The Massachusetts Toxics Use Reduction Institute
University of Massachusetts Lowell

Decision-Making under TURA: Process Overview and Reference Guide

Toxics Use Reduction Institute

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Process Overview and Reference Guide
TURI Methods and Policy Report #28
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The Toxics Use Reduction Act (TURA) Program is implemented by the following state agencies:

Massachusetts Department of Environmental Protection (MassDEP)
One Winter Street, Boston, MA 02108-4746; 617-292-5500
www.mass.gov/dep/toxics/toxicsus.htm

Certifies Toxics Use Reduction (TUR) Planners, receives and reviews toxics use reports submitted by companies, provides guidance, takes enforcement actions, and collects chemical use data and makes it available to the public.

Office of Technical Assistance & Technology (OTA)
100 Cambridge Street, Suite 900, Boston, MA 02114; 617-626-1060
www.mass.gov/eea/ota

A non-regulatory agency within the Executive Office of Energy and Environmental Affairs that provides free, confidential, on-site technical and compliance consultations to Massachusetts businesses and institutions.

Toxics Use Reduction Institute (TURI)
University of Massachusetts Lowell
Wannalancit Mills - 5th Floor, Lowell, MA 01854-2866; 978-934-3275
www.turi.org

Provides education, training, and grants for Massachusetts industry and communities; sponsors research and demonstration sites on cleaners, safer materials and technologies; provides policy analysis; and manages the TURA Science Advisory Board.

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1. Introduction

The Massachusetts Toxics Use Reduction Act (TURA) list of toxic or hazardous substances is designed to be updated over time based on new developments in scientific knowledge, as well as policy considerations. TURA provides for a multi-stage decision-making process involving participation by a Science Advisory Board (SAB); a stakeholders' Advisory Committee; program staff at three implementing agencies (the Toxics Use Reduction Institute, the Office of Technical Assistance and Technology, and the Department of Environmental Protection); and an Administrative Council composed of government agency heads or their representatives. The roles and responsibilities of each of these bodies are described in Appendix A.

This document provides an overview of this decision-making process and serves as a guide for three key areas of decision-making, including adding substances to, or removing substances from, the TURA list of toxic or hazardous substances; designating higher and lower hazard substances within the larger TURA list; and designating priority user segments. This document has been designed as a reference guide for members of the Science Advisory Board, the Advisory Committee, and the Administrative Council.

2. Core Principles of the TURA Program

The core principles of the TURA program are derived from the statutory definition of toxics use reduction, and from the policy goals of TURA, as stated in the Preamble to the Act as adopted in 1989. These policy goals are listed in Appendix I.

Toxics use reduction is defined as:

> "in-plant changes in production processes or raw materials that reduce, avoid, or eliminate the use of toxic or hazardous substances or generation of hazardous byproducts per unit of product, so as to reduce risks to the health of workers, consumers, or the environment, without shifting risks between workers, consumers, or parts of the environment."

Several key principles are expressed in this definition:

- ***Focus on use.*** Many environmental statutes focus strictly on emissions or waste management. The TURA program, in contrast, focuses upstream in the manufacturing process where chemicals are used and wastes are first generated. The definition of toxics use reduction guides those implementing the program to protect human and environmental health by reducing or eliminating the use of toxics wherever possible.

- ***Focus on hazard.*** Many environmental statutes rely on qualitative or quantitative risk assessments as a basis for deciding what measures are necessary to protect human health and the environment. In contrast, under TURA, the focus is on hazard. Hazard is an inherent characteristic of a chemical, such as carcinogenicity, neurotoxicity, or mutagenicity. (See Appendix C for a more complete list of hazards.) The purpose of TURA is to reduce or eliminate hazardous chemicals. There is no requirement to prove that exposure will occur, or to calculate risk, in order to take action to eliminate or reduce a

hazard. The relationship between hazard and risk under TURA is discussed further in section 4.7.

- ***Protection of workers, consumers, and the environment.*** An industrial facility that has no emissions to the environment may still expose workers to toxic substances used within the facility, and may expose consumers to toxic substances incorporated into the product. The definition of toxics use reduction explicitly creates a mandate for the program not only to prevent ambient environmental exposures resulting from industrial emissions, but also to take worker and consumer exposures into account.

- ***Avoiding risk shifting.*** The definition incorporates the concept of avoiding risk shifting among environmental media or among groups of people.

Figure A: TURA decision-making process: Decisions related to the list of Toxic or Hazardous Substances *

* Question may be initiated by MA stakeholders, TURA program staff, Board, Committee, Council, or statutory requirement.
** As needed, the Council may provide a formal statement of a specific question on which it requests SAB input.
*** In many cases, the Advisory Committee also provides input earlier in the process as well.

3. Decision-making steps

Each decision made by the TURA program goes through several steps, ensuring that multiple viewpoints are represented and a wide range of relevant information is taken into account.

All meetings of the SAB, the Advisory Committee, and the Administrative Council, as described below, are open to the public.

The text below describes the process for two types of decisions: decisions related to the list of Toxic or Hazardous Substances (including listing and delisting decisions as well as designation of higher or lower hazard substances); and decisions related to the designation of a Priority User Segment. Figures A and B provide a schematic representation of these processes, respectively.

3.1 Decisions related to the list of Toxic or Hazardous Substances

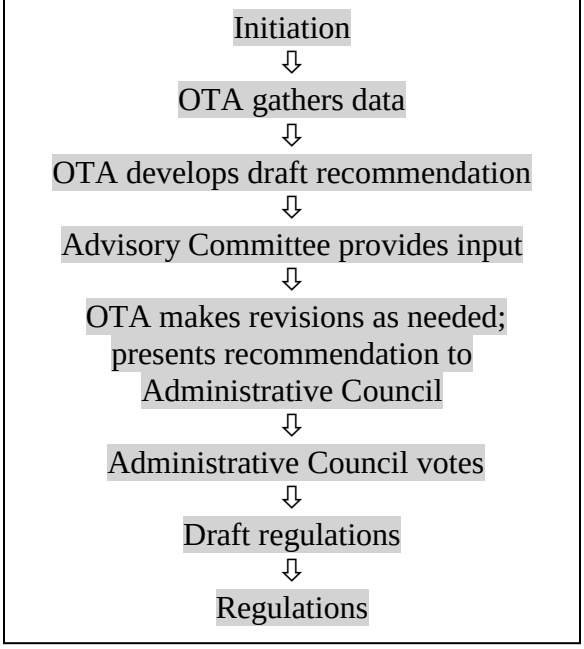
Initiation. A variety of actors may propose a question for consideration by the TURA program. Massachusetts stakeholders, including industry representatives, advocacy organizations, and others, may submit petitions for listing or delisting of substances or the designation of higher or lower hazard substances. The SAB, Advisory Committee, and Administrative Council, as well as TURA program staff, may also propose issues for consideration. Finally, in some

instances the program is obligated by law to consider specific questions.

Once a topic has been identified for consideration, the SAB develops a recommendation. As needed, in some cases the Administrative Council makes a formal request for the SAB's recommendation. The Advisory Committee may also provide input to the Administrative Council at this point. Toxics Use Reduction Institute staff members conduct background research and provide a standardized set of information to the SAB for consideration.

Science Advisory Board Recommendation. The SAB develops its recommendations about the hazards of chemicals based strictly on scientific considerations, without considering policy implications, and finalizes these recommendations through a vote. The SAB recommendation is recorded along with information about the number of members who voted for or against the recommendation, and a brief description of the reasons for the SAB's decision. For additional information on the SAB's deliberative process, see Appendices B, C, and D.

Figure B: TURA decision-making process:
Designation of a Priority User Segment



Policy Analysis. Once the SAB has provided a recommendation, the Toxics Use Reduction Institute (TURI) works with the other implementing agencies to research policy implications. The Institute documents these policy considerations, along with the SAB recommendation, in a policy analysis. The policy analysis includes the Institute's recommendation on the issue, along with information the Institute considers relevant to the decision. For an overview of topics that may be included in a policy analysis, see Appendix E. TURI takes the SAB recommendation into account in developing its own recommendation, but may reach a conclusion different from that of the SAB. For additional information on the topics covered in a typical policy analysis, see Appendix E.

Advisory Committee Input. The Institute presents the Policy Analysis to the Advisory Committee. The Advisory Committee provides input and recommendations, and may offer suggestions for additional research by Institute staff. The Advisory Committee does not hold votes. However, the TURA Executive Director summarizes the Committee's comments, including consensus statements when appropriate, for presentation to the Administrative Council. Advisory Committee members may also submit their own individual feedback to the Council if they wish. TURI makes revisions to its policy analysis, based on the Advisory Committee's comments, if necessary.

