The Commonwealth of Massachusetts
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114

Charles D. Baker
GOVERNOR

Karyn E. Polito
LIEUTENANT GOVERNOR

Matthew A. Beaton
SECRETARY

Tel: (617) 626-1000
Fax: (617) 626-1181
http://www.mass.gov/eea

RESPONSE TO COMMENTS
ON PROPOSED AMENDMENT TO 301 CMR 41.00 (TOXIC OR HAZARDOUS SUBSTANCE LIST) TO DESIGNATE TOLUENE DIISOCYANATE (LISTED AS: 2,4-TDI [584-84-9]; 2,6-TDI [91-08-7]; AND TDI MIXED ISOMERS [26471-62-5]) AS A HIGHER HAZARD SUBSTANCE

Regulatory Authority:
M.G.L. Chapter 21I

October, 2015

SUMMARY

In October 2014, the Executive Office of Energy and Environmental Affairs (EOEEA) proposed revisions to the *Toxic or Hazardous Substance List* at 301 CMR 41.00 to implement changes made by the Administrative Council on Toxics Use Reduction (TURA, M.G.L. c. 21I, as amended in July 2006) during calendar year 2014. Specifically, the Council voted to designate Toluene Diisocyanate (TDI) (listed as CAS: 2,4-TDI [584-84-9]; 2,6-TDI [91-08-7]; and TDI mixed isomers [26471-62-5]), and four other chemicals as Higher Hazard Substances (HHS). Designation as a HHS lowers the threshold for reporting and planning under the Toxics Use Reduction Act (TURA) to 1,000 pounds (from either 10,000 or 25,000 pounds annually, depending on how the chemical is used at the facility).

Toxic chemicals pose a range of risks to the environment and public health. TURA is designed to supplement existing environmental and worker safety regulations. The aim of TURA is to help companies understand available options to reduce or eliminate toxic chemical use, and to encourage them to implement the reduction options identified. These options are frequently cost effective and many create financial savings for companies. Over the course of the program, the vast majority of companies have identified ways to cut toxics use and waste while saving money. In 2006, TURA amendments were designed to establish lower reporting thresholds for particularly hazardous substances, so that the law can be used to minimize the significant threats associated with high priority substances.

REGULATORY DEVELOPMENT PROCESS

EOEEA held a public hearing and solicited public comments on proposed revisions in accordance with M.G.L. Chapter 30A. EOEEA published notice of the public hearing on October 17, 2014 in the following newspapers: the *Springfield Republican, Worcester Telegram and Gazette*, and the *Boston Globe*. These news outlets and others interested in the topic were notified of the public hearing and public comment period via electronic mail. Notifications were made to stakeholders through trade and professional associations. The public hearing was held on Thursday, November 20, 2014, at 100 Cambridge Street, 2nd floor Conference Room B, Boston, MA. Written comments were accepted until 4 P.M. on Friday, November 21, 2014.

Twelve individuals attended the public hearing. EOEEA received oral testimony from three of those individuals in attendance. EOEEA also received fifteen written comments during the public comment period; some of the written comments were documentation of the oral testimony provided at the public hearing.

Twelve sets of comments supported the designation of toluene diisocyanate as a Higher Hazard Substance. Three sets of written comments, in addition to the oral testimony, were received in opposition to the designation of toluene diisocyanate as a Higher Hazard Substance. The comments in opposition were submitted by either a national chemical trade association or national chemical company that had interests in the manufacture of toluene diisocyanate. Comments received in opposition were critical of the science basis for the recommendation and the public process.

There were no written or oral comments received either supporting or opposing the proposed regulations from Massachusetts businesses that are subject or potentially subject to the regulations. The oral and written comments received were summarized with EOEEA's response to each comment, in the *Response to Comments* published in November, 2014.[1]

Although the public had opportunity to comment on the proposal, an additional 60-day comment period for TDI was held in response to concerns about the process and the need for adequate review of new scientific information. EOEEA published notice of the public comment period on January 9, 2015 in the *Boston Globe*. Notifications were made to stakeholders through newsletters and professional associations and each entity that submitted comments during the first 21-day comment period in 2014 were sent notification of the additional 60-day comment period. Comments were accepted until 4 P.M. on Monday, February 23, 2015. In January 2015, the Science Advisory Board (SAB) reviewed the most recently-submitted information. The Administration's final decision concerning this designation has ensured that all perspectives have been fully considered and the review of current science has been comprehensive.

