalogue of Alternatives Materials for Toxic and Hazardous Substances and Products – European Commission's DG Environment's Non-Toxic Environment Initiative – 7th Environmental Action Programme – Swedish Chemicals Agency (KEMI) Environmental Quality Objectives, "A Non-Toxic Environment" – U.S. EPA Safer Choice Program – U.S. OSHA Transitioning to Safer Chemicals

A mix of policy tools is needed to support informed substitution efforts

Although many firms may undertake chemical substitutions in response to regulations, technical or institutional barriers can inhibit the adoption of safer technologies. Experience suggests that a multi-pronged approach of incentives and disincentives is needed to achieve the goals of informed substitution (Tickner and Jacobs 2016). This approach includes requirements for alternatives assessment for chemicals of concern, as well as support structures that facilitate the adoption of safer alternatives. Regulation is necessary, but insufficient on its own to drive informed substitution and the use of alternatives assessment (Tickner *et al.* 2013; Ashford 2013). Regulations that restrict the use or trade of certain chemicals, or make those chemicals unacceptable in the marketplace, can lead to chemical de-selection (eliminating the chemical from a product or process without consideration of alternatives). The right mix of regulatory and non-regulatory (supportive) policies is essential to support innovation and substitution (Box 3).

Box 3: The mix of regulatory and non-regulatory policies to support informed substitution (source: Ashford, 2013)

Regulatory:

- restrictions/limits on chemicals and chemical classes of concern
- requirements for alternatives assessment with clear guidance and enforcement
- information collection requirements – on chemical toxicity, uses/functions, and classification

Supportive:

- training for government and industry on alternatives assessment processes and informed substitution
- technical support networks and funding for evaluation/testing of alternatives and adoption support
- databases of alternatives, chemical toxicity
- demonstration sites, supply chain convening, and case examples of successful implementation
- Recognition of safer substitutes

Past evaluations suggest that institutional capacity within firms to more effectively evaluate and adopt safer alternatives to hazardous chemicals can be enhanced through incentives-based government initiatives that include research and evaluation support, guidance, information on alternatives, demonstration projects, technical assistance, databases, training, and assistance for supply chain networking of firms (Ashford 2013; Tickner and Jacobs 2016). For example, experience in the U.S. shows that toxics use reduction policies that promote substitution are more effective when supplemented with technical support structures to facilitate adoption (Box 4). Allowing companies degrees of flexibility in how they evaluate and adopt alternatives may lead to better outcomes and, therefore, more substitution. If incentive-based approaches are not successful in achieving stakeholder buy-in and cooperation, then regulatory frameworks can be explored and implemented.

Box 4: The importance of policies that include technical support structures: chlorinated solvent substitution (source: Jacobs et al. 2014; MA TURI 2017, Office of Technical Assistance and Technology 2015)

Trichlorethylene (TCE) is a commonly used chlorinated solvent that is a probable carcinogen and one of the most common contaminants found in hazardous waste sites in the United States. In the State of Massachusetts, under the Toxics Use Reduction Act, companies using listed toxic substances are required to annually quantify the use and emissions/waste of these chemicals and conduct an assessment of alternatives to reduce the use of the chemical every two years. With technical and research support from the Massachusetts Toxics Use Reduction Institute (TURI), funded by a small fee on chemicals, manufacturers using TCE in degreasing metal parts and other applications were able to evaluate and implement safer, water-based alternatives, reducing use of this chemical by some 95% in the state and saving companies money.

The TCE case in Massachusetts demonstrates the critical importance of research and technical support in overcoming technical barriers to substitution. To avoid potentially problematic solvent substitutes, a functional substitution approach to solvents as a class would be helpful.

6. Summary of Program and Policy-Relevant Insights and Options for Action

Opportunities to advance the use of alternatives assessment to inform a transition to safer chemicals requires actions by a variety of societal actors, including government, industry and academic scientific communities.