Administrative Council Decision and Development of Regulations. Finally, the Institute provides the policy analysis to the Administrative Council. Based on the policy analysis as well as any comments from the Advisory Committee, the Administrative Council makes a decision through a

vote. This decision is promulgated in draft regulations by the Executive Office of Energy and Environmental Affairs. After a public comment period and incorporation of any resulting changes, the regulations are finalized.

3.2 Decisions related to designation of a Priority User Segment

The specifics of the Priority User Segment designation process are the same as those described above for decisions related to the list of Toxic and Hazardous Substances, except for the elements noted below:

Initiation. The initiation of this decision-making process is determined by statutory time lines. A Priority User Segment can be designated only within a four-year window that starts with the designation of a Higher Hazard Substance. The statute does not require that every Higher Hazard Substance be analyzed for possible designation of a Priority User Segment, but in practice, the program does conduct some analysis for each substance.

OTA recommendation. By statute, OTA is responsible for developing recommendations on Priority User Segment designation. OTA develops this recommendation in consultation with the other implementing agencies as well as the Advisory Committee. OTA then presents its final recommendation to the Administrative Council.

4. Decision-making under Uncertainty

Many decisions undertaken by the TURA program involve elements of scientific or policy uncertainty. Examples of scientific uncertainty include lack of data for a specific human health or environmental endpoint, conflicting epidemiological studies, or lack of information about the mechanism that underlies a given health effect. Policy uncertainty may include lack of information on the precise number of facilities that will be affected by a given decision, or uncertainty about the future monetary cost of a given chemical or technology.

4.1. Scientific uncertainty. Because scientific knowledge is constantly evolving, a certain amount of scientific uncertainty must invariably be taken into account. Science Advisory Board members are responsible for making the best possible recommendation based on the full range of information available to them. This includes, but is not limited to, the chemical-specific information that is provided to the SAB by Institute staff, stakeholders and petitioners. Members also bring their broader knowledge of chemical toxicity issues to bear on situations in which individual data points are missing or equivocal, and apply existing analytical frameworks to develop a robust scientific viewpoint in the face of incomplete information.

4.2. Types of scientific information. In general, the SAB relies on scientific information according to the following hierarchy.

- The preferred source of information, where available, is consensus values from authoritative bodies such as the International Agency for Research on Cancer (IARC), the US Environmental Protection Agency (EPA), and others.
- The second level of information the SAB may consider includes robust toxicological and epidemiological studies. In considering the relevance of such studies, the SAB considers

the over-all weight of the evidence, as well as how current the studies are, the robustness of their methodology, the frequency with which they are cited, and other factors.

4.3. Data gaps. In developing its recommendations the SAB reviews available data on a number of standard health and environmental endpoints. However, for many chemicals, data are lacking for one or more of these endpoints. Thus, SAB members must frequently decide what level of importance to assign to a missing data point, and what assumptions to use in the absence of data.

- It is possible to make a well-informed decision with incomplete data. Modeled data, structure activity relationships, data on similar chemicals, and expert judgment about importance of a given endpoint and exposure routes for that chemical can all be used to inform decision making.
- Where available data indicate a hazard, remaining data gaps may not be significant. For example, if a substance is a carcinogen, the SAB can make a recommendation based on this information, even if no data are available on other health endpoints such as reproductive toxicity or neurotoxicity.
- In some cases, available data suggest that a substance is relatively safe but significant data gaps remain. In this case, the SAB must decide how to interpret the lack of data. In these situations, SAB members consider the information provided by existing data; information about other, similar chemicals; contextual information about the extent to which the chemical has been tested for various endpoints; and information about the endpoint itself.
    - For example, if a newly developed solvent has not been tested for neurotoxicity, the SAB may determine that the data gap is a major concern, because solvents are frequently toxic to the nervous system. In contrast, if an LD50 has not been calculated for a chemical that by other measures has low toxicity, the SAB may determine that the lack of this information is not a basis for concern, because it may be reasonably concluded that the LD50, if calculated, would be high.
    - As of 2009, the Administrative Council has requested that the SAB explicitly address any significant data gaps, providing information on whether a given data gap is a concern, and explaining why or why not.

4.4. Conflicting studies. Many other factors can also contribute to scientific uncertainty. Results from several studies may conflict with one another. A well-studied chemical generally has multiple test results for each health or environmental endpoint. Animal toxicological study results may vary depending on the animal studied and the test protocol employed. Different studies of the same chemical may yield both positive and negative results for a given health effect. (Positive results are those that show an effect; negative results are those that do not show an effect.) In addition, human epidemiological studies commonly produce widely varying results, and may show no positive associations while animal toxicological studies indicate likely toxic effects. All of these situations require critical assessment by experts to determine which are the more applicable and robust studies and results.

It is important to note that where toxicological or other evidence suggests that a chemical is associated with an adverse health effect, the absence of epidemiological data confirming this effect is not a basis for discounting the effect. Epidemiological evidence may, however, increase the level of concern or certainty about a particular endpoint.

4.5. Endpoints without fully standardized test methods. Another common source of uncertainty is a lack of information on an endpoint of concern. For example, substantial information is available on endocrine disruption, but there is a lack of widely agreed upon test methods and standardized listings of endocrine disrupters similar to those available for carcinogenicity. In this and similar cases, where consensus values from authoritative bodies are generally not available, the SAB relies more heavily on robust studies, emerging information and expert judgment.

4.6. Uncertainty about policy and economic factors. Just as the SAB almost always faces some amount of scientific uncertainty, the Institute develops its recommendations in a context of uncertainty about additional, non-science factors, including policy and economic considerations. For example, when predicting the number of facilities that are likely to be affected by a higher hazard designation, the Institute draws upon several data sources as well as input from the Office of Technical Assistance and Technology (OTA) and the Department of Environmental Protection (MassDEP). However, it is impossible to know with certainty how many Massachusetts facilities are using the chemical in question, since most chemical uses are not reportable except under TURA. Thus, program staff members use their professional experience to develop the best possible estimates based on the available data.

4.7. Hazard vs. risk in decision-making. In making policy decisions related to toxic chemicals, it is necessary to distinguish between the concepts of *hazard* and *risk.*

The term *hazard* refers to the inherent properties of a chemical that has the potential to harm people and/or the environment. For example, the statement that "Chemical X is a carcinogen" is a statement of hazard. In contrast, *risk* is a function of both hazard and exposure. The same chemical could be associated with a relatively low risk in one setting, and pose relatively high risks in another.

Some environmental regulations use qualitative or quantitative risk assessment as the basis for decision-making under uncertainty. These regulations begin by asking the question, "What is an acceptable level of exposure, such that there is no significant risk to public health and the environment?" They then use quantitative risk assessment to estimate whether a given activity poses a significant risk. Quantitative risk assessment combines estimates of hazard with estimates of exposure to derive an estimated risk of a specific health or environmental endpoint. For example, a quantitative risk assessment could be used to estimate the number of cancers that may result from the use of a specific chemical in industry.

In contrast, the TURA program does not use quantitative risk assessment as a basis for decision-making. Rather, the TURA program looks for ways to reduce or eliminate hazards. The underlying principle is that eliminating a hazard also eliminates risk posed by chemicals that are used in a variety of settings.

Use of hazard information under TURA. The Science Advisory Board makes recommendations primarily on the basis of hazard. If the SAB considers a substance to be toxic or hazardous, it recommends the substance for inclusion on the TURA list regardless of whether significant exposure scenarios have been identified. Similarly, the SAB recommends substances for higher or lower hazard status based on their inherent hazard, not based on exposure scenarios.

Use of exposure information under TURA. Although hazard is the primary consideration under TURA, exposure may be considered in some circumstances. In general, exposure information may raise, but not lower, the level of concern about a chemical under TURA.

- If there is evidence of widespread public or occupational exposure to a chemical, this raises the level of concern about a substance. In the expert judgment process, individual SAB members draw upon the full range of their experience and knowledge, including information about exposure scenarios.
- Exposure information can be a basis for additional concern about a substance, but not for overlooking hazard. For example, if a substance is highly hazardous, the fact that it is used within a closed system does not alter the hazard assessment. A substance cannot be removed from the TURA list based on an expectation of low exposures. However, if a substance is of medium hazard, but is used in ways that lead to high potential exposures, exposure information may be a basis for increased concern.
- Exposure scenarios may also be taken into account in the policy analysis phase of the decision-making process. For example, in selecting substances to propose for a higher hazard designation, the Institute may propose prioritizing a substance with known exposure scenarios of concern.

4.8. The role of precaution in decision-making under uncertainty. A precautionary approach is one which practices caution to avoid potential future harm even if some scientific information about that harm is lacking. In 2009, the Administrative Council requested that TURI provide background information and references on the precautionary principle as an aid to Council deliberations. A brief overview is provided here, and additional information is provided in Appendix F.

