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Safer alternatives assessment: the Massachusetts process as a model for state governments

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ABSTRACT

In 2006 the Massachusetts Toxics Use Reduction Institute conducted a study to determine if states could identify safer alternatives to five chemicals of concern. The chemicals investigated included di (2-ethylhexyl) phthalate (DEHP), formaldehyde, hexavalent chromium, lead and perchloroethylene. First, the Institute developed a methodology for assessing alternatives to these five chemicals that allowed it to quickly determine priority uses and alternatives to assess and to research the pertinent decision criteria, which included performance, technical, financial environmental and human health parameters. The methodology included important feedback from stakeholders in the state, which helped to focus and enhance the value of the work. Second, the Institute implemented the methodology over a ten month period. Based on the activities conducted by the Institute, safer alternatives were identified for each of the priority uses associated with the five chemicals studied. This report summarizes the methodology employed and provides examples of the results for one of the five chemicals, namely DEHP. The experience of the Institute and the information contained in this report indicates that alternatives assessment was a useful approach to organizing and evaluating information about chemicals and alternatives.

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1. Introduction

There is growing concern among consumers about the presence of toxic chemicals in the products they use. Studies showing these chemicals' persistence in the environment and potentially harmful effects on humans exposed to them are becoming a common place item in the news. Retailers, anxious to maintain their consumer base, are taking a harder look at the products they are willing to sell in their stores. Manufacturers are concerned about providing safer product formulations that will create a sustainable market share and help them to avoid potential future liabilities and costs. Public health and environmental advocacy groups are diligently working to raise public awareness and understanding of the risks associated with toxic chemicals, an activity which in turn puts more pressure on the retailers and manufacturers.

The tightening pressure to remove toxic chemicals from products has understandably come to the attention of municipal, state and federal governments, who are responsible for protecting their constituents and the environment they inhabit while continuing to promote a more productive economy.

In July 2005, the Commonwealth of Massachusetts requested that the Toxics Use Reduction Institute perform an alternatives assessment for five chemicals identified by a coalition of public health, labor and environment advocacy groups. The chosen chemicals included lead, formaldehyde, perchloroethylene, hexavalent chromium, and di(2-ethylhexyl) phthalate (DEHP). For each chemical, the Institute was charged with identifying significant uses in manufacturing, consumer products, and other applications; reviewing health and environmental effects; and evaluating possible alternatives.

Because the study had to be conducted within a very short time frame (approximately 10 months) for a limited budget the Institute needed to quickly focus its work on the highest priority chemicals and applications. Likewise, for each use studied, the Institute chose a subset of possible alternatives for analysis. The Institute analyzed a total of sixteen different use categories and approximately one hundred different alternatives. Examples presented throughout this article are associated with one of the five chemicals studied, DEHP.

The Institute conducted its research in a phased manner, using the methodology described herein. This report presents the streamlined approach used by the Institute; a method that can be

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adapted for use by other governments and companies interested in quickly identifying safer alternatives to chemicals of high concern.

2. Phase I – understanding the concerns associated with the chemical being studied

To fully assess whether an alternative was indeed both technically and economically feasible for its intended use as well as being safer, the characteristics of that chemical was first identified.

2.1. Profile inherent hazard and exposure of the chemical of concern

Information about potential human health and environmental impacts associated with the use or exposure to the chemicals of concern can be found in a number of sources: public databases, peer-reviewed scientific journals, reference materials, industry trade group and advocacy group resources. The objective was to provide background information on each chemical of concern, highlight the associated environmental, health and safety issues, and provide a baseline against which alternatives may be compared.

The Institute has a long-standing history of focusing its work on the inherent hazards associated with toxic chemicals. However, the US federal government and most companies and trade associations have historically considered “risk” when setting policy about the use of chemicals. Risk assessments include an evaluation of the exposure potential associated with the use of a chemical as well as its inherent hazard. Potential human health and environmental hazards are typically inherent to a chemical and are not influenced by the use or exposure potential associated with the chemical. Table 1 presents the pertinent inherent hazard information associated with DEHP.

The potential for human exposure to a chemical of concern is directly influenced by the manufacturing process and use for specific applications. Physical characteristics of the chemical and the product or material in which it is incorporated influence the potential for exposure to the chemical of concern. For DEHP, the physical characteristics and characteristics that could lead to exposure are summarized in Table 2.

The Institute used exposure potential information to help determine the priority of specific uses of each chemical, but also to gain more insight into how alternatives compared to the chemicals of concern for specific uses.

Table 2
Physical characteristics of DEHP influencing exposure potential.

Physical characteristic	DEHP data	Primary sources of information
Water solubility (mg/L)	0.0025	HSDB, 2009
Vapor pressure (mmHg)	1.4×10^{-6}	HSDB, 2009
Octanol–water partition coefficient (K_{ow})	7.6	HSDB, 2009
Flashpoint	215	HSDB, 2009
Migration potential	Possible migration from matrix in lipid soluble	Health Canada, 2002

2.2. Identify function, uses and use categories

Uses of chemicals range from manufacturing processes to services to consumer products. The first task was to identify the suite of uses for the chemicals of concern. Uses may include use in manufacturing operations (e.g., chemical production), use in non-manufacturing operations (e.g., services such as dry-cleaning), as well as incorporation in consumer and industrial products.

