Appendix C: Science Advisory Board Decision Making Principles

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 her or his 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 (the SAB's More Hazardous Chemicals and Less Hazardous Chemicals lists), objective scientific hazard data are gathered for the substances in question. Data points are discussed in the following four major areas: human health; environment; safety; and fate (persistence and bioaccumulation potential).

SAB Guidelines for Listing and De-Listing Recommendations for Chemicals (2010)

The following guidelines were developed by the Toxics Use Reduction Institute's Science Advisory Board in 1995, and revised and updated in 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 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.[3]

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 D]):

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.

Overview of Processes

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. In some instances, outside experts may be invited or stakeholders may request the opportunity to submit or present additional information to the board. Meetings are open to the public and petitioners or other interested parties are welcome to attend.

Requests from the TURA program entities. When requests for recommendations or input 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 and, 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."[4] 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."[5] 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."[6] 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.[7] 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 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.[8] Several years later, the SAB used a similar method to categorize the remaining EPCRA 313 chemicals

on the list (those that had never been reported).

The 2006 TURA amendments required the program to first consider the SAB's More Hazardous list in choosing candidates for Higher Hazard designation. TURI has expanded on that requirement by using the SAB's More and Less Hazardous Chemical Lists as candidate lists for both HHS and LHS designation. In selecting the first set of priorities for HHS 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. When a formal recommendation is required, the SAB votes on the recommendation. 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 board members is needed to have a vote. 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. Votes are taken for recommendations for listing or delisting, SAB categorization as More Hazardous or Less Hazardous, and for other questions where the program or the Council is requesting a formal recommendation.