At the United Nations Conference on Environment and Development, held in Rio de Janeiro in 1992, participating nations signed on to the Rio Declaration on Environment and Development. The Rio Declaration affirms a commitment to application of the precautionary approach, and defines it as follows:

> "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[1]

A related definition was included in the 1998 Wingspread Statement on the Precautionary Principle:

> "When an activity raises threats of harm for human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[2]

[1] Rio Declaration on Environment and Development, The United Nations Conference on Environment and Development, Rio de Janeiro 1992, Principle 15. Available at http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm.

[2] Wingspread Statement on the Precautionary Principle, 1998. Available at http://www.sehn.org/wing.html.

A number of international treaties and certain laws in the European Union state an explicit commitment to applying the precautionary principle in decision making. Within the US, some federal laws implicitly take a precautionary approach. The Food Drug and Cosmetics Act's requirement that all drugs be tested prior to being placed on the market is an example of a precautionary approach.

A precautionary approach is inherent in the design of the TURA program because TURA regulates chemicals based primarily on hazard, not potential or actual exposure. In other words, the TURA program considers how a chemical could affect human health and the environment in the event of exposure, but does not rely on information on actual exposure scenarios.

Appendix A: Statutory Responsibilities of the Science Advisory Board, Advisory Committee, and Administrative Council

This appendix describes the role and responsibilities of the Science Advisory Board, the Advisory Committee, and the Administrative Council. Relevant text from the TURA statute, MGL 21I, is shown in quotes.

Science Advisory Board

The statute created a Science Advisory Board (SAB) to work with the Institute. The SAB's primary role is to provide recommendations to the Institute on the addition or deletion of chemicals from the TURA list, and on the hazard categorization of the TURA list. In addition, the Institute may consult with the SAB for scientific or technical advice concerning other TURA-related issues. The SAB is managed by the Institute.

The SAB provides technical and scientific advice only. It does not provide advice on policy issues.

> "There shall be a Science Advisory Board associated with the Institute consisting of eleven members appointed by the governor, three members shall be nominated by the secretary of the executive office of environmental affairs, three members shall be nominated by the director of the Institute, three members shall be nominated by the director of economic development, one member shall be nominated by the director of labor and workforce development and one member shall be nominated by the secretary of the executive office of health and human services. Four of the initial appointees shall serve for an initial term of one year, four of the initial appointees shall serve for an initial term of two years, and all other appointees shall serve for three year terms. Each member shall have appropriate academic or professional experience. The institute shall consult with the board on issues including, but not limited to, additions and deletions to the toxic or hazardous substance list established in section 9 and the designation of substances as higher hazard substances and lower hazard substances. The members of the board shall serve without compensation, except that they may be reimbursed for out-of-pocket expenses incurred in the course of performing their duties as board members."

Advisory Committee

The Advisory Committee is composed of stakeholder representatives. Its role is to provide advice to the Administrative Council, reflecting the perspectives and expertise of a range of stakeholders.

> "(F) The chairperson of the council shall appoint an advisory committee to the council including, but not limited to, the attorney general, or his designee; 2 persons representing statewide environmental organizations; 2 persons representing organized labor; 4 persons representing businesses in the commonwealth, including 2 representatives of small businesses; 1 person certified as a toxics use reduction planner; 1 person representing a water authority; 2 persons representing a statewide health policy advocacy organizations and 2 members of the general public, 1 of whom shall be a citizen who has been active in a local toxics-related environmental organization."
>
> <u>Ad hoc advisory committees</u>
> "(G) The council shall, whenever it considers it necessary or favorable, establish ad hoc committees. The chairperson of the council, subject to the approval of the majority of the Council, shall appoint members of ad hoc committees. Membership of the ad hoc committees shall not be limited to members of the advisory board."

Administrative Council

The Administrative Council makes TURA program decisions, based on input from the advisory bodies and the implementing agencies. The Council is also mandated to provide input on toxics policy in Massachusetts more broadly. The statute defines the Council's responsibilities as follows.

> Coordination of toxics laws and regulations
> "(A) By January 1, 1991, and on an annual basis thereafter, the council shall identify all federal or state laws or regulations pertaining to chemical production and use, hazardous waste, industrial hygiene, worker safety, public exposure to toxics, and releases of toxics into the environment. The council shall promote increased coordination of efforts to enforce these laws and regulations and also determine how state programs should be coordinated to promote most effectively toxics use reduction in the commonwealth."
>
> Coordination of toxics reporting
> "(B) The council shall, by January 1, 1991, identify all state agency and POTW requirements for reporting on chemical or hazardous substance production, use, release, disposal, and worker exposure and to the maximum extent practicable shall make recommendations to said state agencies and POTW operators in order to standardize, consolidate and coordinate these reporting requirements to minimize unnecessary duplication and provide for up-to-date and consistent information about manufacturing, worker exposure, distribution, process, sale, storage, disposal, release or other use of chemicals on a facility, regional and statewide basis."
>
> Authorization for rulemaking
> "(C) The council shall adopt, and from time to time amend or repeal, rules and regulations which it deems necessary for the proper administration of its responsibilities pursuant to this chapter."
>
> Toxics use reduction policy recommendations and annual report
> "(D) The council shall annually make policy recommendations in a report to the governor regarding toxics use reduction, the implementation of this act, including a detailed report of the expenditures made from the Toxic Use Reduction Fund, a summary of its deliberations and actions regarding its designation of substances as higher hazard substances or lower hazard substances and the achievement of increased toxics use reduction, and shall file a copy of this report with the clerk of the House of Representatives and the clerk of the Senate."
>
> Comment on proposed regulations
> "(E) In order to promote and effect toxics use reduction, the council may comment on all proposed regulations pertaining to toxics production and use, hazardous waste, industrial hygiene, worker safety, public exposure to toxics, or releases of toxics into the environment prior to their promulgation."

Relationships among the Implementing Agencies, the Advisory Bodies, and the Administrative Council

The decision-making process for the TURA program is designed to maintain clear distinctions among the functions carried out by each entity. As described above, the SAB provides scientific input; the Advisory Committee provides stakeholder input; and the Administrative Council synthesizes the input from the advisory bodies as well as the implementing agencies in order to make policy decisions. The program is designed to provide for regular communication among all of these entities. However, each entity develops its recommendations and positions independently.

All three of the TURA implementing agencies interact with both the Advisory Bodies and the Administrative Council, as follows.

- *Science Advisory Board*
  - TURI staff members coordinate the activities of the SAB. This includes convening and facilitating SAB meetings, collecting scientific information requested by the SAB for review, and documenting SAB recommendations.
  - TURI, DEP and OTA each have an agency liaison who participates in SAB deliberations. They participate in discussion, but are not formal board members and do not have a vote.

- *Advisory Committee*
  - The TURA Program Executive Director, who is currently also the director of OTA, coordinates the activities of the Advisory Committee. This includes convening and facilitating Advisory Committee meetings, providing background information, documenting meeting outcomes, and communicating Advisory Committee comments and recommendations to the Administrative Council.
  - TURI, OTA and DEP staff members present information and draft recommendations to the Advisory Committee as appropriate, solicit comments and recommendations, and follow up on Committee recommendations for further research.

- *Administrative Council*
  - The TURA Program Executive Director coordinates the activities of the Administrative Council. This includes convening Council meetings, providing information to the Council, documenting meeting outcomes, and drafting, revising, and promulgating regulations based on Council decisions.
  - TURI, OTA and DEP staff members conduct background research and present information and recommendations to the Administrative Council, according to their responsibilities.
  - The Commissioner of DEP or the Commissioner's designee is a member of the Administrative Council.
    - It should be noted that DEP's role at the Administrative Council is distinct from its *ex officio* role at the SAB. The DEP liaison to the SAB comments on the interpretation of scientific data. In its role at the Administrative Council, the DEP representative is a voting member, and provides input on policy implications of a decision.

Appendix B: Science Advisory Board Decision Making Process

The Science Advisory Board (SAB) develops recommendations based on scientific criteria only, without taking policy considerations into account. In developing a recommendation, the SAB reviews a standardized set of information compiled by Institute staff. In addition, the SAB often requests that Institute staff collect additional, more detailed information on specific endpoints or questions. Individual SAB members also volunteer to conduct their own detailed literature reviews on specific topics as appropriate, and share any additional information they identify with the rest of the members. Finally, each SAB member draws upon his or her expertise and existing knowledge of specific chemical classes, health and environmental endpoints, and areas of particular concern.

Issues brought to the SAB include questions of listing or delisting of substances from the TURA Toxic or Hazardous Substance List, categorization and prioritization of substances, and other issues for which a scientific recommendation or discussion would be helpful to the program.

