



Five Chemicals Study: Alternatives Assessment Process Guidance

Toxics Use Reduction Institute

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Chemicals Being Studied:

Chromium (Hexavalent)
Di (2-Ethylhexyl) Phthalate
Formaldehyde
Lead
Perchloroethylene

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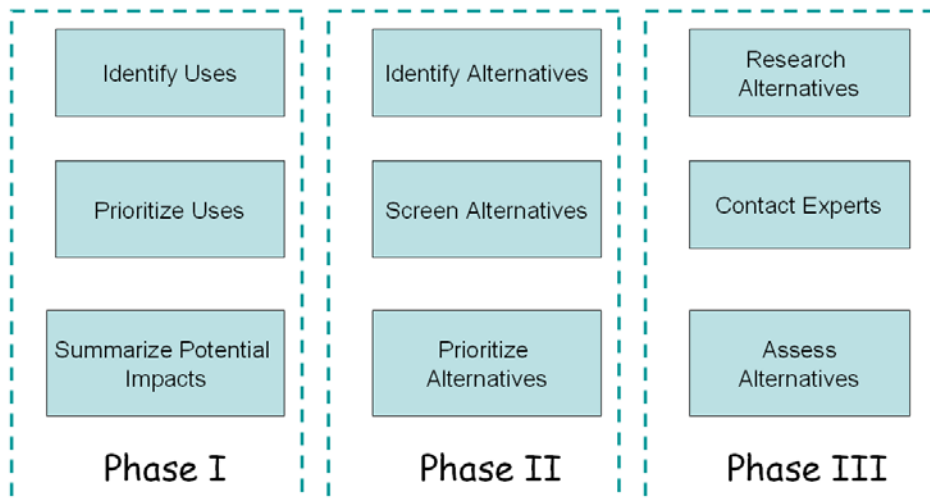
Objective

The Commonwealth of Massachusetts has requested that the Toxics Use Reduction Institute (the Institute) conduct an assessment of the feasibility of adopting alternatives for five toxic or hazardous chemicals (hexavalent chromium, di (2-ethylhexyl) phthalate (DEHP), formaldehyde, lead and perchlorethylene). The text of the Legislative budget item is found in Appendix A.

The goal of this study is to identify alternatives to these five chemicals in a use-specific manner, and compare environmental, performance, economic and human health and safety aspects to determine the feasibility of adopting chemical or technological alternatives. It is important to note that this study is not being conducted in a manner designed to assess the relative safety of one alternative over the other. However, the Institute intends to prioritize and focus its efforts on those alternatives that are expected to be safer.

The objective of this guidance document is to define a consistent process for setting priorities for study and evaluating the alternatives for the five chemicals. The proposed methodology for the five chemicals is outlined in this document. Preferred information sources include Institute publications and research, government documents and databases, and other publicly available, peer reviewed resources. This document also includes suggestions for specific types of resources for certain phases of the study. Each chemical lead will be responsible for implementing the methodology for their respective chemical

The following graphic illustrates the phased approach that is being used in this study.



Phase I will focus on identifying the priority uses in Massachusetts of the five chemicals. In Phase II the Institute will identify alternative chemicals and/or technologies for those priority uses and will utilize a set of screening criteria to determine those alternatives that warrant assessment. Each of these two initial phases will be performed under an aggressive schedule so as to allow as much time as possible for completion of the assessments. Phase III represents the bulk of the assessment work, wherein the Institute will evaluate the economic, technical, environmental and human health and safety parameters of the identified alternatives. In Phase IV the Institute will compile our findings and prepare a thorough report. This phase will culminate in a presentation of our results to the Legislature. Phase V is an internal project management phase that will include publication of the report in electronic format.

Phase I – Chemical Uses

During this phase of the project the Institute will be investigating the various uses of the five chemicals and prioritizing those uses that warrant further study. This phase will include meetings with stakeholders to inform them of our methods and findings relative to uses of the chemicals. Our goal is to use the stakeholder process to solicit input on priorities for study.

1.0 Project Overview Stakeholder Meeting

Involvement of stakeholders will begin with an initial meeting with identified Massachusetts stakeholders. This meeting will include industry, NGO, government, and labor representatives of Massachusetts businesses and organizations. The purpose of this meeting will be to review the objectives of this project, share information about the proposed methodology and receive feedback from stakeholders. At that time we will also give the stakeholders information about the timing of the project and an opportunity to attend subsequent more specific meetings as described herein. This initial meeting will be held on September 26, 2005 and will be a combined meeting of all stakeholders as are able to attend.

2.0 Identify Chemical Uses

The Institute's first task will be to identify the uses for each toxic or hazardous chemical. Uses may include use in manufacturing operations, use in non-manufacturing operations (e.g. services such as dry-cleaning), as well as use in consumer and industrial products.

The following information will be gathered when identifying the various uses of the specific chemical.

- 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 (Massachusetts, domestic, international);
- Major distributors, retailers, or customers of end product (focus on Massachusetts customers);
- Functionality requirements of chemical/component/end-product (i.e., why is it used and what is it used for?); and
- Relevant stakeholders: e.g., businesses, industry associations and environmental/public health organizations.

Information will be gathered from the literature (both published and on-line sources), experts and other data sources. As part of the use identification process, TURI staff may contact and interview representatives from manufacturers, trade associations and customers who use the chemical or its derivatives. However it is more likely that this level of work will be done as part of the alternatives assessment phase (Phase III of this project).

Possible Sources of Information: Chemical Economics Handbook, Kirk-Othmer, TURA data, U.S. EPA Toxics Release Inventory data, U.S. Geological Survey, trade/industry associations.