Roles and options for action among government, industry and the scientific community

Government has an important role to play in establishing the mandates for alternatives assessment and substitution, including: developing criteria for chemicals and materials to avoid in substitution processes (e.g., less-safe and safer chemicals), establishing clear guidance and requirements for the alternatives assessment process, and developing metrics to monitor the substitution process and enforcement for non-compliance. Governments can also establish non-regulatory mechanisms that help achieve program goals and accountability. This can be accomplished by providing actionable data on hazard and exposure trade-offs to inform alternatives assessment, giving guidance, technical and research support, and providing incentives for substitution. In addition, providing clear, consistent signals to the marketplace and convening societal stakeholders ensures not only that that early substitution actions can take place but also that substitutions make sense for the people that are to implement them.

There may be instances where government-conducted alternatives assessments can support industry actions (e.g,. in the case of priority chemicals or sectors where there is societal demand for policy changes, or existing debate around the availability of alternatives for a particular substance). For example, US EPA's Design for Environment Program (currently known as U.S. EPA Safer Choice Program) undertook alternatives assessments for several high-profile chemicals and applications, such as various flame retardant (U.S. EPA 2018). The assessments required significant time, resources and stakeholder engagement. This experience suggests that while only a small number of such government-led assessments could be undertaken, they might have a large impact in driving the transition to safer alternatives by providing baseline analysis to inform industry decision-making.

Given the variety of approaches that countries and businesses have used to implement alternatives assessment, a growing amount of expertise and experience is being generated from past and present alternatives assessments and substitution cases. The field of alternatives assessment is young, and a lack of best practices across regions can hinder global actions towards effective substitution (Tickner *et al.* 2018). Governments can play an important role in establishing systematic efforts to collect and compile relevant case examples and lessons learned that can serve as a critical source of knowledge to identify and address common challenges, identify and share good practices and success stories, and make the business case for substitution. At an international level, governments and other stakeholders could establish clearer, more consistent criteria for safer chemicals and provide guidance on minimum and preferred components and attributes to be included in an alternatives assessment. This would create a means to evaluate the comprehensiveness and quality of assessments.

During the assessment process, capacity building and greater coordination among stakeholders would help build the consistent application of alternatives assessment globally and to maintain some degree of flexibility in the methods used to support different substitution contexts. Capacity building programmes, such as the United Nations Industrial Development Organization (UNIDO) and UNEP Environment National Cleaner Production Centres and Networks), which can enhance working knowledge of alternatives assessment and substitution, are available to all interested parties (UNIDO/UNEP 2018). Stakeholder

engagement is equally important in some contexts in understanding the availability and functionality of the range of alternatives which can be used, depending on the specific circumstances (Box 5).

Box 5. Substitution of methyl bromide: the importance of having a range of alternatives and stakeholder engagement (source: UNEP 2014)

Under the Montreal Protocol there has been a global phase-out of the use of methyl bromide (MeBr), a powerful ozone depletor and human health toxicant linked to prostate and other cancers. For decades methyl bromide was the preferred soil fumigant for controlling a range of pests and pathogens in soil, among other uses. The search for suitable alternatives revealed that no single alternative was effective for all uses. Identification of alternatives needed to be addressed on a case-by-case basis, depending on the specific needs of the end user, regional or climactic differences and economic feasibility. In many cases a combination of different alternatives, including chemical pesticides and non-chemical options such as steam sterilization and integrated pest management techniques, was identified as the best approach for substitution.

There is a need for support and enforcement structures to accompany substitution programs. Many alternatives to the use of methyl bromide, such as integrative pest management (IPM), are knowledge intensive. They require a broad understanding of alternative agricultural practices, as well as access to information on technological developments and improved farming techniques. Engagement and training of stakeholders, the provision of technical assistance, and adaption of alternative technologies to local conditions, are therefore crucial to successful substitution.

See Annex 2 for more details

Developing countries and countries with economies in transition are confronted by several barriers with respect to supporting the informed substitution of chemicals. Even when initiatives to implement substitution requirements in international treaties are in place, there are often limited resources to collect and properly dispose of the toxic materials that were replaced. Technical resources to evaluate chemical hazards or to identify alternatives and enforce substitution requirements under international treaties, are also limited. To remove these barriers, there is a need for technical support, capacity building and case examples of successful substitutions (UNEP and WHO 2014; UNEP 2014) (Box 6). This does not mean that informed substitution cannot and does not happen in developing countries. However, it often requires collaboration between research institutions, governments, employers, and international agencies to address gaps in capacity and information. Thus, evaluating both successful and unsuccessful substitutions, and factors that lead to success or failure, and making the results publicly available, are critical to ensure effective informed substitution and improve capacity in developing countries and those with economies in transition (IFCS 2008). New international efforts, such as the International Sustainable Chemistry Collaborative Centre (ISC3) can provide critical infrastructure to build substitution capacity in developing countries.