The Institute utilized the following sources when gathering this information:

- Major suppliers of the chemical;
- Major derivatives, components and/or end products that incorporate the chemical or use the chemical as a feedstock, and their manufacturers;
- Major distributors, retailers, or customers of the end product;
- Functionality requirements of chemical or component or end-product users; and

Table 1
Inherent hazard characteristics of DEHP.

Chemical characteristic		DEHP data	Primary sources of data
Environmental criteria	Persistence	• 140 days in sediment • 15 days in water • 30 days in soil • 0.75 days in air	EPA PBT Profiler, 2010
	Bioaccumulation	BCF = 310	EPA PBT Profiler, 2010
	Chronic aquatic (fish) toxicity (ChV)	No effect at 0.0025 mg/L	EPA PBT profiler, 2010
Human Health criteria	Carcinogen	• NTP B2 (Reasonably anticipated to be a human carcinogen) • IARC 3 (Not classifiable as to its carcinogenicity to humans)	• National Toxicology Program Report on Carcinogens, Eleventh Edition, 2010 • International Agency for Research on Cancer, 2010
	Reproductive toxicity	No adverse affect level = 3.7 mg/kg bw/d	NTP, 2005
	Lethal dose (LD50)	• 25–34 g/kg (oral, rat) • 10 g/kg (dermal, guinea pig) • 25 g/kg (dermal, rabbit)	HSDB, 2009
	Irritation	• Dermal • Ocular • Respiratory (mucous membranes)	HSDB, 2009
	Metabolite of concern	Mono(2-ethylhexyl)phthalate (MEHP) classified as a reproductive toxicant	CDC, 2005
	Reference dose	0.02 mg/kg/day	HSDB, 2009
	Target organs	• Eyes • Respiratory system • Central nervous system • Liver • Reproductive system • Gastrointestinal tract	NIOSH Pocket Guide to Chemical Hazards, 2005

Table 3
DEHP uses and stakeholder discussion.

Uses/applications	Stakeholder discussion
Consumer products	
Toys	Permanently banned in EU; Potentially vulnerable population exposed; DEHP not currently used in toys in the US because of consumer relations; concern with imported products
Sheet/film (e.g. food packaging)	FDA limits use of DEHP in packaging that touches food
Vinyl shower curtain	Not recommended for study because other applications with similar manufacturing process will be evaluated
Vinyl wall covering	High consumer exposure potential; large usage; ubiquitous
Car undercoating	Alternatives available
Footwear	Alternatives available; further research to determine manufacturing in MA and US and potential consumer exposure.
Upholstery	High consumer exposure potential; large usage; ubiquitous
Medical devices	
Plastic sheet materials (e.g. bags)	High usage; potentially vulnerable population exposed; many alternatives possible; Serious health issue; High concern to many stakeholders
Tubing (e.g. IV tubing)	High usage; potentially vulnerable population exposed; many alternatives possible; serious health issue; High concern to many stakeholders
Industrial/commercial uses	
Resilient flooring (also residential use)	Used in MA; high occupational exposure potential; alternatives available on the market
Roofing	Most roofers do not want or use products containing DEHP; alternatives available
Aluminum foil coating/laminating	Alternatives available
Paper coating	Alternatives available
Extrudable PVC molds/profiles	Used in MA; 1% of total DEHP use; not identified as priority
Electronic component parts	Used in MA; less than 1% of total DEHP use; not identified as priority
Wire/cable coating compounds	Used in MA; DEHP has been greatly reduced in MA due to use of alternative plasticizers

- Concerns of relevant stakeholders, including businesses, industry associations, environmental, public health and labor organizations.

2.3. Stakeholder engagement

The prioritization process was informed by the experiences, concerns and knowledge of a group of stakeholders who were gathered together by the Institute early in the process. Engaging stakeholders is key to attaining a more transparent and participatory process for providing useful information to assist environmentally responsible decision making. A critical aspect is to appropriately involve relevant parties in the assessment process (Thabrew et al., 2009) The stakeholder engagement process became a vital component of the success of this process, in that the feedback of the various stakeholders helped to quickly identify priority uses of the five chemicals studied based on the criteria identified above.

Stakeholders who were invited in to the conversation included representatives from companies using and manufacturing the chemicals of concern and their alternatives, industry trade organizations, labor organizations, environmental and public health advocacy organizations, academic experts and policy makers in Massachusetts. The focus was clearly limited to the impact of chemicals used in Massachusetts, and therefore national trade associations were not included as relevant stakeholders in the early process. They were, however, offered the opportunity to review and comment on Institute research and provide additional information as the assessment process progressed.

As an example, the variety of uses identified as being of priority to the various stakeholders for the plasticizer DEHP is presented in Table 3.