3.0 Prioritize Chemical Uses for Evaluation

3.1 *Develop a preliminary prioritization of chemical uses for further evaluation.*

Each of the five chemicals has a variety of uses associated with it. These uses range from manufacturing process chemical usages to services to consumer product uses. For each of the chemicals, the range of associated uses is so wide and varied that the Institute will not be able to fully evaluate them all in the short time span allowed for this project. Therefore it is necessary to narrow the scope to evaluate uses that are a priority for Massachusetts. Chemical uses will be prioritized using the following criteria:

1. Importance to the Commonwealth of Massachusetts:
 - Use in manufacturing and businesses: Total quantity of chemical used in manufacturing and business operations in Massachusetts (*Possible sources: TURA data, national TRI data, USGS chemical experts*)
 - Use in consumer products: Total quantity of chemical used in products sold in Massachusetts. (*Possible source: Chemical and Economics Handbook, national TRI data, government and trade association data*)
2. Potential availability of alternatives (conduct a quick scan of available alternatives – are they still in the developmental stage or readily available commercially?)
3. Exposure potential (environmental, occupational, and public health). For example, what is the mobility of the chemical for a particular use? If the chemical is used in a product, is the user likely to be exposed to it?
4. Potential value to Massachusetts businesses and citizens of the alternatives assessment results. Specifically, the preferences of the pertinent stakeholders for each chemical will be given priority.
5. Other criteria as appropriate

3.2 *Conduct an internal review of chemical use prioritization*

The Institute will hold an internal meeting to review information collected for criteria 1-3 (above) for each of the chemicals. During this meeting we will discuss the following:

- Sources of information used for prioritization efforts
- Determine the appropriateness of criteria used
- Identify other information that would be helpful to provide to stakeholders

3.3 *Summarize chemical use information*

Based on the results of the internal review, the Institute will update the information for prioritization of chemical uses. An overview document and information matrix will be prepared for use in the Use Prioritization Stakeholder Meeting.

4.0 Use Prioritization Stakeholder Meetings

4.1 *Conduct successive stakeholder meetings*

The Institute will conduct one day-long series of successive chemical-focused stakeholder meetings with representatives from Massachusetts industry, NGOs, government and labor. It is important to note that the Institute will strive for a balance between the various stakeholders so that each chemical's interests are well represented. The stakeholder meeting will be organized to allow those stakeholders or experts in attendance who are interested in all chemicals to attend the entire day, and those who have only an interest in one or more specific chemical to attend only for those sections of the meeting.

The purpose of the meeting will be to accomplish the following:

- Provide information on the chemical use prioritization criteria;
- Review the list of uses researched by the Institute; and
- Solicit input from stakeholders on priority uses for further investigation.

Anticipated Outcome:

- Input from stakeholders for criteria #4.

4.2 *Finalize list of chemical uses to include in the alternatives assessment*

The list of priority chemical uses to be included in the next phase of the five chemicals study will be finalized by examining all criteria. The aim is to have a balanced list reflecting different types of uses and different stakeholder's priorities. The final list will be communicated to the stakeholders

5.0 Five Chemical Impacts

As stated in Appendix A, this study includes not only an identification of the uses of the five chemicals, but also the potential human health and environmental impacts associated with the use of the five chemicals. This will not be a detailed toxicological review; rather it will summarize the current state of knowledge of these impacts. Differences of opinion among experts and variations in test results will be noted where they exist.

Information about potential human health and environmental impacts associated with the use or exposure to the five chemicals can be found in a number of sources: public databases, peer-reviewed scientific journals, reference materials, industry trade group resources (publications and web sites) and advocacy group resources (publications and web sites). The Institute will review various sources of information, and will provide a synopsis of the most current information from publicly available sources about potential human health and environmental impacts associated with use and exposure to each of the five chemicals.

Human health and environmental impacts that will be evaluated include, but may not be limited to those parameters itemized in Appendix B.

Phase II – Chemical Alternatives Identification and Screening

6.0 Identify Potential Chemical, Material and Process Alternatives

The Institute will identify existing and emerging alternatives for each of the high priority uses of the chemicals. The alternatives may include drop-in chemical substitutes, material substitutes, changes to manufacturing operations, changes to component/product design, or other technological solutions. Appropriate industry specific performance requirements for each use will be necessary criteria in determining if an alternative is technically feasible. The Institute will roughly determine each alternative's characteristics relative to those technological criteria to assess feasibility. However, in the case of emerging technologies, further investigation may be warranted without proof of adherence to any applicable performance criteria.

Possible Sources of Information: Trade associations, manufacturers, EPA documents and programs, municipal, state and federal pollution prevention research centers, literature/internet search, and experts.

7.0 Screen and Prioritize Alternatives

7.1 *Expert Review of Screening Criteria*

The Toxics Use Reduction Act's Science Advisory Board (SAB) consists of experts in health and environmental issues, as well as technical chemical experts. The Toxics Use Reduction Act (TURA) of 1989 created the SAB to work with the Institute as described in Massachusetts General Laws, Chapter 21I, Section 6. The Institute may call on the SAB for scientific advice concerning TURA-related issues. For this project, the Institute will request that the SAB review the proposed screening criteria and provide comment and recommendations.

7.2 *Initial Alternatives Screening*

The purpose of the initial screening effort is to eliminate from further study any chemical alternatives that would pose a high risk to the environment or human health. All identified chemical alternatives will be screened based on the following criteria. If an alternative meets any of the following criteria, then it will be eliminated from further consideration as an appropriate alternative. It is important to note that, if no data associated with one or more of the screening parameters are available this chemical will not be screened out based on that parameter.

1. Persistence, Bioaccumulation and Toxicity

The US EPA in its Pollution Prevention Framework¹ references its PBT Profiler software for levels of concern for chemicals that are persistent, bioaccumulative or toxic (PBT). The highest level of concern expressed in the PBT profiler has been chosen for the ultimate screening of chemicals based on PBT. The PBT Profiler will be first run with the CAS number of each ingredient for each alternative. If a CAS number is not found by the PBT profiler, the chemical will be checked to see if it is inorganic or a mixture (PBT Profiler does not handle those substances); in some instances the chemical structure will be drawn and input into the software that way. If a chemical alternative exceeds the criteria for any **two** of the PBT categories it will be screened out from further assessment.