The private sector has a critical role to play in building capacity for informed substitution in developing countries and countries with economies in transition. This includes requirements instituted by multinational companies engaged in manufacturing in developing countries that suppliers implement appropriate, sustainable substitution policies. These companies also need to provide technical support to regional companies and government agencies so they can undertake similar activities. Start-up companies can also play an important role in developing safer substitutes in developing countries, as many of them are associated with university research resources. Strong chemicals management foundations in developing countries remain a priority and can contribute to the success of substitution programmes.

Within industry, experience indicates that companies using chemicals that are subject to alternatives assessment requirements are often best situated to evaluate alternatives that would work for their particular applications. Companies should be responsible for understanding the chemicals they are using (function/uses, toxicity, potential exposures); establishing processes to systematically and thoughtfully evaluate and adopt alternatives, involving workers, communities, and supply chain stakeholders as necessary; evaluating implementation for potential trade-offs and improvement opportunities; and transparently presenting results and decisions. Companies may have to reach out to their supply chains to better understand ingredients in an article or formulation and use conditions.

Box 6. Mercury-free hospitals: the importance of participatory substitution programmes and alternative technology replacements (source: Burgos-Hernandez 2009; World Medical Association 2018)

Mercury is a persistent, bioaccumulative and toxic chemical. Its global phase-out is covered under the 2013 Minamata Convention (www.mercuryconvention.org), which bans new mercury mining and calls for increased controls of mercury emissions and phasing out of mercury use in many products and processes. Hospital use of mercury-containing products is significant. The World Medical Association (WMA) has urged regional and national medical associations to work within their institutions to reduce their mercury use.

In 2009 a joint project led by the University of Massachusetts Lowell, in the United States, implemented mercury replacement programmes in hospitals in Mexico and Ecuador. This programme used a participatory format that vertically engaged and trained all stakeholders on the dangers of mercury. Working groups in each hospital identified mercury thermometers, which are made of glass and easily break, and mercury sphygmomanometers (blood pressure cuffs which must be filled manually with liquid mercury) as significant sources of exposure and ideal candidates for replacement. Mercury thermometers were replaced with digital fever thermometers, and mercury sphygmomanometers were replaced with aneroid sphygmomanometers which use pressurized air.

These replacements illustrate the importance of technology substitutions, where equipment that uses a toxic chemical is replaced with a non-chemical option. Relying on hospital staff to identify problem areas and implement solutions resulted in greater ownership of preventative practices, strengthened networks, and provided a structure for continued training efforts.

See Annex 3 for more details

Stakeholder engagement and collaboration are critical to address gaps in alternatives assessment methods and support the ultimate adoption of safer alternatives. Engaging stakeholders inside and outside of the firm can lead to a more successful implementation of safer substitutions (European Commission 2017). For example, workers often have important information on a production process or potential exposures. They are also the ones who will be implementing an alternative (which may include changes in work processes). Adoption will be more effective if those using an alternative are involved. Actors along the supply chain, from chemical suppliers to product manufacturers to retailers, can share important information on customer needs, options that might be available and how an alternative might impact product quality, as well as information that would help to understand potential trade-offs. Stakeholder engagement helps ensure critical questions are asked during the assessment process to ensure the assessment is sufficiently complete and that implementation of substitutes occurs in an efficient manner, guaranteeing greater adoption.

The academic community can focus research on critical alternatives assessment and substitution needs, including: development of methods and data to more rapidly evaluate chemical hazards, compare

exposure trade-offs, make informed multi-criteria decisions and compare chemical and non-chemical alterantives. Academic research on safer chemicals, materials, manufacturing processes, and practices can be better linked to government and scientific substitution priorities. Academic institutions can be more proactive in delivering multi-disciplinary education of chemists, engineers, and health scientists so that future professionals understand how to integrate substitution thinking into design and investigation. There is a need to strengthen the accessibility of actionable data for substitution. For example, existing toxicology and other datasets of information on chemical functions, hazards, potential exposures, and life cycle impacts need to be made more applicable to alternatives assessment and substitution. In addition, there is the need to enhance the utility of existing tools and toolboxes for conducting alternatives assessment (in addition to databases of information on alternatives and case studies) by including additional sectors, chemical uses and regional needs.