For all Science Advisory Board deliberations regarding the chemical list and categorization of the list, objective scientific hazard data are gathered for the substances in question. Data points are discussed in the following four major areas:

- human health
- environmental effects
- safety
- fate (persistence and bioaccumulation potential)

SAB Guidelines for Listing and De-Listing Recommendations for Chemicals
August 2010

Guidelines developed by the Toxics Use Reduction Institute's Science Advisory Board – March 1, 1995,[3] *revised and updated May 2010*

The role of the Science Advisory Board is to assess substances based on hazard information**,** in order to fulfil the goals of TURA in protecting human health and the environment. A request for listing or delisting of substances under TURA should include a statement justifying the request in view of the goals of TURA.

The decision to list or de-list a substance applies to all uses in the Commonwealth of Massachusetts, not just to the uses or applications at a particular company or facility. It is the responsibility of the Science Advisory Board to provide a recommendation to the Toxics Use Reduction Institute on the toxic or hazardous nature and properties of the substance. The SAB will make its recommendation based on whether there is sufficient evidence to establish any one of the following:

1. The chemical or substance is known or can reasonably be anticipated to cause in humans,
    a. cancer or,
    b. serious or irreversible effects including teratogenic effects, reproductive dysfunction, neurological disorders, heritable genetic mutations or other generational effects, other chronic or

[3] The guidelines shown here were first developed in 1995. They were updated and modified to reflect current practices of the Board in 2010.

sub-chronic health effects including asthma, sensitization, or endocrine disruption, or significant acute effects.

2. The chemical or substance is known or can reasonably be anticipated to cause a significant adverse effect on the environment because of:
    a. its toxicity,
    b. its toxicity and persistence in the environment,
    c. its toxicity and tendency to bioaccumulate in the environment, or
    d. other effects, including ozone depletion, global climate change, or toxicity of breakdown products.
3. The chemical or substance is known to or can reasonably be anticipated to cause adverse human health effects at levels that may result from anticipated handling, use, and disposal under all likely conditions.[4]

Conversely, if the request is to delist, the chemical or substance must not be known or cannot be reasonably anticipated to cause the human or environmental effects identified above in 1, 2 and 3.

The following information will facilitate review by the TURI Science Advisory Board in making its recommendations to the Toxics Use Reduction Institute for subsequent analysis and decision with regard to listing or de-listing (see attached "Chemical and Hazard Characterization" list [Appendix C]):

1. Health hazards
2. Health-based exposure limits
3. Environmental and human health exposure and risk values
4. Environmental and ecosystem hazards
5. Safety and physical hazards
6. Global environmental impacts
7. Chemical information and physical characteristics

In addition, to assist with TURI's policy analysis, petitioners may be asked to submit specific information on the chemical or substance including its use in the Commonwealth of Massachusetts, levels in individual companies or plants where it is used, disposal practices, transportation and handling practices, products or customer uses, and other known uses.

Expert Judgment Approach and Delphi Method

The SAB uses an expert judgment approach to decision making. When categorizing groups of chemicals, the SAB also uses a modified Delphi Method. Each chemical is considered for its overall potential impact, not only for a particular endpoint.

Petitions. When a stakeholder has submitted a petition, the petition is generally discussed over two or more meetings. Petitioners submit scientific justification for the listing or delisting, and additional information is gathered by TURI. Hazard characteristics of the chemical are discussed, as well as the petitioner's reasons for the petition. Generally, questions are generated in one or more meetings and additional information is collected to bring back to the board. Meetings are open to the public and petitioners or other interested parties are welcome to attend.

[4] While quantitative risk and anticipated or actual exposure are not criteria for listing or delisting, use patterns, the form in which it is used, and potential exposure routes may be considered as they may raise the level of concern about a substance's hazard.

Requests from the TURA program entities. When requests for recommendations come from within the program agencies, council, or advisory bodies, TURI gathers scientific information and provides it to the SAB. Similarly, deliberations generally span two or more meetings with additional information gathered in response to questions. In some instances, outside experts may be invited or stakeholders may request the opportunity to submit or present additional information to the board.

Categorization of chemicals. The Science Advisory Board has categorized the TURA list into three categories: 1) More Hazardous Chemicals, 2) Less Hazardous Chemicals, and 3) Uncategorized Chemicals (i.e. all other substances on the list). The objective of this categorization, initiated in 1999, is to assist the program and Massachusetts companies in setting priorities among the many chemicals on the list. The SAB periodically reassesses the categorization to consider new information, and when a substance is added to the list, the SAB determines whether it will be categorized as more or less hazardous, or left uncategorized. These SAB categories are strictly informational, not regulatory.

In the 2006 TURA Amendments, the program was instructed to designate Higher Hazard Substances (HHS) and Lower Hazard Substances (LHS); these designations do have a regulatory impact. HHS are reportable at lower use thresholds and LHS do not require the payment of the per-chemical fee. A maximum of ten substances can be designated in each of these regulatory categories per calendar year. The statute directs that "the council shall first consider designating as a higher hazard substance those substances designated as Category 1/more hazardous by the board."

In its original categorization effort, the SAB considered many different algorithms, but found all of them lacking, particularly in the way they handled issues of uncertainty and missing data. An expert judgment method had been used by Polaroid Corporation to develop its groundbreaking chemical ranking system in 1991, and this approach was determined by the board to be more satisfactory than the algorithm methods.

For categorizing groups of chemicals, the SAB chose to use an approach based on the principles of the Delphi Method. The term Delphi Method came from a study concerning the use of expert opinion called Project Delphi performed by the Rand Corporation in the 1950s for the U. S. Air Force. This study aimed to "obtain the most reliable consensus of opinion of a group of experts."[5] The Delphi Method is appropriate when "accurate information is unavailable or expensive to obtain or evaluation models require subjective inputs to the point where they become the dominating parameters."[6] The rationale behind the method is that "if the opinion of one expert on an uncertain point is useful, the opinion of many experts - when boiled down to a single group opinion - should be even better."[7] The original method uses a series of questionnaires to solicit the opinions of the experts. The results of the questionnaires are summarized by an investigator who provides feedback to the experts. A modified questionnaire is then used to obtain a second round of opinions and the process continues until consensus is reached.

The Science Advisory Board's method for the original categorization began with data collection on all chemicals that had ever been reported.[8] From that list, each expert identified fifty "more hazardous chemicals" and fifty "less hazardous chemicals," respectively. Each member used his or her own ranking scheme based on the data and his or her area of professional expertise. The votes from each expert were tabulated and the chemicals were ranked by the number of expert votes received for the category. Successive rounds of voting

[5] Linstone, H.A., and Turoff, M., "The Delphi Method: Techniques and Applications," Addison-Wesley, Reading, Mass., 1975, pp. 3-12.
[6] ibid
[7] Gautschi, T.F., "Delphi Method Predicts the Future," Design News, Feb. 1990, p. 414.
[8] See the text box at the end of Appendix C for the screening endpoints used.

narrowed the lists down to approximately 25 – 30 chemicals for further discussion. Detailed information on selection of the original More and Less Hazardous Lists can be found in TURI's Methods and Policy Report No. 18.[9] Several years later, the SAB used a similar method to categorize the remaining chemicals on the list (those that had never been reported).

The 2006 TURA amendments required the program to draw upon the SAB's More and Less Hazardous lists in choosing candidates for Higher and Lower Hazard designation. TURI asked the SAB to provide a shorter list of high priority substances from their More Hazardous list as a starting point. The SAB used a modified Delphi Method approach to propose a set of eleven substances for high priority consideration using the same method (each member beginning by choosing 10 potential Higher Hazard Substances).

Voting procedure. Once all the information has been reviewed and discussed by Board members, a vote is taken. Only members who are present at the meeting can vote. A quorum (majority) of current board members is needed to have a vote (for example, if there are 9 members currently on the board, a quorum is 5). Members who are not present can send in opinions to be considered by the group prior to voting, but absent members cannot vote by proxy.

[9] Toxics Use Reduction Institute, "Categorization of the Toxics Use Reduction List of Toxic and Hazardous Substances" March 1999, available at: http://www.turi.org/TURI_Publications/TURI_Methods_Policy_Reports/Categorization_of_the_Toxics_Use_Reduction_List_of_Toxic_and_Hazardous_Substances._1999

Appendix C: Chemical and Hazard Characterization

The following hazard information and data are gathered, as appropriate and if available, for each substance.

Notes:

- This is a reasonably comprehensive list, and is more than the "minimum data set" the SAB would consider sufficient in order to make a recommendation.
- It is not prioritized in terms of importance.
- Consensus values and designations from governmental and authoritative bodies are preferred (e.g., IARC, GHS, NIOSH, WMO, USEPA).[10] When warranted and available, additional detailed information from toxicological and epidemiological studies is evaluated.