¹ Go to www.epa.gov/opptintr/p2framework. Criteria can be found at <http://www.pbtprofiler.net/criteria.asp>.

- a. Persistence: The US EPA PBT Profiler defines very persistent chemicals in terms of their half life² in specific media, as follows:

Environmental Medium	Half-Life
Water	> 180 days
Soil	> 180 days
Air	> 2 days ³
Sediment	> 180 days

If any **one** of the environmental media half lives is exceeded, the chemical is considered to be persistent for this study. We have included the “persistent” classification for half life in air since no “very persistent” criteria is established within the PBT Profiler.

- b. Bioaccumulation: As defined in the PBT Profiler, the US EPA considers a chemical very bioaccumulative if it has a bioconcentration factor (BCF⁴) greater than 5,000 (or log K_{ow} greater than 5)⁵.
- c. Aquatic Toxicity: According to the PBT Profiler, chronic aquatic toxicity values less than 0.1 mg/L indicate that a chemical is of high concern. The parameter used to evaluate for freshwater fish species toxicity is based on 30-day exposure duration, with the endpoint for evaluation expressed in ChV⁶ (mg/l). Toxicity data for other aquatic species are not included in this initial screening criterion. In many cases data for aquatic toxicity is not available. In this case the chemical will not be screened out based on toxicity, and can only be screened out as a PBT if the criteria for P and B are exceeded.

2. Carcinogenicity

For the purposes of this study, a chemical will be screened out if it is classified under one of the following classifications:

US EPA Classifications⁷:

Group A: Known Human Carcinogen

Group B1: Probable Human Carcinogen (Limited human evidence)

² Half-life is the length of time it takes for the concentration of a substance to be reduced by one-half relative to its initial level, assuming first-order decay kinetics.

³ Note that this value is classified as “persistent” rather than “very persistent” by the PBT Profiler

⁴ The bioconcentration factor (BCF) is a measure of the ability for a water-borne chemical substance to concentrate in fatty tissue of fish and aquatic organisms relative to its surroundings. EPA defines bioconcentration as the net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water through gill membranes or other external body surfaces (60 FR 15366). In general, chemicals that have the potential to bioconcentrate also have the potential to bioaccumulate. Because BCF values are much easier to measure (and estimate), the BCF is frequently used to determine the potential for a chemical to bioaccumulate.

⁵ This value (either the BCF or the equivalent log K_{ow}) is associated with highly bioaccumulative chemicals and is used as an initial screening value for this study.

⁶ ChV is the chronic (long-term) toxicity value to fish over the timeframe specified. This is the same as a chronic no-effect-concentration (NEC) and the geometric mean of the maximum allowable toxicant concentration (MATC). The MATC is the range of concentrations between the lowest-observed-effect concentration (LOEC) and the no-observed-effect concentration (NOEC).

⁷ Guidelines for Carcinogen Risk Assessment, September 24, 1986, Federal Register 51(185):33992-34003 or go to http://www.epa.gov/ncea/raf/car2sab/guidelines_1986.pdf

Group B2: Probable Human Carcinogen (Sufficient evidence in animals)

IARC Classifications⁸:

Group 1: Known Human Carcinogen

Group 2A: Probable Human Carcinogen

Sources of information: IUPUI (Indiana University - Purdue University - Indianapolis) EH&S Program web site, which lists carcinogen status by CAS number (http://www.ehs.iupui.edu/ehs/prog_carcinogen.asp)

3. More Hazardous Chemicals

If a chemical is listed on the Massachusetts Toxics Use Reduction (TUR) Science Advisory Board's list of More Hazardous Chemicals it shall be eliminated from consideration as a viable chemical alternative. The TUR program list of more hazardous chemicals⁹ has been developed by the TUR Program Science Advisory Board. 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.

The following table provides the list of TUR more hazardous chemicals and their associated CAS numbers:

Chemical Name	CAS #
Acrylamide	79-06-1
Acrylonitrile	107-13-1
Arsenic compounds	NA
Arsenic	7440-38-2
Cadmium compounds	NA
Cadmium	7440-43-9
Carbon tetrachloride	56-23-5
Chlorine	7782-50-5
Chloroform	67-66-3
Chromic acid	1333-82-0
Chromium compounds (+6)	NA
Cyanide compounds	NA
Dibromochloropropane	96-12-8
Dichloroethane	107-06-2
Diethylsulfate	64-67-5
Dimethyl formamide	68-12-2
Dioxane	123-91-1
Epichlorohydrin	106-89-8
Ethylene oxide	75-21-8
Formaldehyde	50-00-0
Hydrazine	302-01-2

⁸ Go to <http://www.cie.iarc.fr/monoeval/grlist.html> for more information on the International Agency for Research on Cancer (IARC) classification system for carcinogens

⁹ Massachusetts Toxics Use Reduction Institute "Categorization of the Toxics Use Reduction List of Toxic and Hazardous Substances" (1999), Methods and Policy Report No. 18.