The following people/organizations submitted comments during the 60-day comment period ending February 23, 2015:

In support of designation:

Sylvia Broude
Executive Director, Toxics Action Center

Steven Gauthier
Local 201 IUE/CWA
North Shore Labor Council

Tolle Graham
Labor & Environment Coordinator, Massachusetts Coalition for Occupational Safety and Health

Erica Mattison
Legislative Director, Environmental League of Massachusetts

Elizabeth Saunders

[1] http://www.mass.gov/eea/docs/eea/ota/programs/2014-final-response301-cmr-41-00.pdf

Massachusetts Director, Clean Water Action

Elise Pechter MPH, CIH
Industrial Hygienist

Rachel Wilson, MPH, Registered Respiratory Therapist

In opposition to designation:

Steven Rosario, American Chemistry Council (ACC)

Sahar Osman-Sypher
Director, Diisocyanates Panel, American Chemistry Council

Carol S. Eicher, Innocor Foam Technologies

Comments received in support of designation

From Sylvia Broude, Executive Director, Toxics Action Center; Steven Gauthier, Local 201 IUE/CWA, North Shore Labor Council; Tolle Graham, Labor and Environment Coordinator, Massachusetts Coalition for Occupational Safety and Health; Erica Mattison, Legislative Director, Environmental League of Massachusetts; Elizabeth Saunders, Director, Clean Water Action:

The designation is a "great step forward for the TURA program," bringing it closer to "its full potential for preventing pollution from industrial use of toxic chemicals and protecting the health of Massachusetts residents and workers." The writers refer to a letter submitted in the first comment period from 31 organizations and individuals in support of the proposal.

The commenters note that in January 2015 the US EPA "called for new measures to be taken to curb the use of toluene diisocyanates" and that this "should signal a pressing need to take action in Massachusetts." EPA's proposed Significant New Use Rule (SNUR) would allow it to evaluate and possibly take action "to prohibit or limit the use of the chemicals at greater than 0.1% in coatings, adhesives, elastomers, binders and sealants and in imported consumer products." The commenters state that exposure through both dermal contact and inhalation is a potential issue for industrial workers using these materials as well as for homeowners who do their own repair or renovation. It is noted that homeowners are not legally required to receive health and safety training on the handling of such products and "may be unknowingly overexposed to these toxins."

The commenters further note that TDI is regulated as hazardous and has been linked to significant health damage. Exposures can cause dermal irritation, asthma, inhalation sensitization, and lung damage, and severe exposure can cause death. Because of this and the fact that there are significant opportunities for preventing exposure, designation as Higher Hazard is a

"sensible and effective use of the TURA program" and will advance its mission of improving human and environmental health in the Commonwealth.

Additional technical points from two of the commenters are summarized below.

Elise Pechter, Industrial Hygienist:

Pechter stated that TDI is a "respiratory and dermal sensitizer, as well as an irritant and suspect carcinogen" (IARC 2B), and that she wanted to add to comments she submitted in the first period, after representatives of American Chemistry Council (ACC) "misrepresented occupational health surveillance data, giving an inaccurate interpretation about what is known about the potential for TDI to cause asthma." She stated that the ACC "did not pay sufficient attention to the issue of sensitization" and misrepresented OSHA's methods, TDI measurement and the difficulty of assessing TDI in the workplace. "Failing to accurately assess illness associated with TDI and exposures in the workplace both contribute to an underestimation of the hazards posed by TDI."

Air sampling and analysis issues: Pechter states that researchers have shown that underestimation may occur because of the distribution of monomer in both vapor and aerosol phases, because methods often do not capture polyisocyanates, and because isocyanates are unstable and reactive. Pechter cites several papers on these points. "For example, Thomasen (2011) found that capture of HDI depended on whether the autobody paint was fast-drying or slow-drying and found differential capture of monomer and polymer; Lesage et al., 2007 found that filter sampling methods for MDI were up to 40% lower than results from impinger methods. This may also be true for TDI." Pure analytical methods exist only for monomeric isocyanates. Pechter notes that the "failure of the usual sampling methods to capture all isocyanates dictates that we look at all air sampling results, including those from OSHA, as an underestimation of exposure."

Isocyanate asthma. Providing links to original data, Pechter states that the testimony of BASF's Dr. Perrod at the hearing that TDI is not a leading cause of asthma is "completely incorrect." She provides detailed information including the following points:

- Massachusetts Department of Public Health data on workplace exposures (the Sentinel Event Notification System for Occupational Risks (SENSOR)), shows that isocyanates "were the 8th leading cause of identified sentinel cases of work-related asthma," not the 16th leading cause as Perrod claimed.
- "In the four states that conduct sentinel surveillance, isocyanates were the ninth leading cause."
- In Michigan (one of the states performing work-related asthma surveillance), "isocyanates were associated with 12.5% of all work-related asthma cases."

Pechter agrees with ACC comments that cases of work-related asthma have declined in the surveillance states, and declines have been described in the UK and Canada, but that this may reflect several other causes, including declining numbers of occupational health clinics, failure to conduct surveillance and pressure on workers not to report, as well as improved controls, and the use of less volatile isocyanates. Assessing whether workers are being sensitized is complicated

by the absence of a "readily available and accurate test." Peer-reviewed literature shows isocyanates remain a leading cause of work-related asthma in industrialized countries. "Among the workers who developed work-related asthma associated with isocyanates in Massachusetts, more than half did not know which isocyanate they had been exposed to," suggesting a failure by employers to comply with hazard communication requirements.