2.4. Develop a preliminary prioritization of chemical uses for further evaluation

For each chemical of concern, the range of associated uses is wide and varied. Therefore it was necessary to narrow the scope to focus our evaluation on uses that are a priority. The Institute prioritized uses of the chemicals of concern using the following criteria:

- Total quantity of chemical used in manufacturing and business operations in the state (the Massachusetts Toxics Use Reduction Act requires that companies using toxic chemicals report those uses. This information is available on the Institute's website,[1] and was used for this purpose)
- Potential availability of alternatives (based on preliminary research and feedback from stakeholders)
- Environmental, occupational, and public health exposure potential. This included consideration of the mobility of the chemical for a particular use and whether the chemical was used in a product in a way that could lead to user exposure.
- Potential value of the alternatives assessment results to state businesses and citizens.

The priority uses identified for DEHP, based on these criteria and the feedback of our stakeholders and research conducted, are summarized in Table 4.

For the remainder of this article, only the alternative assessment results for the resilient flooring application will be presented.

3. Phase II − alternatives identification and prioritization

This phase of the process involved more extensive research to identify possible existing or emerging alternatives to the chemicals of concern for the specific applications being studied. The knowledge of stakeholders was used to help facilitate this process. Alternatives were only identified for the priority uses determined in the previous section.

3.1. Identify alternatives for priority uses only

Alternatives to the chemicals of concern potentially include drop-in chemical substitutes, material substitutes, changes to manufacturing operations, changes to component/product design, or other technological solutions. The Institute considered all possibilities as it researched potential safer alternatives to the five chemicals being studied. Appropriate industry-specific performance requirements for each use were necessary criteria in

[1] www.turi.org.

Table 4
DEHP list of priority uses.

Use	Criteria applied to determine as priority
Medical sheet/bag devices in neonatal care	Potential public exposure; Many device manufacturers in Massachusetts; Many alternatives available
Medical tubing devices in neonatal care	Potential public exposure; Many device manufacturers in Massachusetts; Many alternatives available
Resilient flooring	Largest DEHP manufacturer in Massachusetts; Potential occupational and public exposure; Many alternatives available
Vinyl wall coverings	Potential occupational and public exposure; Many alternatives available

determining if an alternative was technically feasible. Each alternative's characteristic was evaluated relative to those technological criteria to determine if it represented a reasonable alternative to the chemical of concern for the specific use.

For resilient flooring the Institute focused on the use of DEHP to soften and provide resiliency to poly vinyl chloride (PVC) residential flooring applications. When considering alternatives for this application, both alternative plasticizers and alternative materials that do not require plasticizers were considered. The Institute used information from stakeholders, industry experts and literature research to identify the potential alternatives summarized in Table 5.

3.2. Pre-screen alternatives

The Institute conducted a pre-screening step to eliminate from further study any chemical alternatives that would pose a high risk to the environment or human health. All identified chemical alternatives were screened based on the following criteria:

- PBT (persistent, bioaccumulative toxin)
- Carcinogen
- Present on Massachusetts More Hazardous Chemical list

If an alternative met any of the pre-screening criteria, it was eliminated from further consideration as an appropriate alternative. It is important to note that, when no data associated with one or more of the pre-screening parameters were available the chemical was not screened out based on that parameter.

Table 5
Available alternatives to DEHP in resilient flooring.

Alternative category	Potential alternative
Phthalate-based plasticizers	• DINP (di isononyl phthalate) • DIDP (di isodecyl phthalate) • DEHT (di(2-ethylhexyl)terephthalate) • BBP (butyl benzyl phthalate) • DHP (di isohexyl phthalate) • BOP (butyl, 2-ethylhexyl phthalate) • DBP (dibutyl phthalate) • DIHP (di (isoheptyl)phthalate)
Other plasticizers	• DEHA (di(ethylhexyl) adipate) • DEHPA (di(2-ethylhexyl) phosphate) • TCP (tricresyl phosphate) • ATBC (o-acetyl tributyl citrate) • DBS (dibutyl sebacate) • TEGDB (triethylene glycol dibenzoate) • DGD (dipropylene glycol dibenzoate) • DEGDB (diethylene glycol dibenzoate) • 97A (hexanadedioic acid, di-C7-9-branched and linear alkyl esters) • TXIB (butane ester 2,2,4-trimethyl 1,3-pentanediol di isobutyrate
Materials	• Natural Linoleum • Cork • Polyolefin • Polyethylene/limestone blend • Rubber

3.2.1. Persistence, bioaccumulation and toxicity

Developing data on persistence, bioaccumulation potential and toxicity are especially important from an environmental assessment standpoint. In order to present more comprehensive data, the Institute utilized the US EPA PBT Profiler software for those chemicals for which there was no currently available persistence, bioaccumulation or toxicity data (U.S. EPA PBT, 2010). The PBT Profiler evaluation was conducted by a subset of the assessment team, consisting of chemists and chemical engineers trained to appropriately interpret the data, in order to assure consistent use and interpretation of the results of this tool. Other publicly available scientific-based and peer-reviewed estimation tools that were identified and tested over the course of this study were also used to augment the available information about each of the chemical substitutes evaluated.