Chemical Name	CAS #
Hydrogen cyanide	74-90-8
Hydrogen fluoride	7664-39-3
Lead	7439-92-1
Lead compounds	NA
Methylene bisphenyl isocyanate	101-68-8
Nitrobenzene	98-95-3
Nickel compounds	NA
Phosgene	75-44-5
Propyleneimine	75-55-8
Propylene oxide	75-56-9
Selenium and selenium compounds	7782-49-2 (elemental)
Silver chromate	7784-01-2
Sulfuric acid	7664-93-9
Sulfuric acid (fuming)	7664-93-9
Tetrachloroethylene	127-18-4
Toluene diisocyanate (mixed isomers)	26471-62-5
Trichloroethylene	79-01-6

7.3 *Prioritize Alternatives for Further Evaluation*

The purpose of the prioritization effort is to focus assessments on the most feasible alternatives for a particular use. Our intention at this stage is 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 will consider the following:

1. **Performance:** Known performance of alternative. Performance criteria should be specific to the use of the chemical/material, and may include items such as maintenance and durability as well as specific performance requirements. Consider the potential for future performance enhancements.
2. **Availability:** Number of suppliers/manufacturers that commercially provide the alternative. In addition, information about the volume of the alternative produced may be important (i.e., is the alternative available only in very small quantities).
3. **Manufacturing Location:** Is the product manufactured in Massachusetts or outside of Massachusetts? Products or materials manufactured in Massachusetts would receive a higher prioritization for evaluation as this may have a greater impact on the Massachusetts economy.
4. **Cost:** Current costs associated with the alternative compared to that of the hazardous chemical. Consider the potential for future cost reductions (e.g., economies of scale due to higher volume production). If available, consider other significant costs such as raw material costs, storage and handling costs, disposal costs, etc.
5. **Environmental, Health, and Safety:** Known environmental, health and safety risks or benefits compared to that of the hazardous chemical.
6. **Global Market Effect:** Information about pending or existing global restrictions that might materially affect the ability of an industry to market its products internationally. Since our world has become an increasingly global marketplace, taking into account the impact of

international marketability on a product is essential for sustained economic viability for most industry sectors.

7. **Other:** Other use specific criteria as appropriate. For example, in some instances multiple similar alternatives exist for a particular use. In this case one alternative that is representative of that type will be chosen for further study.

Additionally, if the initial alternatives screening, as described in Section 7.2, identifies a substance that exceeds the “median” level of concern for PBT as defined by the PBT Profiler, this will be noted and considered along with the above criteria. The Institute’s goal is to identify a list of alternatives for further evaluation that is achievable in the timeframe allotted.

7.4 *Conduct an internal review of alternatives information and screening*

The Institute will hold an internal meeting to review the information on alternatives and the screening out of unacceptable alternatives for each of the chemical's uses. The following will be discussed:

- Sources of information used for the screening and prioritization efforts;
- The appropriateness for criteria used; and
- Other information that would be helpful for screening and prioritization.

7.5 *Summarize screening and prioritization information of alternatives*

Based on the result of the internal review, the Institute will update the screening and prioritization information of alternatives for use by external stakeholders and experts.

8.0 Alternatives Prioritization Stakeholder Meetings

8.1 *Conduct successive stakeholder meetings*

The Institute will conduct one day-long series of successive chemical-focused stakeholder meetings with Massachusetts representatives from industry, NGOs, labor and government. This stakeholder meeting organization will allow those stakeholders or experts in attendance who are interested in all chemicals to attend the entire day, and those who have only an interest in one or more specific chemicals to attend only for those sections of the meeting.

The purpose of the meeting will be to accomplish the following:

- Provide information on the prioritization criteria developed for alternatives for chemicals;
- Review the list of alternatives developed by the Institute and our suggestions on alternatives warranting further study;
- Review uses and alternatives – depending on the number of likely feasible alternatives identified, the Institute may reduce the number of uses being evaluated; and
- Solicit input from stakeholders for each of the above topics.

Anticipated Outcome:

- Develop a list of priority uses and alternatives for further study – the Institute recognizes that each chemical may have a different balance of uses to be studied and alternatives per use to be studied.

The decision of how many uses and alternatives to study will be informed by our discussions with stakeholders as well as our ability to address options in a consistent, thorough and scientific manner in the time allowed.

8.2 *Finalize the list of alternatives to include in the alternatives assessment*

The list of uses and alternatives to be included in the alternatives assessment will be finalized and communicated to the stakeholders.

Phase III – Alternatives Assessment

9.0 Complete Assessment for High Priority Alternatives

9.1 *Compile data for high priority uses of chemical and its alternatives*

For each of the high priority uses of the chemical and for each identified priority alternative, the Institute will compile and assess data for the following four assessment categories. Appendix B provides detailed lists of the parameters to be studied.

- Technical/Performance (including longevity, key performance requirements, key physical characteristics and key quality parameters);
- Financial (including purchase price, availability of alternative and associated capital costs);
- Environmental (including PBT, environmental mobility and other environmental hazards); and
- Human Health/Safety (including acute and chronic human effects, other hazards such as flammability and corrosivity and exposure potential).

The Institute will use 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 (i.e., published) sources. Our primary source of this data will be the sources available from the National Library of Medicine's Toxicology Data Network (ToxNet)¹⁰.
- For human health, data based on human epidemiological studies will be used preferentially. Data based on tests of non-human sources will be used if human epidemiological data is not available. If neither human epidemiological data nor data based on non-human sources is available, data derived from models will be used; and
- If modeled data is to be used, the Institute will use models approved by the US EPA.

When presenting data for any of these categories, the Institute will rely on information obtained from authoritative bodies¹¹, with the most recent validated data presented first. When faced with multiple or conflicting data, the Institute will preferentially use data that has been referenced by a US governmental agency such as EPA, CDC and OSHA. Specific sources of information for individual parameters are provided in Appendix B.

¹⁰ Go to <http://toxnet.nlm.nih.gov/> for more information

¹¹ 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.

Not all data listed in Appendix B will be available for all chemicals being evaluated. However some of the data are more important for the purposes of this assessment and every effort will be made to obtain these data. These priority data are indicated in Appendix B by an asterisk (*).

Some of the assessment data will be specific for each use of the chemical and its alternatives, and some assessment data will be the same for various uses of the chemical and its alternatives. The Institute will devise a way of indicating which data are use-specific in its final reporting format.

Developing data on persistence, bioaccumulation potential and toxicity are deemed to be especially important from an environmental assessment standpoint. In order to present more comprehensive data, we will utilize the US EPA PBT Profiler¹² software for those chemicals for which there is no currently available persistence, bioaccumulation or toxicity data. The PBT Profiler evaluation will be conducted by a subset of the Assessment Team, consisting of chemists and chemical engineers who can 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 are identified and tested over the course of this study may also be used to augment the available information about each of the chemical substitutes evaluated.