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Annex 1. Alternatives for the progressive phasing-out of Endosulfan: The case of Cuba

Nilda Pérez[1] and Fernando Bejarano[2]

Introduction

Endosulfan is a broad spectrum, organochlorine insecticide employed for controlling insects and mites. In use since the 1950s, it has been employed on a global scale for vegetable and fruit crops as well as for cucurbits, roots and tubers, beans and soy, fruit trees, vineyards, cereals, coffee, tea and cacao, tobacco, ornamental and cut flowers, cotton, and forests. It is used mainly to control insects such as lepidoptera (moths and butterflies), hemiptera (bedbugs, whiteflies, leafhoppers, coccids, pseudococids, aphids), coleoptera (chrysomelids, scarabaeidae), and thysanoptera (thrips), as well as phytophagous mites.

Problem statement

Endosulfan poses risks to human and animal health and to the environment. It causes poisonings that can prove fatal; it accumulates in the fatty tissues of humans and animals and in breast milk; it is stored in food webs; it is an endocrine disruptor; it produces alterations in nervous systems, the skin, and other organs. It accumulates in a broad array of matrices. Endosulfan is included in Annex A (Elimination) of the Stockholm Convention on Persistent Organic Pollutants, in the Rotterdam Convention on Prior Informed Consent [3], and is considered a Highly Hazardous Pesticide under FAO-WHO and PAN International[4] criteria.

Substitution process used

Endosulfan ceased appearing in the phytosanitary strategies planned by Cuba's Plant Health Department since the 2010-2011 campaign. It is being replaced in controlling Coffee borer beetle; lepidoptera larvae and thrips in garlic and onion; lepidoptera larvae, chrysomelids, whitefly, and leafhoppers in cucurbits, beans, potatoes, peppers, tobacco and tomatoes; and furling lepidoptera larvae, leaf-miner flies, and coleoptera defoliators in forests.

General precautionary measures are proposed for managing the above-mentioned harmful organisms such as the planting of corn, millet or sunflower barriers; taking into account the geographical proximity to crops susceptible to the same pests; adjusting plantings to the optimum date; and applying the established pest signaling methodologies. Another measure, regardless of the organism in question, is the identification of populations of natural enemies, both predators as well as parasitoids and entomopathogens.

To illustrate how the alternatives are implemented, control of Thrips palmi in potato cultivation is provided as an example. The first task is to verify the presence of natural enemies, especially the predatory insects Orius insidiosus, coccinellids, and chrysopids, among others, and predatory mites. Based on this knowledge, the following measures are proposed, which could include beginning treatments with entomopathogenic bacterium Bacillus thuringiensis strain 13, and entomopathogenic fungi Beauveria

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[3]FAO-UNEP (2011) ENDOSULFAN decision guidance document. Rotterdam Convention. Application of Prior Informed Consent for banned or severely restricted chemical products, October 2011
[4] PAN (2016) PAN International List of Highly Hazardous Pesticides. http://www.pan-international.org

bassiana, Metarhizium anisopliae, and Lecanicillium lecanii. Only when the population, at any stage, exceeds 10 individuals per leaf, the population density of natural enemies is unfavorable, and the plantation is physiologically active will the insecticides diafentiuron or spirotetramat be employed, always taking into account that to protect against natural enemies, the treatments will be directed only to the parts in which the application rate has been reached, and therefore untreated areas will also remain.