Health Hazards[11]

Acute Toxicity
- Oral LD50 - median lethal dose
- Dermal LD50 - median lethal dose
- Inhalation LC50 - median lethal concentration
  - (gases, vapors, dust and mists)
- EC50 - half maximal effective concentration

Chronic or Subchronic Toxicity - target organ and systemic[12]
- Genotoxicity, mutagenicity
  - IARC carcinogen classification, EPA carcinogen classification
  - q* - unit risk for carcinogenicity (slope factor)
  - germ cell mutagenicity
  - epigenetic effects
- Neurotoxicity
- Developmental toxicity
- Reproductive toxicity
- Endocrine disruption
- Other target organ toxicity
  - e.g., liver, kidney, blood, immune system

Skin, Eye and Respiratory effects
- Irritant - Skin, eye and respiratory
  - For all respiratory effects, consider particle size
- Corrosive - Skin, eye and respiratory
- Causes permanent damage (e.g., fibrogenicity) - Skin, eye and respiratory
- Sensitizer - Skin and respiratory
- Asthmagen - initiator, exacerbator
- Skin Absorption - Kp - permeability coefficient through the skin
  - skin absorption/permeability enhancer for other substances in mixture

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[10] IARC: International Agency for Research on Cancer, GHS: Globally Harmonized System of Classification and Labeling of Chemicals, NIOSH: National Institute for Occupational Safety and Health, WMO: World Meteorological Organization, USEPA: United States Environmental Protection Agency

[11] In evaluating hazards, consider routes of entry and, where appropriate, note whether effects are reversible or irreversible

[12] Note that EPA typically uses "systemic toxicity" to refer to any effect other than carcinogenicity or mutagenicity induced by chronic exposure to a toxic chemical. "[S]ystemic toxicity is treated as if there is an identifiable exposure threshold (both for the individual and for populations) below which there are no observable adverse effects. This characteristic distinguishes systemic endpoints from carcinogenic and mutagenic endpoints, which are often treated as nonthreshold processes." http://www.epa.gov/iris/rfd.htm

Chronic or Subchronic Dose Response assessment
(applicable to many different endpoints)
LOAEL (lowest observed adverse effect level)
NOAEL (no observed adverse effect level)
Benchmark Dose Response (BMD)[13]
Use dose response relationship to predict a BMD that is associated with a predetermined benchmark response (BMR), such as a 10% increase in the incidence of a particular lesion. Models still under development, EPA plans to use for non-cancer risk assessment.
Metabolites *(for information on pathways)*
Synergistic or antagonistic effects

Health-based Exposure limits (include safety factors, etc.)
Occupational air exposure limits: OSHA PEL, NIOSH REL, ACGIH TLV-TWA and TLV-STEL, IDLH, C (ceiling limits)
Biomonitoring action limits
Drinking water standards

Environmental and Human Health Exposure and Risk Values[14]
Chronic non-cancer toxicity
RfD - reference dose, RfC - reference concentration
MRL - ATSDR Minimal risk level
Adverse effect levels: DNEL - derived no effect level, PNEC - predicted no effect concentration, PNEL - predicted no effect level

Environmental and Eco-System Hazards
Persistence (air, water, soil, sediment)
Bioconcentration - bioconcentration factor (BCF)
K_{ow} - octanol/water coefficient
Ecological/aquatic toxicity - LC_{50}, EC_{50}, ErC_{50} ChV, NOAEC/NOEC
Breakdown/degradation/combustion products
Consider range of health and environmental impacts of products
Other observed ecological effects (e.g., BOD)
Secondary environmental effects (e.g., eutrophication, biodiversity, upstream impacts)
Fate and Transport considerations
Factors affecting bioavailability

Safety/Physical Hazards
Vapor pressure
Flammability
Flash point
Flammability rating
Auto ignition point
Combustion products
Explosivity (UEL, LEL, shock sensitive)
Oxidizer
Corrosivity

[13] http://www.epa.gov/NCEA/bmds/about.html
[14] Derived values that include uncertainty, safety or other factors.

pH
Reactivity
strong reaction with water, air, organics, etc.
Odor threshold
Particle size and shape, respirable fraction
Other physical hazards associated with process
Heat, gases under pressure, noise, vibration, ergonomic hazard

Global Environmental Impacts

Ozone depletion potential (ODP)
Global Climate Change
Acid rain formation
Greenhouse gas production

Chemical Information and Physical Characteristics

CAS #
Name, synonyms, trade names
Chemical formula and structure
RTECS #, EINECS #
Physical state, odor at room temperature and pressure
Melting point, boiling point
Solubility
Specific Gravity

Priority Endpoints considered in past decision-making

For initial categorization of reported chemicals in 1999 and the categorization of the full EPCRA list, the Board discussed and chose the following eight screening endpoints:

- Carcinogenicity (IARC Classification)
- Oral LD50
- Reference dose (RfD)
- Threshold limit value (TLV) and/or permissible exposure limit (PEL)
- Aquatic LC50
- Flash point (FP)
- pH (used pKa and pKb)
- Bioconcentration factor (BCF)

In addition, the Board asked that the following endpoints be added to the basic data set when they recommended candidates for the first 10 Higher Hazard Substances under the 2006 Amendments:

- Persistence, Bioaccumulation, and Toxicity values (PBT)
- Mutagenicity
- Developmental Toxicity
- Neurotoxicity
- Reproductive Toxicity
- Minimal Risk Levels (MRLs)

Appendix D: Role of Professional and Expert Judgment

The role of professional judgment in decision-making is widely recognized in the academic and policy literature. A wide variety of laws, within the US and internationally, explicitly incorporate an element of expert judgment. The table below, published by John D. Hamilton, et al. in 2006, provides an overview of these laws and the ways in which they rely upon professional judgment.

Guidance on professional judgment in hazard assessment from regulatory authorities and standard-setting bodies in Europe, Canada and the United States[15]		
Regulatory authority or standard-setting body and publication	**Key excerpts**	**Relevant technical areas**
Interorganization Programme for the Sound Management of Chemicals (IOMC) Coordinating Group for the Harmonization of Chemical Classification Systems, which managed the Globally Harmonized System for Hazard Classification and Labeling (GHS)	"The approach to classifying mixtures includes the application of expert judgment in a number of areas in order to ensure existing information can be used for as many mixtures as possible to provide protection for human health and the environment. Expert judgment may also be required in interpreting data for hazard classification of substances…" (1.3.2.4.8)	• Application of GHS in non-workplace settings (1.1.3.1.3) • Building-block nature of GHS (1.1.3.1.5.3) • Reliability of test methods (1.3.2.4.2) • Biological availability of substances and mixtures (1.3.2.4.5) • Weight-of-evidence determinations (1.3.2.4.9.1) • Data quality and consistency (1.3.2.4.9.3) • Conflicting results from human and animal data (1.3.2.4.9.3) • Route-of-exposure, mechanistic, and metabolic considerations for human relevance (1.3.2.4.9.4) • Use of cutoff values or concentration limits (1.3.3.2) • Synergistic or antagonistic effects (1.3.3.3) • Use of non-standardized or supplemental information (1.4.6.3) • Treatment of confidential business information (1.4.8)
European Commission Commission Directive 2001/59/EC, on the classification of dangerous substances	"In some cases there may be doubt over the application of the relevant criteria, especially where these require the use of expert judgment"	• Application of guidance criteria for substances (Annex VI, 1.7.2) • Data requirements for classification and labeling, including "information derived from practical experience" (Annex VI, 1.6.1)
Organization for Economic Cooperation and Development, ENV/JM/MONO (2001) 6, OECD Series on Testing and Assessment Number 33	"For many end-points the criteria are semi-quantitative or qualitative and expert judgment is required to interpret the data for classification purposes"	• Judgments regarding the quality of existing data from old tests (Chapter 1.3, 19) • Confirmation of clinical signs of toxicity, and reliability of information for acute effects for animal studies (Chapter 2.1, 37) • Weight-of-evidence determinations regarding skin and eye irritation (Chapter 2.3, 76) • Evaluation of test results on heritable effects in human germ-cells (Chapter 2.5, 128 and 134)

[15] Reproduced from John D. Hamilton et al., "The Role of Professional Judgment in Chemical Hazard Assessment and Communication," *Regulatory Toxicology and Pharmacology* 46 (2006), 84-92.