9.2 Develop user experience data associated with alternatives

While conducting the technical/performance assessment, the Institute will identify any industry-specific performance requirements that must be met for each feasible alternative. One primary source of this information will be industry/user experience with the chemicals and their substitutes. Institute staff may contact and interview representatives from manufacturers, trade associations and customers who use the chemical or its derivatives.

Additionally, the Institute will look for readily available information on key life cycle considerations that may affect the feasibility of the alternative. This is not intended to be a comprehensive life cycle assessment. Rather, key life cycle considerations would include such issues as waste disposal limitations, energy usage required during manufacture, impact on product recyclability or reuse potential, etc. This information will be presented in the final report only when more than one source corroborates the data, and when it may materially impact the overall assessment of one alternative's feasibility.

9.3 Evaluation of data for high priority alternatives

The environmental, technical, financial and human health data obtained for each alternative will then be organized and evaluated to assess its feasibility as a substitute for the chemical and use. User experience and pertinent and reliable life cycle considerations will be included in this evaluation. The Institute will dedicate a subset of the overall project team to conducting this evaluation in order to assure consistency and quality of data and presentation.

It is important to recognize that the Institute will not be assigning a judgment of the preference of alternatives relative to each other or to the chemical and use they are replacing. No weighting factors will be provided when or if data are aggregated. Rather, all collected data will be presented along with guidance for interpretation (an Institute project to be completed subsequent to the completion of this study). This will allow the readers of our final report to determine for themselves, based on their specific requirements, which alternative (if any) is preferable.

¹² Go to <http://www.pbtprofiler.net/> for more information

9.3.1 Evaluating chemical alternatives

For purposes of this study, a chemical is 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 will be relatively straightforward, where information associated with the parameters in Appendix B are obtained, verified and presented in a way that maximizes usefulness to those looking for tools to help in designing products using alternative chemicals. This will be done primarily in a tabular or matrix format.

9.3.2 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 needs to be considered in the assessment in a manner similar to that used for individual chemicals (as above). The Institute will obtain environmental and human health information about each of the chemical constituents, and performance and cost information for the overall formulation when doing the assessment. If information on the mixture is available from a manufacturer’s MSDS, then that information will be used for available parameters.

For the purposes of this study, the Institute will focus on the primary constituents of each formulation being evaluated. Specifically, constituents present in amounts exceeding 1% will be included in the review. When formulation breakdowns are presented on associated MSDSs with ranges, the Institute will assume the average weight percentage of the range presented. This is the only time that a weighting factor will be included in our assessment of alternatives. As the EH&S factors associated with the constituents of a mixture are determined, their relative significance to the overall EH&S characteristic of the mixture will be determined based on the weight percent within the mixture.

The actual approach to evaluating the EH&S impact of a mixture will differ 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 will be added and the overall impacts of the combined chemicals will be assessed. If the health effects are different (e.g., one chemical is a CNS depressant, while another is a respiratory irritant), the effects will be evaluated separately based on the weight percentages of each constituent.¹³

9.3.3 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. Human-made materials like petroleum-based plastics are synthesized from chemicals.

In some cases the chemical being studied is 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, there may be opportunities to find alternative materials that are inherently more flexible, therefore bypassing 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.

¹³ This approach to mixtures is widely used in occupational and environmental health. See e.g. Craig, et al., “Recommended Default Methodology for Analysis of Airborne Exposures to Mixtures of Chemicals in Emergencies,” *Ann Occ Env Hyg* 14 (9): 609-17, 1999.

For this study the Institute will look 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 will not be a comprehensive life cycle assessment. Rather, when our research indicates that at a particular point in a material's life cycle there are important positive or negative impacts these will be mentioned qualitatively relative to the material being substituted. In this way, the reader can determine which materials satisfy their own particular needs.

9.3.4 Evaluating process alternatives

For the purposes of this study, 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 perchlorethylene 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 will be included in the study where appropriate, and their feasibility assessed qualitatively. When our research indicates that there are important positive or negative attributes or impacts relative to the substance being substituted, these will be mentioned.

9.3.5 Quality Assurance/Quality Control (QA/QC)

All EH&S data will be collected by one TURI staff member and independently evaluated by a second staff member. The initial data will be entered into a spreadsheet; this will include the chemical name and CAS number, the actual data, and the sources of the data. The second staff member will independently check the accuracy of the CAS number and consult the original data source. Whenever an inconsistency is encountered, the reviewer will consult with the collector of the original data and a consensus will be reached. Any unresolved conflicts will be brought to the Principal Investigator for final resolution.

Phase IV – Study Report

10.0 Statewide Economic Impact of Switching to Alternatives

An important component of the overall study funded by the Massachusetts Legislature is an analysis of potential impacts on employment level and economic competitiveness of the Commonwealth from adopting any alternative chemical or technology. Dependable economic predictions are lengthy and expensive to prepare, and specific economic data for the five targeted chemical alternatives and Massachusetts industry will not be available until late in the study. For this reason case material will be used to create a useful list of economic factors probably present. Further development of the influences, duration, dynamics, interactions, sector specificity or other characteristic of these economic factors will lead to useful tools for decisions about alternatives.

This evaluation will be completed using the following process:

1. Case materials will be created for the following sectors: formaldehyde in building materials, lead in electronics, and perchloroethylene in dry cleaning.
2. Ten experts in the economics of technology change from Associated Industries of Massachusetts, the Small Business Association, the Massachusetts Manufacturing Partnership, Tufts University, Northeastern University, the University of Massachusetts, the Economic Development Research Group, Tellus Institute, and the Environmental Management

Accounting Research & Information Center will be gathered for a facilitated discussion. Using the case materials, a list of economic factors and their influences will be developed.