Identification and prioritization of substitutes

The phasing-out of pesticides is a priority of the Cuban government and is part of national agro-environmental policy. [5] Since the creation of Territorial Plant Protection Stations in 1974, the phytosanitary strategies for each crop and planting season are decided in accordance with national planning that is adjusted on a territorial basis taking into account the conditions of each region. Today phytosanitary protection is integrated into environmental policy. The National 2016-2020 Biological Diversity Program had adapted the 20 Aichi Targets and proposes in Target 5 that "Areas allocated for agriculture and forestry are to be sustainably managed, based on the effective application of territorial and legal dispositions" and in Action F it pledges to "develop actions that contribute to integrated agroecological pest management".[6]

Implementation of alternatives

Lessons learned

A key lesson is that substitution is a gradual process that takes time. The identification and evaluation of alternatives cannot be improvised and requires preparation. It takes time to research and investigate possible alternatives, and for innovation, implementation, and adoption of new technologies and training technicians and farmers. In the case of Cuba, the National Program for the Production of Biological Agents ("Medios Biológicos") was approved in 1988, and the construction of a network of biological control laboratories began on a nationwide level. It has been the basis, albeit not the only one, for the phase-out programs in the use of some pesticides and their elimination in the case of others. Today Cuba has extensive experience in the artisan production and use of biological control agents, including insects and entomophagous mites (predators and parasitoids); fungi, bacteria, and entomopathogenic nematodes; and antagonist fungi.

Cuban specialists learned that substitution cannot be based on a single alternative. In the agroecological approach, eliminating the use of a pesticide cannot be seen as a simple substitution of inputs. In other words, the idea is not "to remove one chemical to replace it with another chemical of lower risk or to apply a biological agent". The implementation of this approach allowed for the withdrawal of endosulfan from the Official List of Authorized Pesticides, and the decrease in the use of other chemical pesticides. The aim was to introduce changes in the management of agroecosystems that would guarantee the success of the substitution program and the movement over time toward sustainability in pest management.

As a result of the phasing-out of the use of pesticides and other changes in agroecosystems management,

[5] Febles González JM (2016) Análisis y diagnóstico de políticas agroambientales en Cuba. Fortalecimiento de las políticas agroambientales en los países de América Latina y el Caribe, Proyecto GCP/RLA/195/BRA. FAO, Havana: 74 pp.

[6] CITMA (2016) *Cuba. Metas nacionales para la diversidad biológica 2016-2020*. Proyecto PNUD/GEF «Plan Nacional de Diversidad Biológica para apoyar la implementación del Plan Estratégico del CDB 2011-2020 en la República de Cuba». Ministry of Science, Technology, and Environment, Havana, Cuba

technicians and farmers perceived an increase in the populations of natural enemies and a notable reduction in the rates of pest infestation along with a decrease in the frequency of the appearance of new outbreaks. This perception is an indication that current Cuban agroecosystems are healthier and more resilient.[7]

Among the most important lessons learned is that a large part of the success can be attributed to the integration of the sectors interested in pest substitution and training and extension programs.
Another lesson is that the idea of the need to adopt a systemic approach to the problem of pests was confirmed and strengthened. This systemic approach is part of the science of agroecology. To achieve success in the construction of an ecological agri-food system, thoroughgoing changes must be introduced in the design of the farms. The new designs have to be based on the principles that enable the components of biological diversity to function and build resilience.

Accumulated experience allows us to ponder the lessons learned. There are many questions that must be answered and what is being done needs to be improved. In this and other substitution processes, the need to increase the articulation between biological control and agroecological pest management practices became clear, since their greatest contribution is the conservation of natural enemies. It is necessary to continue perfecting the production of biological control agents and to seek ways that would allow for strengthening the conservation of natural enemies. Research in biological control should put the emphasis on this strategy, which up until now has received less attention. Furthermore, the interactions between cultivation-weeds-harmful organisms should be further studied, because very little is known in the country on the role played by weeds in the conservation of natural enemies as well as in pest proliferation. Research must also be continued with products of botanical origin, and the use of those most studied, such as paradise (Melia azedarach) and neem (Azadirachta indica) needs to be extended. In addition, the potential of Tagetes sp. must be considered, since little attention has been paid to it thus far and the cultivation and small-scale use of plants with pesticidal properties should be increased.

Conclusion

Endosulfan substitution is technically and economically feasible, taking into account principles involving the conservation and bioregulatory function of natural enemies. This is in addition to the use of biological control agents -produced locally- along with the application of cultural control practices; the use of botanical extracts and other agroecological alternatives and finally, the focused application of other chemical insecticides. Also of importance is training, laboratory support, and the participation of all sectors interested in eliminating the use of endosulfan based on territorial planning and coordination with clear objectives.