Guidance on professional judgment in hazard assessment from regulatory authorities and standard-setting bodies in Europe, Canada and the United States[15]		
Regulatory authority or standard-setting body and publication	**Key excerpts**	**Relevant technical areas**
		• Interpreting the criteria for classification for developmental effects (Chapter 2.7, 188) • Adequacy of animal data, other experimental data, and structure-activity relationships (Chapter 2.7, 200) • Classification of immediate versus delayed effects (Chapter 2.7, 209) • Placement of substances with human evidence of target organ/systemic toxicity in Category 2 (Chapter 2.7, 214) • Classification of mixtures (Chapter 3.1, 297–303)
Health Canada Workplace Hazardous Materials Information System (WHMIS) Information Bulletin: *Guidelines for the Disclosure of Toxicological Information on a Material Safety Data Sheet* (1997)	"Professional judgment will generally be required to determine the extent and nature of hazard disclosure, particularly where the data are extensive, conflicting or contradictory. In order to be understandable by the intended user, the preparer of the MSDS should summarize the hazard and should make an effort to minimize the disclosure of extraneous scientific or technical jargon."	Professional judgment applies to criteria listed in Part IV of the Controlled Products Regulations (CPR), or criteria listed in the Transportation of Dangerous Goods Regulations (TDGR), including: • Interpretation of variable test results for specified and non-specified test methods related to toxicological and non-toxicological criteria • Extrapolation of data and classifications from products with data to products lacking data • Determination of whether test results provide evidence of a physiological effect and • Determination of whether a substance or tested mixture not on CPR-referenced lists should be classified as carcinogenic. Professional judgment is specifically prohibited when a substance or tested mixture is included in referenced lists under CPR or TDGR
U.S. Occupational Safety and Health Administration (OSHA) Hazard Communication Standard, 29 Code of Federal Regulations (CFR E, 2006)	"Hazard evaluation is a process which relies heavily on the professional judgment of the evaluator, particularly in the area of chronic hazards."	• Health hazard definitions (e.g., carcinogen, corrosive, highly toxic, irritant, sensitizer, toxic, target organ effects) (Appendix A) • Hazard determination (Appendix B) • Definition of trade secrets (Appendix D) • Guidelines for Employer Compliance (Appendix E)

Guidance on professional judgment in hazard assessment from regulatory authorities and standard-setting bodies in Europe, Canada and the United States[15]		
Regulatory authority or standard-setting body and publication	**Key excerpts**	**Relevant technical areas**
U.S. American National Standards Institute (ANSI) Precautionary Labeling (ANSI Z129.1-2000)	"Implementation of these (precautionary labeling) principles requires the use of professional judgment to integrate them with regulatory requirements and individual company policies." (2.1) "… the health hazard evaluation process relies, to a great extent, on the use of professional judgment." (3.2.3)	• Extrapolations of conversion factors for exposure (e.g., estimates of 1-hour inhalation exposures from 4-hour exposure data) (3.2.2, and Notes to Annex Tables B.1, B., and B.3) • Data evaluation to determine whether substance is an acute or chronic health hazard (3.2.3) • Selection of precautionary label text (4.2), including the priority for and inclusion of text information (4.3.1 and Annex A) • Labeling of untested mixtures based on tested components within the mixture (5.3.2) • Determination of specific, appropriate statements for target organ toxicity on a case-by-case basis (Table 2) and statements of hazard for carcinogens, teratogens, and reproductive/development toxicants (Table 3)
U.S. ANSI Material Safety Data Sheets—Preparation (ANSI Z400.1-2003)	"Professional judgment plays an important role in determining hazards."	• Relevance of human health data to health hazard determinations (5.2.2) and relevance of environmental data to environmental hazards (5.2.3) • Recommendations for immediate medical attention and possible delayed effects (4.1) • Presentation of representative data useful for intended audiences, and narrative interpretations of toxicological data where no specific judgment exists (Section 11) • Accuracy of MSDS content regarding hazards and handling of substances (Section 4, Part 2)
Consumer Products Safety Commission (CPSC), Federal Register Volume 49, No. 105, 6/30/84	"Other alternative sources of information include literature that records the results of prior animal testing or the results of limited human tests, and expert opinion."	No specific areas identified.
Source: John D. Hamilton et al., "The Role of Professional Judgment in Chemical Hazard Assessment and Communication," *Regulatory Toxicology and Pharmacology* 46 (2006), 84-92.		

Appendix E: Policy Considerations

TURI's policy analysis for listing and delisting decisions, and for Higher and Lower Hazard Substance designations, can cover a number of topics. The structure of the policy analysis and the level of detail in individual sections vary to some extent, depending on the science and policy considerations that arise in each case. This Appendix summarizes the topics that may be covered in a Policy Analysis for a Higher Hazard Substance designation for one or more chemicals. Similar topics may be covered in policy analyses for other decisions.

- *State of the Science:* Summary of the information considered by the SAB, as well as the SAB's recommendation.
- *Use in Massachusetts:* Existing TURA data (where available) on use of the chemical reported under TURA to date. May also include a review of Tier II data (hazardous chemical storage data reporting required under EPCRA) and Hazardous Waste reporting data, as well as non-Massachusetts use information, where this may be useful in identifying users not currently subject to TURA.
- *Number of facilities affected:* An estimate of the number of facilities likely to be affected by a listing, delisting, or Higher or Lower Hazard Substance designation. For delistings or lower hazard designations, this figure can be taken directly from the TURA data. For listings or higher hazard designations, the figure can only be estimated from sources including economic databases, consultation with industry representatives, and professional experience of program staff.
- *Opportunities:* Information on opportunities for toxics use reduction for the chemical in question, including examination of sector-specific opportunities and challenges.
- *Regulatory context:* Other regulations relevant for the chemical in question. As appropriate, this may include a discussion of other Massachusetts requirements; requirements in other states; requirements at the federal level; and, in some cases, requirements adopted in other countries or in international agreements.
- *Financial implications:* To the extent possible, the Institute estimates the fees and reporting/planning costs that facilities are likely to face.
- *Implications for the TURA program:* Policy and implementation considerations for the TURA program. This may include information on prior experience of program staff in working with specific sectors; availability of information resources for individual chemicals; and consistency with past TURA program policy decisions.

Appendix F: The Role of Precaution in Decision-making under Uncertainty: Additional Information

In 2009, the Administrative Council requested that TURI provide background information and references on the precautionary principle as an aid to Council deliberations. This Appendix provides a very brief introduction to the Precautionary Principle, along with references for further reading.

Definitions. The Precautionary Principle has been defined formally in a number of contexts.

At the Earth Summit held in Rio de Janeiro in 1992, the international community enshrined the precautionary principle in the Rio Declaration on Environment and Development using the following formulation: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[16]

As summarized by a group of scientists in the 1998 Wingspread Statement on the Precautionary Principle, the Precautionary Principle holds that "When an activity raises threats of harm for human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."

The Precautionary Principle can also be formulated as a set of three key elements:[17]

(1) When there is a reasonable suspicion of harm, and
(2) There is scientific uncertainty about cause and effect, then
(3) There is a duty to take action to prevent harm.

Another formulation states: [18] "Instead of asking the basic risk-assessment question, 'How much harm is allowable?' the precautionary approach asks, 'How little harm is possible?'"

Role of the Precautionary Principle in law. The precautionary principle has been incorporated explicitly into a variety of laws and international treaties[19], including the Second North Sea Declaration (1987), the Third North Sea Conference (1990), the Framework Convention on Climate Change (1992), the Montreal Protocol on Substances that Deplete the Ozone Layer (1989), the Rio Declaration on Environment and Development (1992), and the Stockholm Convention on Persistent Organic Pollutants (2001).

The precautionary principle is also incorporated implicitly into many pieces of legislation at the federal level in the US, although it is not mentioned by name in the legislation. These laws give government agencies the authority to take action to prevent harm, without waiting for proof of such harm. For example, the Food and Drug Administration (FDA) requirement that new drugs be tested for adverse health effects before being placed on the market is a precautionary requirement. The President's Council on Sustainable Development stated in 1996 that "even in the face of scientific uncertainty, society should take reasonable actions to avert risks where the potential harm to human health and the environment is thought to be serious or irreparable.'"

[16] Nancy J. Myers and Carolyn Raffensperger, *Precautionary Tools for Reshaping Environmental Policy* (Cambridge, MA: MIT Press, 2006), p. 13
[17] Peter Montague, "The Precautionary Principle in the Real World" (January 21, 2008).
[18] ibid
[19] Myers and Raffensperger p. 5.

Useful references on the Precautionary Principle

A wide variety of government, academic and NGO publications provide detailed information on the Precautionary Principle. A sampling of these sources is provided here.

Government and academic resources:

American Public Health Association (APHA). "Statement on the Precautionary Principle and Children's Health" (Policy No. 200011), adopted January 1, 2000. Available at APHA's online Policy Statement Database, http://www.apha.org/advocacy/policy/policysearch/default.htm?id=216. Also available in the *American Journal of Public Health* Vol. 91 (3), 495, March 2001, http://ajph.aphapublications.org/cgi/reprint/91/3/495.