3. A discussion summary and report draft will be shared with the group of experts for further comment and validation.
4. The final report will include a summary of the discussion, including viewpoints, limitations of this approach, and any useful frameworks or tables that can be offered.

11.0 Assessment Report

The report will be structured in a way that the reader can focus on specific chemicals if desired, or can use the entire document (see report content guidelines in Appendix C). The report structure will begin with an overall introduction to the study objectives and methods, then focus on the individual five chemicals for details about the assessment of the chemicals and their studied alternatives, and finally will provide a summary of the economic evaluation of the impact of the use of alternatives on the Massachusetts economy (see Section 10). The report will be synthesized into an executive summary that will be available individually or as part of the overall report.

In general, the Institute will make use of tables and graphs as much as possible to facilitate quick access and understanding of information used in this study. Appendices will be used for larger data sets that do not materially affect the reader's ability to understand our logic, but that may provide additional information for greater understanding. All relevant information will be provided, aggregated only as is appropriate for that particular section. However, significant data for one chemical's application may be quite different from that of another application or chemical

11.1 *Conduct internal review of draft report*

The draft report will be reviewed by internal reviewers for accuracy, completeness, adherence to the alternative assessment methodology outlined in this document, and consistency of language and presentation. The Institute will then update the draft report based upon the feedback provided by the internal reviewers.

11.2 *Conduct external review of draft report*

The Institute will establish a list of experts to conduct an external review of the updated draft report. Relevant sections of the draft report will be sent to selected experts and stakeholders for review. At least two weeks will be allowed for review and feedback from external parties.

The Institute will conduct the following steps to develop the final version of the report:

- Review feedback provided by external parties.
- Conduct follow-up with external parties as necessary to fully understand the feedback provided.
- Determine whether or not the draft report should be updated for each point provided by external reviewers.
- Update the draft version of the report as necessary.

11.3 *Publish final report*

The Institute will publish the final report in the following formats:

- Electronically, available on our website (www.turi.org)

- Hard copy bound reports. A limited number of printed reports will be created for dissemination to stakeholders, experts and key members of the Massachusetts Legislature, including all members of the Joint Committee on Environment, Natural Resources and Agriculture.
- Hard copy bound executive summary reports. This summation of the findings of our work will be provided to each member of the Massachusetts Legislature.

12.0 Report Out to Legislature

The Institute will present the results of this work to the Massachusetts Legislative body in the following ways:

1. Submission of the full written report
2. Submission of an executive summary
3. In person briefings

Phase V – Project Wrap Up and Outreach

Subsequent to presentation of our results to the Massachusetts Legislature the Institute will focus on filing and record keeping responsibilities associated with the study, including cataloging of documents and resources used to complete this study, publication and archiving of the report, etc.

Outreach activities will comprise an important part of the follow-up activities of this study. The Institute plans to prepare a case study that will summarize the methodology, the resources required, and the effectiveness of the approach for use by other government agencies interested in doing this type of work. In addition, the Institute intends to create a guidance document to assist users of the report in interpreting and utilizing the information provided therein.

APPENDIX A: Massachusetts Legislative Budget Item for Five Chemicals Study

FY06 Budget Item, from FY06 Budget Conference Report (House and Senate overrode Governor's veto of budget item 14 July 2005)

7100-0350

For an assessment at the Toxics Use Reduction Institute on the feasibility of adopting chemical or technological alternatives for the following toxic or hazardous substances:

**Lead,
Formaldehyde,
Perchloroethylene,
Hexavalent chromium, and
Di-(2 ethylhexyl) phthalate (DEHP);**

provided, that the assessment shall, for each named toxic or hazardous substance, identify:

- (1) **Significant uses** of the toxic substance in manufacturing, consumer products and any other applications;
- (2) **Potential human health and environmental impacts;**
- (3) Any **alternative chemicals or technologies**, both proven and emergent, and an analysis of their potential to serve as substitutes for any of the toxic or hazardous substances listed above, which shall include an assessment of:
 - (a) **Specific applications** of any alternative chemical or technology;
 - (b) **Potential impacts on the environment, human health, workers, employment level and economic competitiveness** of the commonwealth from adopting and implementing any alternative chemical or technology as substitutes;
 - (c) The **economic opportunities or feasibility of adopting** and implementing any alternative chemical or technology as a substitute including, but not limited to, consideration of the potential effects on capital, operating and production unit costs, and product price, to result from the substitution;

and provided further, that the Institute shall report its findings to the joint committee on environment, natural resources and agriculture by July 1, 2006

Note: emphasis added

APPENDIX B – Five Chemical Study Assessment Criteria/Sources of Information

Technical/Performance Assessment for Component/End-product

Technical/Performance Parameter	Measure/Metric	Sources of Information
<i>Component/End-product</i>		
Longevity/Life in Service	<ul style="list-style-type: none"> • Useful life of component/end-product • Shelf/storage life of component/end-product 	Manufacturer specifications
<u>Key</u> standards for component/end-product: safety, flammability, others (determined by chemical application)	Examples include: <ul style="list-style-type: none"> • UL 910 • DIN 4102 • ASTM E662 • ISO 6940 • IEC 332-3C • Others 	Industry associations, manufacturer specifications
* <u>Key</u> physical characteristics (determined by chemical application)	Examples include: <ul style="list-style-type: none"> • Size • Weight • Density • Color • Other 	Manufacturer specifications
* <u>Key</u> performance requirements (determined by chemical application)	Examples include: <ul style="list-style-type: none"> • Tensile strength • Tear strength • Compressibility • Flame retardant • Power requirements • Accuracy • Resistance to shock/vibration • Noise level • Operating temperature • Other 	Manufacturer specifications
* <u>Key</u> quality/reliability parameters (determined by chemical application)	Examples include: <ul style="list-style-type: none"> • Mean time between failure (MTBF) • Mean time to repair (MTTR) • Mean cycles between failure (MCBF) • Other 	Manufacturer specifications