[7] Pérez N (2010) Alternativas al uso de plaguicidas. Revista Virtual REDESMA (Environment and Sustainable Development Network) Available at: http://www.revistavirtual.redesma.org.

Annex 2. Phasing out Methyl Bromide in Developing Countries (from UNEP report, 2014)

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Introduction

Methyl bromide (MeBr) is a broad-spectrum fumigant used for pest and disease control in a wide range of applications. It has been used globally as a chemical of choice to eradicate everything from weeds to nematodes, rodents, and insects. MeBr is also a powerful ozone depleting substance (ODS). It was brought under the control of the Montreal Protocol, an international effort to help stem the depletion of the ozone layer, in 1992[1].

Background

MeBr was introduced to farmers in the 1970s and became a preferred agent for controlling soil-borne pests, diseases, and weeds, particularly in high-value crops like strawberries, tomatoes, peppers, cut flowers, and tobacco. MeBr is also used for quarantine and pre-shipment treatment (QPS) to prevent the transfer of non-native pests to other countries[2].

Problem statement

In addition to being an effective pesticide, MeBr is also a powerful ozone depleter and is highly toxic to human health[3]. A 1997 amendment to the Montreal Protocol included a phase out of MeBr in developed and developing countries by 2005 and 2015, respectively. However, because the Montreal Protocol does not include all applications of MeBr, including use of of MeBr for QPS. Additionally, countries can apply for special permits to use MeBr under Critical Use Exemptions (CUEs). To date, there is a significant amount of MeBr that has been used under these exemptions. For example, Pesticide Action Network (PAN) – Europe reported that the amount of MeBr used in 2005 under critical use exemptions was more than 4,000 tonnes, equal to almost 30% of registered consumption of MeBr in 1993[4].

Substitution process used

Two, broad categories of substitution have been used to replace MeBr: In-kind substitutions, which replace MeBr with another fumigant producing similar effects, (i.e., dicholoropropene) and not-in-kind substitutions, which replace MeBr with a non-chemical alternative, such as a change in process or engineering (i.e., using heat treatment or hermetic storage). Whatever the methodology, a substitution process needs to consider economic and political feasibility as well as an educational component and stakeholder engagement to encourage adoption of the alternative.

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[1] United States Envrionmental Protection Agency (USEPA). International Treaties and Cooperation about the Protection of the Stratospheric Ozone Layer. https://www.epa.gov/ozone-layer-protection/international-treaties-and-cooperation-about-protection-stratospheric-ozone. Accessed 12/28/2018.

[2] United Nations Environmental Program (UNEP). 2014. Phasing-out Methyl Bromide in Developing Countries: A success story and its challenges.

[3] USEPA. 2016. Methyl Bromide (Bromomethane): 74-83-9. https://www.epa.gov/sites/production/files/2016-09/documents/methyl-bromide.pdf

[4] Pesticide Action Network Europe (PAN-Europe). Briefing no. 4: Methyl Bromide – Phase out and alternatives. https://www.pan-europe.info/old/Archive/publications/MethylBromide.htm. Accessed 12/28/2018.

Identification and prioritization of substitutions

Identification of alternatives to MeBr was typically handled on a case-by-case basis, and considered specific needs of the end user, regional or climactic differences, and economic feasibility of the alternative. In many cases, a combination of different alternatives was identified as the best approach for substitution.

Implementation of alternatives:Lessons learned

The phase-out of MeBr has been important in raising awareness of the depletion of the ozone layer and what steps need to be taken to help protect it. Because of the focus on farming, the program has also contributed to an increase in knowledge of alternative farming practices, including improvement on pest management practices and production techniques[5].

Key factors in the success of programs to replace MeBr were political willingness to implement alternatives as well as ability for local economies to sustain the impact of a shift in pest management practices. Training key stakeholders was also key to the success of MeBr substitution programs. Many alternatives to MeBr, such as integrative pest management (IPM) are knowledge intensive and require a broad understanding of alternative farming practices as well as having access to information on new developments and improved techniques.