City and County of San Francisco (2003). "White Paper: The Precautionary Principle and the City and County of San Francisco." Available at http://www.sfenvironment.org/downloads/library/13precprinwhitepaper.pdf

European Environment Agency, 2001. *Late lessons from early warnings: the precautionary principle 1896-2000*. Copenhagen: European Environment Agency. Environmental Issue Report No 22. Available at http://www.eea.europa.eu/publications/environmental_issue_report_2001_22.

Kriebel, David et al (2001). "The Precautionary Principle in Environmental Science," *Environmental Health Perspectives* Vol. 109 (9), pages 871-876. Available at http://ehp03.niehs.nih.gov/article/fetchArticle.action?articleURI=info:doi/10.1289/ehp.01109871.

O'Brien, Mary (2000). *Making Better Environmental Decisions: An Alternative to Risk Assessment*. Cambridge, Massachusetts: Massachusetts Institute of Technology (MIT) Press.

Tickner, Joel, David Kriebel, and Sara Wright (2003). "A Compass for Health: Rethinking Precaution and its Role in Science and Public Health," *International Journal of Epidemiology* Vol. 32, pages 489-492.

Tickner, Joel and Marco Martuzzi (2004). *The Precautionary Principle: Protecting Public Health, the Environment and the Future of our Children*. Geneva: World Health Organization.

Wingspread Conference Center, "Widespread Statement on the Precautionary Principle," Racine, Wisconsin, January 23-25, 1998. Available at http://www.gdrc.org/u-gov/precaution-3.html

NGO resources:

International Chemical Secretariat (ChemSec). "The Precautionary Principle: A Common Sense Way to Protect Our Health and Environment. Booklet #1: Toxic Chemicals: What is the Problem?" and "The Precautionary Principle: A Common Sense Way to Protect Our Health and Environment. Booklet #2: From Science to Policy: Precaution in Decision-Making." Available at http://www.chemsec.org/images/stories/publications/ChemSec_publications/Booklet_1C.pdf and http://www.chemsec.org/images/stories/publications/ChemSec_publications/Booklet_2_C.pdf.

Montague, Peter (2006). "Getting Beyond Risk Assessment," *Rachel's Democracy & Health News #846*, March 16, 2006. Available at http://www.chej.org/BESAFE/about-precaution/presentations/Peter_Montague_Risk_Assessment.pdf; Montague, Peter (2008). "The Precautionary Principle in the Real World," Environmental Research Foundation, January 21, 2008. Available at http://www.rachel.org/lib/pp_def.htm

Appendix G: Criteria used in Setting TURA Program Priorities

In addition to making these decisions about listing, delisting, and categorizing chemicals, the TURA program must also make choices about where to focus its limited program resources (including staff time and funds for grants or demonstration projects, when applicable). The following criteria may be taken into account when considering how best to focus program resources. These criteria are not listed in order of priority.

1) **Hazard (see SAB's complete list of endpoints for more detail)**
   a) Inherent hazard of substance and consensus exposure limits
      i) Health hazards
      ii) Health-based exposure limits
      iii) Environmental hazards
      iv) Safety/physical hazards
      v) Global impacts
      vi) Chemical information and physical characteristics
   b) Data gaps, uncertainty

2) **Total use and prevalence in MA**
   a) Total quantity
   b) Number of facilities
   c) Type of use
   d) End products

3) **Potential exposure**
   a) Emissions, routes of exposure
      i) Point air, fugitive air, water, land
   b) Worker
      i) Occupational Surveillance
   c) Children
   d) Body burden - use as indicator of exposure
   e) Ecological/biota exposure
   f) Life cycle exposures
      i) during use, recycling, end of life

4) **Future use**
   a) Expected quantity/amount
      i) Is this an industry/product/material of the future?
   b) Design for the Environment (DfE) Opportunities
   c) Occupational prevention through design opportunities
   d) "Green jobs"
      i) Clean Energy manufacturing
      ii) Making manufacturing safer

5) **Opportunities for:**
   a) Use reduction (alternatives or more efficient use, other technologies)
   b) Byproduct reduction
   c) Economic opportunity for alternatives
   d) DfE
   e) Financial feasibility

6) **Alternatives**
   a) Range, feasibility, and uncertainty of alternatives
   b) Hazard impact of switching to alternatives
   c) Technical impact of switching to alternatives
   d) Economic impact of switching to alternatives

7) **Other drivers**
   a) International regulations
   b) Customer requirements
   c) Other regulations (MA, US)
   d) Worker concerns
   e) Public concerns

8) **Program resources/capacity**
   a) Other state/federal capacity
      i) Is this a niche for TURA program, or are others already working on it?
   b) Existing TURA/TUR Planner expertise
   c) Amount of help needed
   d) Resource intensiveness
      i) "bang for buck"

9) **Environmental, Health and Social Implications for MA**
   a) Long- and short-term potential for benefits and disbenefits for:
      i) public health
      ii) worker health
      iii) environmental impacts
      iv) social impacts

10) **Economic Implications for MA**
   a) Impact on large toxics users
   b) Impact on smaller toxics users
   c) Potential environmental, public and worker health cost savings
   d) Green jobs
   e) Preservation of manufacturing jobs
   f) Competitive Advantage
      i) Financial feasibility of TUR Opportunities

ii) Market opportunities for greener products
iii) Potential for innovation

11) Supply chain considerations

a) What part of the supply chain is located in Massachusetts?
b) Ability to bring key parts of the supply chain into dialogue
c) Niche for TURA as supply chain convener

12) Overall feasibility and appropriateness

a) Appropriateness of TURA as policy vehicle
b) Impact of decision as incentive or disincentive for change
   i) Ease of communication of issues and options
   ii) Clarity and availability of information

Appendix H: Policy Goals of TURA

The following text is the preamble to the Toxics Use Reduction Act as adopted in 1989.

SECTION 1. WHEREAS, the Commonwealth of Massachusetts has suffered environmental and public and occupational health problems caused by releases of toxic and hazardous substances, it is hereby resolved that an effective way to promote industrial hygiene, worker safety, and protection of the environment and public health in the commonwealth is through reductions in the use of toxic and hazardous substances. To this end, the policy goals of this act shall be:

1. To establish for the Commonwealth a statewide goal of reducing toxic waste generated by fifty percent (50%) by the year 1997 using toxics use reduction as the means of meeting this goal.

2. To establish toxics use reduction as the preferred means for achieving compliance with any federal or state law or regulation pertaining to toxics production and use, hazardous waste, industrial hygiene, worker safety, public exposure to toxics, or releases of toxics into the environment and for minimizing the risks associated with the use of toxic or hazardous substances and the production of toxic or hazardous substances or hazardous wastes;

3. To sustain, safeguard and promote the competitive advantage of Massachusetts businesses, large and small, while advancing innovation in toxics use reduction and management;

4. To promote reductions in the production and use of toxic and hazardous substances within the commonwealth, both through the programs established in section three of this act and through existing toxics-related state programs;

5. To enhance and strengthen the enforcement of existing environmental laws and regulations within the commonwealth; and

6. To promote coordination and cooperation between all state departments and agencies administering toxics-related programs.

Appendix I: History of listing and de-listing decisions, and designation of Higher and Lower Hazard Substances, under TURA

As of May 2014, over the life over the TURA program, two substances have been added to the TURA list and fourteen have been delisted. This does not include changes that have been adopted automatically under TURA as a result of changes made at the federal level to the list of chemicals subject to reporting under the Toxics Release Inventory (EPCRA 313). These decisions are summarized below.

Listing decisions

Crystalline silica was added to the TURA list in 2000. The listing was proposed by an individual working in the field of occupational health. The SAB voted unanimously in favor of listing and TURI supported this recommendation. The primary reason for the decision to list the substance was that crystalline silica was categorized as an IARC Group 1 carcinogen.

N-propyl bromide (nPB) was added to the TURA list in 2009. In this case, the initiative for the listing came from within the TURA program and its advisory bodies as part of the program's effort to evaluate alternatives to substances already designated as Higher Hazard Substances under TURA. The SAB voted unanimously in favor of listing and TURI supported this recommendation.

Delisting decisions

The program has received 18 de-listing petitions, 14 of which have been granted, at least in part, while others have been refused. Two delisting recommendations were initiated by the SAB for consistency with other delistings of metal alloys. These are shown, along with a summary of the reason for delisting, in Table 1, below. In all but one case, TURI's recommendation was the same as that of the SAB. In one case (butyl benzyl phthalate), TURI's recommendation differed from that of the SAB, based on policy considerations.