Technical/Performance Parameter	Measure/Metric	Source of Information
<i>Manufacturing processes</i>		
Key performance characteristics for chemicals used in manufacturing processes	Examples include: <ul style="list-style-type: none"> • Energy consumption • Equipment requirements • Process change requirements 	Industry/manufacturing expertise

Financial Assessment

Financial Parameter	Measure/Metric	Sources of Information
<i>Primary Data</i>		
* Initial purchase price for chemical/alternative	Retail price	Price catalogues or websites of manufacturers, distributors, retailers, etc.
Initial purchase cost for end-product/component	Retail price	Price catalogues or websites of manufacturers, distributors, retailers, etc.
* Availability of chemical/alternative	Number of chemical suppliers	Chemical Economics Handbook ¹⁴ Special Chem ¹⁵
Availability of component/end-product	Number of component manufacturers	Industry associations
Capital costs	Cost for additional equipment required for switch to alternative	Industry experts, Industry trade associations
<i>Additional Data if Available</i>		
Key manufacturing costs for component/end-product	Energy consumption, maintenance costs	U.S. Department of Energy (Energy Information Administration) ¹⁶
Key operating costs during use of end-product	Energy consumption, maintenance costs	Energy Information Administration
Replacement rate	Product life, shelf/storage life	Product data sheets
Key end-of-product life costs	Disposal fee	Massachusetts DEP ¹⁷ Wastecap ¹⁸
Other intangible costs	Employee and consumer training costs	Industry trade associations, if available
	Regulatory compliance costs	TURA EPA
	Safety costs (e.g., PPE, control devices, special storage measures)	OSHA MSDS
	Insurance costs	Industry trade associations, if available

¹⁴ SRI Consulting, Menlo Park, CA

¹⁵ <http://www.specialchem.com/>

¹⁶ <http://www.eia.doe.gov/>

¹⁷ <http://www.mass.gov/dep/toxics/toxicsus.htm>

¹⁸ <http://www.wastecap.org/>

	Financial Parameter	Measure/Metric	Sources of Information
		Taxes, fees	Industry trade associations, if available
		Other <u>key</u> costs	Industry trade associations, if available
	Financial evaluation	Return on investment, internal rate of return, payback period, net present value	Manufacturer, customer, or industry financial requirements

Environmental Assessment

	Environmental Parameter	Measure/Metric	Concern Level	Sources of Information
<i>Persistence, Bioaccumulative, Toxicity (PBT)</i>				
*	Persistence/ Biological Degradability	Half-life (days): soil, marine, freshwater, air, sediments	High: Half-life in water, soil, sediment > 180 days Medium: between 60 and 180 days Low: < 60 days	HSDB ¹⁹ PBT Profiler ²⁰
*	Bioaccumulation	<ul style="list-style-type: none"> Log K_{ow} Bioconcentration Factor (BCF) 	High: BCF > 5,000 Medium: BCF between 1,000 and 5,000 Low: BCF < 1,000	HSDB PBT Profiler
*	Aquatic Toxicity - Acute	<ul style="list-style-type: none"> Fish 96 hour LC₅₀, Daphnid 48 hour LC₅₀, Algae 72 or 96 hour EC₅₀ 	High: Value is < 1 mg/L Medium: Value is between 1 and 100 mg/L Low: Value is > 100 mg/L	HSDB
*	Aquatic Toxicity - Chronic	<ul style="list-style-type: none"> Fish 30 day ChV, Daphnid ChV or 16 day EC₅₀, Algae ChV 	High: Value is < 0.1 mg/L Medium: Value is between 0.1 and 10 mg/L Low: Value is > 10 mg/L	HSDB PBT Profiler
	Water Quality	µg/l	Depends on the chemical and the water source (e.g., drinking water, ground water, surface water)	HSDB U.S. EPA Water Quality Criteria ²¹
	Hazardous Air Pollutants	Yes or No	Depends on the chemical	National Emission Standards for Hazardous Air Pollutants ²²
<i>Environmental Mobility</i>				
	Affinity for Water	Water solubility (mg/l)	NA - Provides indication of ability of chemical to migrate into water	HSDB PBT Profiler ²³ MSDS

¹⁹ Hazardous Substances Data Bank, National Library of Medicine [<http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB>]

²⁰ US EPA PBT Profiler [<http://www.pbtprofiler.net>]

²¹ US EPA [http://oaspub.epa.gov/wqsdatabase/wqsi_epa_criteria.rep_parameter]

²² US EPA [<http://www.epa.gov/ttn/atw/188polls.html>]

²³ experimental data included with PBT Profiler (not modeling results)

Environmental Parameter	Measure/Metric	Concern Level	Sources of Information
Affinity for Soil	K_d (soil sorption coefficient)	NA - Provides indication of ability of chemical to become bound into the soil matrix	HSDB PBT Profiler MSDS
Affinity for Sediments	K_{oc} (organic carbon partition coefficient)	NA - Provides indication of ability of chemical to become bound into sediments	HSDB PBT Profiler MSDS
Affinity for Lipids	K_{ow} (octanol-water partition coefficient)	NA - Provides indication of ability of chemical to become adsorbed into fatty portions	HSDB MSDS
<i>Other Environmental Hazards</i>			
Degradation Products	Degradation products of concern	Literature indicates potential env. or human health effect due to exposure to degradation products	Peer-reviewed scientific literature
Biodiversity	Endangered species affected	Literature indicates potential harm to regionally susceptible species	Peer-reviewed scientific literature
Ozone Depleting Chemicals (ODC)	CFC, HCFC, halons, carbon tetrachloride, methyl bromide and bromochloromethane	Listed as a Class 1 or Class 2 ODC	World Meteorological Association ²⁴
Greenhouse Gases	Global warming potential (GWP) of the chemical compared to that of CO ₂	GWP > 1	Third Assessment Report values, Intergovernmental Panel on Climate Change (IPCC) ²⁵