- Persistence: The US EPA PBT Profiler defines very persistent chemicals in terms of their half life in specific media (U.S. EPA PBT, 2010). If any one of the environmental media half lives was exceeded, the chemical was considered to be persistent for this study.
- Bioaccumulation: As defined in the PBT Profiler, the US EPA considers a chemical very bioaccumulative if it has a bioconcentration factor (BCF) greater than 5000 (or $\log K_{ow}$ greater than 5) (U.S. EPA PBT, 2010).
- Aquatic toxicity: According to the PBT Profiler, chronic aquatic toxicity values less than 0.1 mg/L indicate that a chemical was of high concern (U.S. EPA PBT, 2010). The parameter used to evaluate for freshwater fish species toxicity was based on 30-day exposure duration, with the endpoint for evaluation expressed in ChV (mg/L). In many cases data for aquatic toxicity was not available. In this case the chemical was not screened out based on toxicity, and was only screened out as a PBT if the criteria for both P and B were exceeded.

3.2.2. Carcinogenicity

For the purposes of this study, a chemical was screened out if it was identified as a carcinogen under one of the following classifications:

- US EPA Classifications (USEPA, 1986):
  - Group A: Known Human Carcinogen
  - Group B1: Probable Human Carcinogen (Limited human evidence)
  - Group B2: Probable Human Carcinogen (Sufficient evidence in animals)
- IARC Classifications (IARC, 2000):
  - Group 1: Known Human Carcinogen
  - Group 2A: Probable Human Carcinogen

3.2.3. Chemicals present on specific lists

The Institute used the TUR Science Advisory Board's list of More Hazardous Chemicals (Mass TURI, 1999) as an additional pre-screening list for its alternatives assessment process. In this list, "hazard" includes inherent toxicity, potential for exposure through dispersal in the work place (based on the physico-chemical properties of the chemicals, e.g., vapor pressure) and indicators of safety of use (e.g., flammability). Potential for exposure and indicators of safety do not include site-specific conditions. Chemicals found on the list were eliminated from consideration as a viable chemical alternative.

3.2.4. Alternatives screened out from further consideration

As part of the initial screening effort to determine alternatives to eliminate, several plasticizer alternatives were identified as having persistence, bioaccumulative or toxic values that exceeded the screening criteria with one of the other PBT criteria approaching a level of concern. Hence they were not screened out as PBTs, but were flagged as being of concern because they approach the associated PBT screening levels. However, because there were numerous plasticizer alternatives identified for this use that did not approach levels of concern, none of these questionable alternatives were considered vital to the goals of the study, and were not evaluated further. The chemicals that were screened out for further analysis included:

- DIHP (di (isoheptyl) phthalate) – Failed due to sediment persistence and aquatic toxicity
- 97A (hexanadedioic acid, di-C7-9-branched and linear alkyl esters) – Failed due to sediment persistence and aquatic toxicity
- TXIB (butane ester 2,2,4-trimethyl 1,3-pentanediol di isobutyrate) – Failed due to sediment persistence and aquatic toxicity (also exhibits high bioaccumulation, though it does not exceed the screening level)

No materials were screened out at this point in the assessment, though several potential alternatives initially identified were eliminated from further consideration because they did not meet the resiliency criterion (*i.e.,* able to return to their original form after compacting) established as part of the study. These materials included concrete, terrazzo, concrete and recycled glass blend, wood and bamboo.

3.3. Prioritize alternatives for further evaluation

The purpose of the prioritization effort was to focus the Institute's assessments on the most feasible alternatives for each specific priority use. Our intention at this stage was to do a high level evaluation of the potential alternatives to identify any factors leading to immediate screening out of the chemical or informing the prioritization of the alternative as a potentially feasible alternative to one of the five chemicals. The Institute considered the following:

- *Performance*: Performance criteria specific to the use of the chemical/material, which could include items such as maintenance and durability as well as specific performance requirements. The potential for future performance enhancements was considered.
- *Availability*: Number of suppliers/manufacturers that commercially provide the alternative. In addition, information about the volume of the alternative produced was considered (i.e., was the alternative available only in very small quantities and therefore less feasible).
- *Manufacturing location*: Products or materials manufactured in Massachusetts received a higher prioritization for evaluation as this may have a greater impact on the Massachusetts economy.
- *Cost*: Current costs associated with the alternative compared to that of the chemical of concern. The potential for future cost reductions (e.g., economies of scale due to higher volume production) was considered. If available, other significant costs such as raw material costs, storage and handling costs and disposal costs were also considered.
- *Environmental, health, and safety*: Known environmental, health and safety risks or benefits as compared to that of the chemical of concern. Frequently there was a paucity of data about alternatives, which was noted and addressed in the assessment phase.
- *Global market effect*: Information about pending or existing global restrictions that might materially affect the ability of an industry to market its products internationally was considered.
- *Other*: Other use specific criteria were used as appropriate. For example, in some instances multiple similar alternatives exist for a particular use. In this case one alternative that was representative of that type was chosen for further study.

Table 6 presents the final list of alternatives considered for resilient flooring applications.