Many challenges facing MeBr substitution programs exist at the community level, including decreasing the knowledge gap, changing consumer preferences, implementing regulatory factors, and ensuring that potential alternatives are commercially available and economically and technically comparable to how MeBr has been used in specific areas. Adaptation of alternative technologies to local conditions is crucial to the success of the alternative(s).

Because MeBr is still used in QPS, an application not covered under the Montreal Convention, there is potential for the chemical to be illegally diverted and used in what would otherwise be controlled applications. Lack of resources and high turnover rates of enforcement officials bring further challenges to reduction of MeBr in developing countries. However, linking this substitution initiative with other regional or local programs focused on human and environmental health, particularly those that can offer training, educational, and/or technical assistance to learn about the dangers of MeBr and help with identifying alternatives, could be helpful in future success of this program and should be considered.

Conclusion

MeBr substitution has been very successful: all developed countries phased out controlled uses of MeBr by 2005 and, as of 2013, over 85% of controlled uses of MeBr in developing countries were replaced with alternatives. This process has shown that flexibility within substitution programs, as opposed to a “one size fits all” mentality works to increase likelihood of a successful substitution program. Additionally, the MeBr story illustrates how creating links with other environmental and sustainability initiatives and promoting the sharing information between local and regional production sectors is fundamental to the success of a substitution initiative.

[5] UNEP. 2014. Phasing-out Methyl Bromide in Developing Countries: A success story and its challenges.

Annex 3. Reducing Mercury in Hospital in Ecuador and Mexico

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Introduction

This case study summarizes a collaborative project to reduce the use of mercury in hospitals in Mexico and Ecuador. The effort was spearheaded by the U.S. EPA, with help from a team from the University of Massachusetts, Lowell, USA; the Institute for the Development of Production and Work Environment (IFA), Quito, Ecuador; and the university of Sonora (UNISON), Hermosillo, Mexico[1]. The methodology for mercury reduction focused on educating all hospital staff on the environmental and human health dangers of mercury and provided training for the various tools available for mercury reduction, including identifying and adopting safer alternatives. The idea behind this participatory approach for intervention is to provide hospital workers with the needed knowledge to continue mercury reduction efforts on their own, making achieving reduction goals more realistic.

Background

The physical properties of elemental mercury make it useful in several applications. Liquid mercury is a cohesive fluid that is sensitive to small temperature and pressure changes, which makes it ideal for use in fever thermometers and sphygmomanometers (blood pressure cuffs). Mercury also forms a strong, durable solid when combined with metal powders into an amalgam[2], and is frequently used in dental fillings.

Problem statement

Despite its practical applications, mercury is also a persistent, bioaccumulative, and toxic substance that is inherently dangerous to humans and the environment. Mercury is a neurotoxin that can cause health effects after acute and/or chronic exposure. Elemental mercury released into the environment forms methyl mercury, which is bioaccumulative and toxic to exposed humans and animals and, as there is no safe disposal method for mercury, there is no way to properly mitigate its release[3].

Waste mercury is a global problem. Mining, burning coal, and other anthropogenic activities are the primary cause for release of elemental mercury into the environment. The UN's Minamata Convention on Mercury, a global treaty to protect humans and the environment from the toxic effects of mercury, was ratified in 2017[4]. The treaty bans new mercury mines, calls for controls on emissions, as well as a phase-out of mercury use in a variety of products and processes. In addition to adopting the Minamata Convention,

[1] University of Massachusetts Lowell (UMass Lowell). 2012. Eliminating Mercury in Health Care: A workbook to identify safer alternatives. Guidance for designing, implementing, and evaluating mercury reduction in your hospital.
[2] Environment Canada (EC). 2013. Mercury: Chemical Properties. https://www.canada.ca/en/environment-climate-change/services/pollutants/mercury-environment/about/chemical-properties.html. Accessed 12/28/2018.
[3] World Health Organization (WHO). 2017. Fact Sheet: Mercury and Health. https://www.who.int/news-room/fact-sheets/detail/mercury-and-health. Accessed 12/28/2018.
[4] UNEP. 2017. Minamata Convention on Mercury: Text and Annexes. September. http://www.mercuryconvention.org/Portals/11/documents/Booklets/COP1%20version/Minamata-Convention-booklet-eng-full.pdf. Accessed 12/28/2018

many countries and regions around the world have their own regulations controlling mercury use and emissions.[5,6]

While mercury releases from hospital use may be smaller compared to larger, industrial sources[7], it is a problem that is easily defined and, also, easily solved. This case study summarizes a collaborative effort to reduce the use of mercury thermometers and sphygmomanometers in hospitals in Ecuador and Mexico. The ultimate goal of the project was to give hospitals the framework for reducing mercury use, and, looking to the future, be able to practice pollution prevention on their own.