Human Health and Safety Assessment

Human Health and Safety Parameter	Measure/Metric	Concern Level	Sources of Information
<i>Acute Human Effects</i>			
* Lethal Dose/Concentration	Inhalation LC50 (ppm) Oral LD50 (mg/kg) Dermal LD50 (mg/kg)	Lower than chemical of concern	HSDB RTECS

²⁴ *The Scientific Assessment of Ozone Depletion, 2002*, A report of the World Meteorological Association's Global Ozone Research and Monitoring Project, accessed via EPA's web site at <http://www.epa.gov/ozone/ods.html> and www.epa.gov/ozone/ods2.html

²⁵ Table 4, Greenhouse Gases and Global Warming Potential Values: Excerpt from the Inventory of US Greenhouse Emissions and Sinks: 1990-2000, USEPA, April 2002. (accessed via www.epa.gov/ozone/ods.html)

	Human Health and Safety Parameter	Measure/Metric	Concern Level	Sources of Information
*	Immediately Dangerous to Life or Health (IDLH)	ppm (gas or vapor) mg/m ³ (particle)	Lower than chemical of concern	NIOSH
*	Worker Exposure Limit	<ul style="list-style-type: none"> Permissible exposure limit (PEL) (ppm, gas or vapor) (mg/m³, particle) Recommended exposure limit (REL) (ppm or mg/m³) Threshold limit value (TLV) (ppm or mg/m³) 	[Use the lowest of the three]	NIOSH American Conference of Govt. Industrial Hygienists (ACGIH) ²⁶
	Irritation	Dermal Ocular Respiratory	Positive evidence	HSDB NIOSH MSDS
Chronic Human Effects				
	Metabolites	Metabolites of concern	Literature indicates potential env. or human health effect due to exposure to metabolite	Peer-reviewed scientific literature
	Reference Dose (RfD)	mg/kg/day	Lower than chemical of concern	HSDB IRIS
*	Carcinogenicity	<ul style="list-style-type: none"> U.S. EPA Group A, B1, B2, C, D, E, IARC Group 1, 2A, 2B, 3, 4 	High: Known or Probable – EPA: A, B1, B2 IARC: 1, 2A Medium: Possible – EPA: C, IARC: 2B Low: Unclassifiable or Not Likely – EPA: D, E, IARC: 3, 4	EPA ²⁷ , International Agency for Research on Cancer (IARC) ²⁸
	Skin Sensitization	Yes/No	Positive evidence	Sax ²⁹ HSDB MSDS
	Mutagenicity	Yes/No	Listed with an R46 or R68 EU risk phrase	ESIS ³⁰ CA Proposition 65 RTECS ³¹
	Endocrine Disruption	any indication	Positive evidence in the peer-reviewed literature	Peer reviewed scientific literature

²⁶ ACGIH (2005): TLVs and BEIs Based on the documentation of the threshold limit values for chemical substances and physical agents & biological exposure indices.

²⁷ U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program List of known (<http://ntp.niehs.nih.gov/ntp/roc/eleventh/known.pdf>) and reasonably suspected (<http://ntp.niehs.nih.gov/ntp/roc/eleventh/reason.pdf>) carcinogens

²⁸ <http://www-cie.iarc.fr/monoeval/crthall.html>

²⁹ Sax, N. I. and Lewis, R. J., Sr., *Rapid Guide to Hazardous Chemicals in the Workplace*, Van Nostrand Co., Inc., 1986.

³⁰ European Chemical Substances information System - Annex I to Directive 67/548/EEC on Classification and Labeling of Dangerous Substances <http://ecb.jrc.it/esis/esis.php?PGM=hpv>

³¹ RTECS will be used only if information is not available from other sources and is critical to assessment

	Human Health and Safety Parameter	Measure/Metric	Concern Level	Sources of Information
	Reproductive or Developmental Toxicity	Yes/No	Listed as an R60 or R61 EU risk phrase	ESIS, California Proposition 65 ³² RTECS ³³
	Target Organs	<ul style="list-style-type: none"> Identification of target organs 	Positive evidence	HSDB NIOSH MSDS
<i>Other Physical Characteristics</i>				
*	Corrosivity	pH scale	pH < 2 pH > 12	NFPA ³⁴ HMIS ³⁵ MSDS
*	Reactivity	0, 1, 2, 3, 4	2, 3 or 4	NFPA HMIS MSDS
*	Flash Point	Degrees Celsius	<38°C	MSDS
	Flammability			NIOSH
*	Vapor Pressure	mm Hg at 25°C	Higher than chemical of concern	HSDB NIOSH PBT Profiler MSDS
<i>Exposure Potential</i>				
	Dermal Absorption	Yes/No		HSDB; NIOSH; MSDS

³² www.oehha.ca.gov/prop65/prop65_list/Newlist.html

³³ RTECS will be used only if information is not available from other sources and is critical to assessment

³⁴ <http://safety.science.tamu.edu/nfpa.html>

³⁵ <http://www.paint.org/hmis/index.cfm>

APPENDIX C: Five Chemical Study Report Table of Contents

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- Priority Alternatives for Use 1
- Other Alternatives Information

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- Alternatives Screened Out
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- Environmental Assessment for all alternatives
- Human Health Assessment for all alternatives
- Summary of Alternatives for Use 1

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- Economic Assessment for all alternatives
- Environmental Assessment for all alternatives
- Human Health Assessment for all alternatives
- Summary of Alternatives for Use 2

3.4.3 Use 3 Report

- Technical Assessment for all alternatives
- Economic Assessment for all alternatives
- Environmental Assessment for all alternatives
- Human Health Assessment for all alternatives
- Summary of Alternatives for Use 3

3.5 Lead Assessment Summary

8. Statewide Impact on Massachusetts Economy