4. Phase III – alternatives assessment

Risk assessments use many categories of information including scientific, technological, and legal information. These types of information are potentially helpful in identifying and reducing the risks of hazardous chemicals (Koch and Ashford, 2006). Similarly, the alternatives assessment methodology used for this study includes the collection and analysis of many different types of information.

4.1. Types of alternatives to be considered

The Institute organized and evaluated environmental, technical, financial and human health data obtained for each alternative to assess its feasibility as a substitute for the chemical and use. The main types of alternatives that were considered included chemical, mixture and material alternatives as well as process alternatives.

4.1.1. Evaluating chemical alternatives

In this study, a chemical was considered to be any element, chemical compound or mixture of elements and/or compounds. Chemicals are the constituents of materials. A chemical "mixture," also known as a chemical "preparation," includes multiple chemicals.

A chemical alternative represents the simplest case, where the chemical being studied can be directly substituted with another chemical that satisfies the functional requirements for the particular use. In this instance, the evaluation was relatively straightforward; information could be obtained, verified and presented in a way that maximizes usefulness of the information for those interested in designing products using alternative chemicals.

Table 6
Priority alternatives for resilient flooring.

Priority alternative plasticizers	Priority alternative materials
DEHT	Natural linoleum
DINP	Cork
DGD	Polyolefin
DEHA	

4.1.2. Evaluating mixtures

Often the chemicals being evaluated are used in formulations of multiple chemicals. In this case, each of the chemical constituents of the mixture had to be considered in the assessment, in a manner similar to that used for individual chemicals (as above). The Institute obtained environmental and human health information about each of the chemical constituents, and performance and cost information for the overall formulation when doing the assessment. When information on the weight percent of constituents in the mixture was available from a manufacturer's materials safety data sheet (MSDS) that information was used.

The Institute focused on the primary constituents of each formulation being evaluated. Specifically, constituents present in amounts exceeding 1% were included in the review. When formulation breakdowns were presented on associated MSDSs with ranges, the Institute assumed the average weight percentage of the range presented. This was the only time that a weighting factor was included in our assessment of alternatives. As the EH&S factors associated with the constituents of a mixture were determined, their relative significance to the overall EH&S characteristic of the mixture was determined based on the weight percent within the mixture.

The actual approach to evaluating the EH&S impact of a mixture differed depending on whether the chemicals in the mixture cause similar or different health effects. If the health effects are similar (e.g., two constituents are CNS depressants), their weight percentages were added and the overall impacts of the combined chemicals were assessed. If the health effects were different (e.g., one chemical was a CNS depressant, while another was a respiratory irritant), the effects were evaluated separately based on the weight percentages of each constituent (Craig et al., 1999).

4.1.3. Evaluating material alternatives

A material is defined as the basic matter (as metal, wood, plastic, fiber) from which the whole or the greater part of something physical (as a machine, tool, building, fabric) is made. In some cases the chemical being studied was used to impart particular qualities in a material. For instance, DEHP is used in PVC to make this otherwise rigid plastic flexible. Rather than find other ways to make the material (PVC) less rigid, opportunities to find alternative materials that are inherently more flexible were available that precluded the need for this particular chemical additive.

When evaluating material alternatives performance and cost considerations are still important. However the impact of a material on environmental or human health may not be as readily assessed as it can be for chemical substitutes. For materials, life cycle considerations may become more important. For this study the Institute looked both at EH&S impacts when appropriate and at life cycle issues that based on our research appear to be of most significance relative to the material being replaced. It is important to note that this was not a comprehensive life cycle assessment. Rather, when our research indicated that there may be important positive or negative impacts at a particular point in a material's life cycle these were mentioned qualitatively relative to the material being substituted.

4.1.4. Evaluating process alternatives

Process alternatives are those that employ a different technology, process or approach to achieve the objective or function of the original product or process. For example, when considering alternatives to perchloroethylene in vapor degreasing, one approach might be to change the upstream process to use lubricants that either don't require cleaning, or are easier to remove using water-based surfactants. The feasibility of this type of alternative can be assessed, but it is very difficult to compare the EH&S impacts quantitatively. These types of alternatives were therefore included in the study where appropriate, and their feasibility assessed qualitatively. When our research indicated that there are important positive or negative attributes or impacts relative to the substance being substituted, these were mentioned.

4.2. Criteria considered for alternatives

The alternatives assessment phase included comparison of health and environmental effects, technical feasibility, and financial feasibility for the prioritized alternatives for each studied use to the chemicals of concern. It is important to note that this study was not designed to assess the relative safety of one alternative over the other. Rather, alternatives were compared to the study chemical as a baseline.

4.2.1. Health and environmental effects

The Institute evaluated a subset of environment, health and safety (EH&S) endpoints. The Institute did not perform a detailed toxicological review for each alternative. Rather, the study relied on information obtained from authoritative bodies, emphasizing the most recent validated data or data that has been referenced by a US government agency. Where this type of information was not available, or where more recent studies called into question the results previously published by authoritative bodies, supplementary information was noted. In cases in which it was necessary to evaluate chemicals in mixtures, the assessment considered each of the chemical constituents, excluding those making up 1% or less by mass of the mixture.