Table 1: Listing and Delisting Decisions: Summary of Recommendations and Final Outcome
(not including decisions made under the review of CERCLA chemicals mandated by the 2006 amendments to TURA)

Chemical	SAB Recommendation*	Supplemental Information on SAB recommendation	Status or Outcome
Nickel in alloy form	Delist except for aerosols (less than 50 um)	Unanimous vote.	Delisting petition request accepted by Admin Council per TURI/SAB recommendation.
Chromium in alloy form	Delist except for aerosols (less than 50 um)	Unanimous vote.	Delisting petition request accepted by Admin Council per TURI/SAB recommendation.
Pure copper metal	Delist except for aerosols (less than 50 um)	Unanimous vote.	Delisting petition request accepted by Admin Council per TURI/SAB recommendation.
Manganese in alloy form	Delist except for aerosols (less than 50 um)	Unanimous vote.	Delisting petition request accepted by Admin Council per TURI/SAB recommendation.
Cobalt in alloy form	Delist except for aerosols (less than 50 um)	Unanimous vote.	Delisting petition request accepted by Admin Council per TURI/SAB recommendation.

* Except where otherwise noted, TURI's recommendation was the same as that of the SAB.			
Chemical	**SAB Recommendation***	**Supplemental Information**	**Status or Outcome**
Chromium (III) oxide	Delist	Unanimous vote. Chromium (III) oxide is not known to cause significant human health effects, is not known to cause significant adverse effects on the environment and does not bioaccumulate, and the oxidation of chromium (III) to chromium (VI) is not likely to occur.	Delisting petition request accepted by Admin Council per TURI/SAB recommendation.
Sodium hydroxide	Not delist	Majority decision to not delist. Decision based primarily on its potential for acute toxicity to workers. For specific applications, there may be uses of sodium hydroxide for which there is scientific justification to determine that sodium hydroxide is the least hazardous material and presents the least risk; this should be considered by the Administrative Council.	Delisting petition request denied by Admin Council per TURI/SAB recommendation.
Hydroquinone	Delist, except for manufacture	Unanimous vote. Material has moderate to low toxicity.	Delisting petition request accepted by Admin Council per TURI/SAB recommendation.
Butyl benzyl phthalate	Delist. (However, TURI recommended against delisting based on policy considerations.)	Unanimous vote.	Based on policy considerations related to the emerging science on estrogenic activity of phthalates in general, TURI recommended retaining the substance pending further data. The Administrative Council denied the delisting petition per TURI's recommendation.
Ethyl Acetate	Not delist	Unanimous vote. Recommendation based primarily on its potential for acute toxicity to workers.	Delisting petition request denied by Admin Council per TURI/SAB recommendation.
Acetic Acid	Delist at concentrations below 12%	Unanimous vote.	Delisting petition request accepted by Admin Council per TURI/SAB recommendation.
Sodium Hypochlorite	Not delist	Majority decision to not delist.	Delisting petition request denied by Admin Council per TURI/SAB recommendation.
Acetone	No recommendation	Board vote was split.	Delisting request denied. Decision to review acetone during upcoming categorization of the list of chemicals. *(Note: Acetone later categorized as Less Hazardous)*
Zinc oxide	Delist	Unanimous vote.	Delisting petition request accepted by Admin Council per TURI/SAB recommendation.
Copper-silver alloy	Delist copper-silver alloys except for aerosols (less than 50 um)	Unanimous vote.	Delisting petition request accepted by Admin Council with qualifications as per TURI/SAB recommendation.

* Except where otherwise noted, TURI supported the SAB's recommendation.			
Chemical	**SAB Recommendation***	**Supplemental Information**	**Status or Outcome**
Zinc stearate	Delist	Unanimous vote. Zinc stearate is not known to cause significant human health effects; it is not known to cause significant adverse effects on the environment; and it does not present a safety hazard. The toxicity of zinc stearate fumes do not pose a significant threat in the manner in which it is used in the Commonwealth.	Delisting petition request accepted by Admin Council per TURI/SAB recommendation.
Pure copper metal	Delist except for aerosols (less than 50 um)	Delisting originated in SAB to be consistent with previous decisions. Unanimous vote.	TURI/SAB recommendation accepted by Admin Council
Pure silver metal	Delist except for aerosols (less than 50 um)	Delisting originated in SAB to be consistent with previous decisions. Unanimous vote.	TURI/SAB recommendation accepted by Admin Council
Crystalline Silica	List particle sizes less than 10 um	Unanimous vote.	TURI/SAB recommendation accepted by Admin Council
n-Propyl Bromide (1-bromopropane)	List	Unanimous vote. Considered for listing as part of evaluation of alternatives to Higher Hazard Substances.	TURI/SAB recommendation accepted by Admin Council
* Except where otherwise noted, TURI supported the SAB's recommendation.			

Review of the CERCLA chemicals. The TURA Toxic or Hazardous Substances list was compiled originally from two federal lists: the Toxics Release Inventory (TRI) created under the Emergency Planning and Community Right-to-Know Act (EPCRA), and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) substances list. The 2006 Amendments to TURA required the Science Advisory Board (SAB) and TURI to review all the chemicals on the TURA Toxic or Hazardous Substances list that originated from the CERCLA list, and make a recommendation to the Council as to which chemicals should be retained. If the program did not take action on a chemical, the statutory default was for the chemical to be removed from the TURA list.

The review of the CERCLA chemicals differed from other processes the SAB had undertaken. TURI asked the SAB to consider which substances were higher and lower priority for retention on the TURA list, based on the intent of stakeholders in the negotiations of the 2006 Amendments to focus the program and the list on substances of most importance to Massachusetts firms. Based on this guidance, the SAB recommended some substances for retention and some for no action (de-listing).

In its review, the Administrative Council chose a different approach.

- For substances that had never been reported under TURA, the Administrative Council decided to retain them on the list, regardless of the SAB's recommendation.
- For substances that had been reported at some point, the Administrative Council asked the SAB to look in more detail at the substances, and apply the same standard of evidence that would ordinarily be applied in consideration of a de-listing petition. In light of this guidance, the SAB revised some of its recommendations.

The final recommendations of the SAB, and decisions reached by the Council, can be reviewed at:
http://www.turi.org/Our_Work/Chemicals_Policy/Decision-Making_Under_TURA/Councils_and_Committees/TURA_Science_Advisory_Board/SAB_Recommendations/July-2008-Policy-Analysis-for-CERCLA-Chemicals

Higher Hazard Substance Designations

The Higher Hazard Substance designation lowers the threshold for reporting, planning, and paying TURA fees to 1,000 pounds per year.

As of May 2014, methylene chloride, formaldehyde, hexavalent chromium compounds, perchloroethylene (PCE), trichloroethylene (TCE), cadmium, and cadmium compounds have been designated as Higher Hazard Substances. Persistent, bio-accumulative, and toxic (PBT) substances as defined by US EPA, which already have lower reporting thresholds, are also automatically designated as Higher Hazard Substances.

Chemical	**Year designated**	**Effective as of reporting year**
Methylene chloride (75-09-2)	2013	2014
Hexavalent chromium (MassDEP category 1216) Formaldehyde (50-00-0)	2011	2012
Perchloroethylene (127-18-4)	2008	2009
Trichloroethylene (79-01-6) Cadmium (7440-43-9) Cadmium Compounds (MassDEP category 1004)	2007	2008
PBTs (automatic by statute; already had lower reporting thresholds): Aldrin, Benzo(g,h,i)perylene, Chlordane, Heptachlor, Hexachlorobenzene, Isodrin, Lead, Lead Compounds, Mercury, Mercury Compounds, Methoxychlor, Octachlorostyrene, Pendimethalin, Pentachlorobenzene, Polychlorinated biphenyls (PCBs), Tetrabromobisphenol, Toxaphene, Trifluralin, Dioxin & dioxin-like compunds, Polycyclic aromatic compounds (PACs)	2007	2007

Lower Hazard Substance Designations

The Lower Hazard Substance designation eliminates the per-chemical fee. Reporting and planning requirements for these chemicals are unchanged.

The TURA program has also designated ten Lower Hazard Substances: isobutyl alcohol, sec-butyl alcohol, n-butyl alcohol, butyl acetate, isobutyl acetate, ferric chloride, ferric sulfate, ferrous chloride, ferrous sulfate (heptahydrate), and ferrous sulfate.

Chemical	**Year designated**	**Effective as of reporting year**
Butyl acetate (123-86-4) Isobutyl acetate (110-19-0) Ferric chloride (7705-08-0) Ferric sulfate (10028-22-5) Ferrous chloride (7758-94-3) Ferrous sulfate (heptahydrate) (7782-63-0) Ferrous sulfate (7720-78-7)	2009	2010
Isobutyl alcohol (78-83-1) sec-Butyl alcohol (78-92-2) n-Butyl alcohol (71-36-3)	2008	2009