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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University of Massachusetts Lowell

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The Toxics Use Reduction Act (TURA) Program is implemented by the following state agencies:

Massachusetts Department of ENVIRONMENTAL PROTECTION

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.

OTA
OFFICE OF TECHNICAL ASSISTANCE & TECHNOLOGY

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.

TURI
TOXICS USE REDUCTION INSTITUTE
University of Massachusetts Lowell

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 two key areas of decision-making: adding substances to, or removing substances from, the TURA list of toxic or hazardous substances; and designating higher and lower hazard substances within the larger TURA list. Elements of the process described here may also be applicable to other types of decisions under TURA, such as designation of 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.) 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.

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. The diagram to the right provides a schematic representation of this decision-making process.

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

3.1. 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 Administrative Council requests that the SAB provide a recommendation.[1] 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.

TURA decision-making process*

Initiation*
⇩
Administrative Council states question
⇩
TURI gathers data
⇩
SAB votes on a recommendation
⇩
TURI prepares policy analysis
⇩
Advisory Committee provides input**
⇩
TURI makes revisions & conducts additional research as needed
⇩
Administrative Council votes
⇩
Draft regulations
⇩
Regulations

* Question may be initiated by MA stakeholders, TURA program staff, Board, Committee, Council, or statutory requirement.
** In many cases, the Advisory Committee also provides input earlier in the process as well.

[1] This is a new procedure introduced in 2009, designed to ensure clarity and consistency in the charge given to the SAB.

3.2. 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.

3.3. 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. Based on all the information available, the Institute makes a recommendation on the issue. 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.

3.4. Advisory Committee Input. The Institute presents the Policy Analysis to the Advisory Committee. The Advisory Committee provides input and recommendations based on the information presented in the Policy Analysis, 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 are also invited to submit their own individual feedback to the Council. TURI makes revisions to its policy analysis, based on the Advisory Committee's comments, if necessary.

3.5. 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.

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. It also includes bringing their broader knowledge of chemical toxicity issues to bear on situations in which individual data points are missing or equivocal, and applying 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 absence of data is a major source of 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 data gaps, providing information to the Council 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 vary depending on the animal studied and test protocol. 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 should not be considered a valid basis for discounting the effect. Epidemiological evidence may, however, increase the level of concern 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 and standardized listings of endocrine disrupters similar to those available for carcinogenicity or reproductive toxicity. In this and similar cases, where consensus values from authoritative bodies are generally not available, the SAB relies more heavily on robust, peer-reviewed studies.

4.6. Uncertainty about policy and economic factors. Just as the SAB is almost always faced with some amount of scientific uncertainty in developing its recommendations, the Institute also 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.*

Definitions. 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.[2] 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.

[2] Significant risk may be expressed as potential excess lifetime cancer risk (e.g., 1 in 1,000,000) or as a Hazard Index for non-cancer outcomes.

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."[3]

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."[4]

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.

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[3] 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.

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