The Institute used the following protocol when evaluating environmental and human health data:

- All data must represent current science and be derived from peer-reviewed and publicly available sources. Our primary sources of this data were those available from the National Library of Medicine's Hazardous Substances Data Bank (HSDB, 2009)
- For human health, data based on human epidemiological studies were used preferentially. Data based on tests of non-human sources were used if human epidemiological data was not available. If neither human epidemiological data nor data based on non-human sources was available, data derived from models were used; and
- If modeled data was used, the Institute used models approved by the US EPA.

When presenting data for any of these categories, the Institute relied on information obtained from authoritative bodies,[2] with the most recent validated data presented first. When faced with multiple or conflicting data, the Institute preferentially used data that has been referenced by a US governmental agency such as EPA, CDC and OSHA. Examples of data included in the health and environmental effects assessment include aquatic toxicity, water quality, persistence, bioaccumulation, environmental mobility, degradation products, lethal dose, worker exposure limits, metabolites of concern, carcinogenicity, mutagenicity, endocrine disruption, reproductive toxicity, corrosivity, reactivity, vapor pressure, and potential for dermal adsorption.

[2] Authoritative bodies include the US Environmental Protection Agency, the Occupational Safety and Health Administration, the National Toxicology Program, the International Agency on Research of Cancer, National Institute of Health, and the Center for Disease Control, etc.

4.2.2. Technical feasibility

The study identified and assessed application-specific performance requirements that must be met for each feasible alternative. The performance information that the Institute was able to obtain varied considerably among uses. For some uses, information was obtained from published studies or directly from technical experts or several users of the alternatives. For other uses, the Institute relied on information provided by product manufacturers. Examples of parameters considered for technical feasibility included: product longevity, performance standards (e.g. UL, ASTM, or ISO standards), physical characteristics (e.g. processability, density, or color), and quality requirements (e.g. durability, maintenance requirements).

4.2.3. Financial feasibility

Data sources for financial information included manufacturers, stakeholders, the Chemical Economics Handbook and other standard reference sources (Bizzari et al., 2003). In many cases, particularly for emerging alternatives, no quantitative cost information was available. In other cases, sufficient cost information existed to conclude that the alternative was either more or less costly than the current chemical use. The Institute recognized as part of its assessment that cost comparisons are snapshots in time, and may also be of limited relevance for emerging technologies and technologies that are gaining in popularity, since learning curves, economies of scale, and other factors can reduce costs over time. Examples of parameters considered for financial feasibility included: purchase price, commercial availability, capital costs for equipment associated with adopting the alternative, operating costs, and manufacturing costs.

4.2.4. User experience data associated with alternatives

While conducting the technical/performance assessment, the Institute identified any industry-specific performance requirements that must be met for each feasible alternative. The primary source of this information was industry/user experience with the chemicals and their substitutes. Institute staff contacted and interviewed representatives from manufacturers, trade associations and customers who use the chemical or its derivatives to gather pertinent information.

4.2.5. Life cycle implications of alternative materials

Considering the life cycle of a material can provide a quantitative basis for assessing potential alternatives with respect to the impact adopting alternatives might have on the overall environmental performance of the system (Azapagic and Clift, 1998). Because of the limitations placed on this study (specifically the limited amount of time available to conduct the study) as well as the overall goal, which was merely to determine if safer alternatives could be identified, the Institute made the decision to not engage in a comprehensive life cycle assessment of material alternatives. The Institute did, however, look for readily available information on key life cycle considerations (such as waste disposal limitations, energy usage required during manufacture, impact on product recyclability or reuse potential) that might have affected the feasibility of the alternative. This information was presented in the final report only when more than one source corroborated the data, and when it was deemed to materially impact the overall assessment of one alternative's feasibility.

4.3. Summary of criteria for assessing resilient flooring alternatives

Table 7 summarizes the criteria used to assess plasticizer alternatives to DEHP. Table 8 summarizes the criteria used to assess material alternatives to PVC modified with DEHP.

5. Results and discussion

DEHP used in PVC for resilient flooring applications provides an excellent example of the results of the assessment process. Both chemical and material alternatives were identified and assessed for this use of DEHP (as was done for all priority uses of each of the five chemicals of concern studied).

5.1. Summary of results for alternative chemicals

Based on our evaluation of the four plasticizer alternatives to DEHP for resilient flooring applications, and using the primary criteria that impacted the ability of manufacturer's to adopt safer alternatives, a matrix was created that compares the alternatives to DEHP, as shown in Table 9.

Table 7
DEHP plasticizer alternative assessment criteria.