Substitution process used

The project organizers in both Ecuador and Mexico developed a participatory approach to mercury reduction that engaged all stakeholders potentially affected by moving away from products reliant on mercury. Evaluation of mercury use and assessment of substitutions followed a six-step process and considered both environmental and human health. This is a holistic approach that addressed system-wide change, which is more likely to be successful in attaining long-term reduction goals over focusing on one area, such as environmental policy.

Identification and prioritization of mercury reduction

Working groups in both Ecuador and Mexico concluded that mercury thermometers and sphygmomanometers, still in wide use in participant hospitals in both countries, were ideal candidates for replacements with safer alternatives. Digital fever thermometers, while more expensive than mercury thermometers, are commercially available in both Mexico and Ecuador. Likewise, aneroid sphygmomanometers, which are comparable in price to mercury sphygmomanometers but safer due to their lack of liquid mercury, are also readily available.

Implementation of alternatives

Mercury reduction programs were already in place in project hospitals in Mexico, and replacement of mercury-containing thermometers and sphygmomanometers, while gradual, were very well received by hospital staff. However, implementation of replacements did not go without glitches. Late in the second year of the program, there were reports that the pedestals on the aneroid sphygmomanometers, on which the equipment is mounted and wheeled around, were breaking. Once this issue was noted, hospitals switched to another brand of aneroid sphygmomanometers with a more durable base, and the issue was resolved.

Lessons learned

Implementation of this mercury reduction program at participant hospitals revealed several important points about the importance of stakeholder participation and training. Walk-throughs in hospitals in Ecuador revealed that the hospital had several hundred digital thermometers in an onsite warehouse, however only mercury thermometers were in use at the hospital. Walk-throughs at another hospital revealed that hospital clinics had a mix of mercury sphygmomanometers and aneroid sphygmomanometers. These findings are important because they show that obtaining safer alternatives, despite the higher cost, is

[5] USEPA. Environmental Laws that Apply to Mercury. https://www.epa.gov/mercury/environmental-laws-apply-mercury. Accessed 12/28/2018.
[6] USEPA. International Actions for Reducing Mercury Emissions and Use. https://www.epa.gov/international-cooperation/international-actions-reducing-mercury-emissions-and-use. Accessed 12/28/2018.
[7] USEPA. Mercury Emissions: The Global Context. https://www.epa.gov/international-cooperation/mercury-emissions-global-context. Accessed 12/28/2018.

possible. However, in order for a substitution program to be effective, the program needs not only to acquire the safer alternative, but also needs to spend time promoting the alternative.

Constant turnover of hospital staff and administration and heavy workloads created issues with content and scheduling of training modules in Mexico. Solutions included more frequent training as well as inclusion of basic information on the hazards of mercury in all training modules. Implementing online training modules is another solution for both scheduling and content.

Conclusion

This project ultimately strengthened efforts to prevent mercury pollution and exposure in Ecuador and Mexico in several ways: 1) The process for identifying problem areas and implementing solutions resulted in creation and strengthening of networks connecting hospitals, government, community, and academics in each country; 2) Hospital staff and environmental specialists received necessary training to recognize and mitigate for mercury-containing items. This training creates a self-sustaining structure where stakeholders can continue to participate in mercury reduction programs; 3) In creating a workbook by which to train and guide stakeholders in mercury reduction, the program provided a framework by which other institutions can create mercury or other pollution reduction programs.

At this time, mercury elimination in hospitals in developing countries is still constrained by economic resources and the lack of official federal government policies for mercury. The federal government's leadership is critical. Government support for eliminating the use of mercury in the health sector should address purchasing criteria to prevent the acquisition of mercury, allocation of resources for procurement of mercury-free alternatives, and assistance with the handling of waste mercury. With this support, hospitals can move more quickly to their goals of becoming mercury-free facilities.