Category	Assessment criteria
Performance	The following performance criteria are important when substituting plasticizers in flooring and wall covering operations: • Lower plasticizer volatility, measured by plasticizer's vapor pressure, increases a product's expected lifetime. Ideally, the volatility of a substitute plasticizer should be equal to or lower than DEHP. • Compatibility measures how well a plasticizer is suited to PVC. Plasticizers with low compatibility are known to migrate out of plastic over the life of a product. • Molecular weight is a good indication of tensile elongation. Higher molecular weight plasticizers tend to result in longer product life • Compounding and calendaring processability compared to DEHP. These processes are most common when manufacturing flexible PVC. Alternatives should ideally process as well as or better than DEHP.
Financial	Cost data from industry sources in March 2006, based on a hardness rating of 70 Shore A. Cost estimates use plasticizer substitution factors to determine the relative amount of plasticizer, compared to DEHP, needed to obtain a particular level of hardness. For example, a factor of 1.1 indicates to achieve similar hardness; 1.1 times the amount of DEHP used is required.
Environmental Health and Safety	• Critical criteria were associated with the initial screen (*i.e.,* no PBT, Class 1 or 2 carcinogens or TURA SAB more hazardous chemicals). No chemicals that exceeded these criteria were put forward for further assessment. • If a plasticizer exhibits PBT values that approach levels of concern, as identified by the EPA in its PBT Profiler methodology, it will be considered less favorably in the assessment phase. • Additional parameters that are considered when assessing plasticizer alternatives have been identified based on the characteristics of DEHP and specific concerns relative to the likelihood of an effect occurring. These additional health criteria include: water solubility, octanol–water partition coefficient (a measure of hydrophobicity), organic carbon partition coefficient (sediment affinity indicator), lethal dose value (using the oral rat value as the benchmark), immediately dangerous to life and health (IDLH) value, permissible exposure limit, reference dose, carcinogen classification, toxicity (EU R-phrase or present on the California Proposition 65 list), and vapor pressure.

Table 8
DEHP/PVC alternative material assessment criteria.

Life cycle phase	Environment and Human Health Issues	Positive aspects of DEHP/PVC
Raw materials	• Extraction and refining of petroleum based feedstocks. • Ethylene feedstock is non-renewable • Few suppliers offer recycled content • A minority of DEHP/PVC is manufactured from chlorine made using the mercury cell process	• Some vinyl sheet manufacturers use up to 25% post-industrial recycled DEHP/PVC and reclaimed wood fibers in product.
Manufacture	• Human health impacts of PVC precursor chemicals • Energy use impacts: greenhouse gas, particulate, other • Potential worker exposure to DEHP during manufacture	• Post-industrial vinyl scrap is recyclable
Installation	• Volatile organic compounds emitted from styrene butadiene floor adhesives	• Adhesives typically water-based, safer than older solvent-based types
Use and maintenance	• DEHP exposure, though this is expected to be low due to the low vapor pressure • VOC emissions (rate depends on product type) • Most varieties require routine stripping and waxing, which may have associated VOC emissions	• Waxing and cleaning with mild detergent
End of life	• Potential for chlorine derivative (dioxin and furan) emissions from improper combustion (accidental fire, backyard burning) • Chlorine derivatives may be found in fly ash of properly controlled incinerators • Not compostable • Lack of recycling infrastructure to recycle DEHP/PVC flooring	• Recyclable

In this table you can find a summary of the data used to assess how the alternatives compare to DEHP for this specific use. In addition, to simplify the comparison summary, only the most pertinent criteria are shown in the table. The alternatives were assessed for each criterion as being similar to (=), better than (+) or worse than (−) DEHP for this application. A "?" symbol is shown to indicate that sufficient information was not available to make this kind of assessment.

5.2. *Summary of results for alternative materials*

Material alternatives were also considered as replacements for the DEHP/PVC blend used as resilient flooring in residential, industrial and commercial settings. Based on our evaluation of the various material alternatives to DEHP amended PVC for resilient flooring applications, and using the primary criteria that impacted the ability of manufacturer's to adopt safer alternatives, a matrix was created that compares the alternatives to DEHP/PVC, as shown in Table 10.

In this example you can see that the criteria focused on were associated more qualitatively with life cycle considerations than quantitative data.

5.3. *Discussion*

While the work of the Institute indicated that alternatives assessment can be done efficiently, resulting in valuable information to promote the adoption of safer alternatives in specific applications, it is clear that this work is limited in scope and can be built upon to create a more universally applicable methodology. To this end, the Institute gathered representatives from a number of states in 2008 to discuss the need for shared resources and a common language with respect to assessing the availability of safer alternatives for chemicals of concern. The state representatives decided to work collaboratively to create a protocol for conducting safer alternatives assessments. The intent was to create a flexible and adaptive set of steps that form the shared understanding of what constitutes a safer alternative to a chemical of

Table 9
Summary of plasticizer alternatives assessment for resilient flooring.

Assessment criteria		DEHP (Reference)	Comparison relative to DEHP			
			DEHT	DINP	DGD	DEHA
Technical/Performance criteria	Volatility	1.4×10^{-6} mm Hg	−	+	=	+
	Compounding	Good	?	=	=	=
	Tensile elongation (life of product)	MW 390	=	=	=	=
	PVC compatibility	Good	=	=	=	−
	Loss of plasticizer (Manufacture, Use)	Acceptable (M, U)	=	= (M); − (U)	=	−
Cost	Cost/lb applied	$0.70 (March 2006)	=	=	=	=
Environmental criteria	Persistence	Sediment (140 days)	=	=	=	+
	Bioaccumulation	BCF = 310	+ (BCF = 25)	+ (BCF = 3.2)	+ (BCF = 190)	+ (BCF = 61)
	Aquatic (Fish) toxicity	>0.0025 mg/L	= (>0.015 mg/L)	= (>0.14 mg/L)	= (0.55 mg/L)	+ (>100 mg/L)
Human health criteria	Carcinogen	EPA B2, IARC 3	?	= (indicated in rodents)	?	?
	Reproductive toxicity	Yes (Prop 65, EU; NOAEL = 3.7–100 mg/kg bw/d)	+	+	+	= (potential fetotoxicity)
	Occ. exposure to emissions (mfg)	Yes	=	=	?	−
	LD50	34 g/kg	?	+	+	−
	Irritation	Yes (Dermal, Ocular, Respiratory)	= (D,O); + (R)	+	=	+ (D); = (O,R)

Table 10
Summary of plasticizer alternatives assessment for resilient flooring.

Assessment criteria		DEHP/PVC reference	Comparison of materials to DEHP/PVC		
			Linoleum	Cork	Polyolefin
Performance criteria	Color/pattern choices	Large	=	−	=
	Ease of maintenance	Easy	=	=	=
	Recyclable	Yes	−	−	=
Cost	Purchase and installation cost	$2–$10/ft^2	=	=	=
	Expected lifespan of material	25+ years	+	+	+
Environmental criteria	Derived from sustainable material	No	+	+	=
	Use environmentally preferred materials for installation	Possible	=	+	=
	Energy use/GHG emissions (mfg)	Reference	+	?	=
	Biodegradable/compostable	No	+	+	=
Human health criteria	Emissions of VOCs during Manufacture (M), Installation (I), or Use (U)	Yes (M, I, U)	=	=	= (M, I); + (U)

concern. The goal was not to dictate precisely how to conduct the assessment, but rather to lay out basic steps generally agreed upon at that meeting, and to provide a set of resources to draw from when a unique alternatives assessment is performed.

The states have been working together since that time to create the common protocol, which includes the elements described in this paper as well as additional steps that are essential to a comprehensive protocol for alternatives assessments. Specifically, the identification and prioritization of chemicals of concern needs to be considered. For the Institute, this step was completed by the coalition of advocacy groups and the state legislature. But the process of identifying and prioritizing chemicals of concern is an important step in the process that is being defined within the collaborative work of the states.

Another important next step that is needed to facilitate the ability of governments to utilize alternatives assessments to inform their chemicals policy is to create a searchable and comprehensive database of chemicals that provides information on the human health and environmental effects associated with the chemicals, along with the performance and cost criteria that affect the feasibility of a chemical as an alternative to the chemicals of concern. This work is currently being considered by a coalition of US states, as well as by other organizations worldwide.

The US Environmental Protection Agency is now creating Chemical Action Plans for chemicals that it identifies as being of high concern. These plans will encompass many of the activities of the alternatives assessment methodology presented herein. Indeed, one of the first chemical classes to be addressed under this new program is phthalates.

Finally, it is important that policy makers and technical assistance providers discover innovative ways to promote the adoption of safer alternatives. These incentives may range from regulatory restrictions on the use of specific chemicals of high concern for specific uses (such as the Safer Children's Products Act in Maine, which will identify and limit the use of chemicals of high concern in children's products), to creating tax incentives for companies to switch from the use of identified chemicals of concern to "safer" chemicals. One of the challenges in this area is in fact the definition of "safer" in this context. Currently, and as presented in this methodology, a "safer" chemical is a chemical that is not considered to be "worse" than a chemical of concern based on an assessment of the environmental and human health and safety criteria established for the chemical of concern.

6. Conclusions

The detailed information provided by the Institute at the conclusion of the work was designed to serve as a valuable resource for anyone interested in understanding the alternatives to the five chemicals that were examined. The alternatives assessment was designed to be useful to policy makers, industry, public health and environmental professionals and advocates, and other stakeholders. In every case, at least one alternative was identified that was commercially available, was likely to meet the technical requirements of many users, and was likely to have reduced environmental and occupational health and safety impacts compared with the chemical of concern.

The active involvement of all stakeholders was key to the success of this project. Their expertise, willingness to collaborate and share perspectives, and review of the report were invaluable. The involvement of a wide range of stakeholders throughout the project resulted in a more accurate assessment, more valuable results, and increased understanding of the issues, challenges and perspectives among stakeholders. Stakeholder contributions to this project also revealed in detail the substantial investment firms have made in developing safer products.

Many promising alternatives were identified during this study. Some of these will require further work to determine their practicality and applicability for specific applications. Such work will speed up the adoption of these alternatives, and could include detailed discussions with vendors and users, independent laboratory testing of technologies, pilot-scale industrial installations, supply chain workgroups and demonstration sites. The Institute has had success using these approaches for industrial toxics use reduction, and believes that there are many parallels for small businesses and consumer products.

The Institute's experience with this study has also yielded important lessons about the methodology of alternatives assessment. The experience of the Institute and the information contained in this report indicate that alternatives assessment was a useful approach to organizing and evaluating information about chemicals and alternatives.

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