Pechter concludes that "isocyanates remain a leading cause of work-related asthma in Massachusetts, in the five states that conduct surveillance and in industrialized countries in general. The misrepresentation of the facts appears to be a deliberate effort to underplay the danger of TDI." More of Pechter's comments are noted below in the response to the ACC's comments.

Rachel Wilson, MPH, RRT:

Wilson asserts that the adverse health effects of exposure to TDI are shown by a "variety of toxicological animal and longitudinal human based studies."Wilson cites a 2002 study for the fact that diisocyanates are "the most frequently reported cause of chemical-induced occupational asthma with an estimated prevalence of 5-15% of exposed workers." She cites two sources, including the state of California, for the finding that "hyperresponsive airways, airway inflammation (elevated lymphocytes, eosinophils and neutrophils) and isocyanate sensitization may persist" for months or years after the occupational exposure has ceased, and "is not considered uncommon."

Describing several possible adverse effects, she notes that there is a variable latency period concerning asthma and typically there is no presentation until "several months or years following the initial exposure," signifying that the "physiological reaction may not be entirely immunological or IgE specific and may have some non-immunological components." Sensitization can lead to increased severity of adverse health impacts, and sensitization can be caused either by chronic or high acute exposures. She cites three sources for the finding that exposures at levels below OSHA's limits "have been known to cause asthmatic exacerbation in sensitized individuals." Comments by Wilson concerning the mechanism by which diisocyanates damage pulmonary tissue are discussed below in the response to ACC's comments.

Wilson also addresses the issue of carcinogenicity, the classification of which has been contested by the ACC. Carcinogencity is not a focus of this response because carcinogenicity was not the primary reason for the proposal to designate TDI as Higher Hazard. She notes also that the reference concentration for TDI mixture is based on a five-year study of 277 workers that found decreased lung function following TDI exposure, and that the California Reference Exposure Level considers "increased respiratory susceptibility of children."

Response:

The program appreciates the diligent use of citations in the comments provided, enabling verification of statements made. The general contention of comments in support that TDI is a leading cause of work-related asthma is amply supported by the available evidence.

The program takes note of the comment that do-it-yourselfers are not required to receive hazard communication and that they may be unwittingly exposed to hazards that could be avoided. While these health effects will not be directly addressed by a Higher Hazard Substance listing, such listing should help generate awareness that can lead to better preventive action by this group of potentially affected individuals.

Comments received in opposition to designation

From Steven Rosario, on behalf of the American Chemistry Council:

Having "the Administrative Council take up this issue before the Science Advisory Board has had the opportunity to formally adopt a position on this recommendation" was a flawed process and therefore their designation of TDI as a Higher Hazard Substance by the Administrative Council was premature. TDI was placed on the SAB's list of "more hazardous substances" in 1999. Rosario notes that "Prior to the SAB's meeting on January 7, 2015 we cannot find any evidence that TDI was either further reviewed since 1999 or any formal action or vote by the SAB recommending that TDI be designated as an HHS" was taken. He comments that the Council should have the "benefit of SAB's input and recommendation on this matter before making a determination that could have far reaching implication. Unfortunately, the stakeholders were never given the opportunity to present to the SAB until recently on January 7, 2015." He contends that "the SAB *'has not'* voted to make TDI a high hazard substance contrary to the statements in the TDI Summary of Policy Analysis developed by TURI" and that therefore "the Administrative Council, in making its decision to designate TDI an HHS, relied on a faulty document that was not accurate in its description of the SAB's recorded position regarding TDI nor did it contain accurate information regarding the hazards of TDI." He concludes that "Thus, any justification for supporting such a designation based on the science is totally absent without the input of the SAB."

Rosario states it is "disconcerting to note that during the SAB's discussions it was stated that it is not the role of the SAB to provide recommendations to the Administrative Council regarding HHS designation." He also "takes issue" with the fact that the Director of TURI, Michael Ellenbecker, submitted personal comments supporting the designation of TDI as a HHS, and alleges that this constitutes a conflict of interest, or unethical conduct by the head of TURI, "who is supposed to act as a neutral arbiter on subjects before the SAB and not an advocate." Rosario states that the designation by the Council of TDI as a Higher Hazard Substance should "be set aside due to the lack of scientific support and recommendation by the SAB. Additionally we request that if the Administrative Council finds it necessary to take action on TDI that it send the matter to the SAB with a directive that the SAB further evaluate (with stakeholder input) and provide a recommendation to the Administrative Council as to whether TDI should be designated an HHS."

Response:

Interested parties are advised to also review the November 2014 Response to Comments, as many of the claims made in the second comment period are repetitive or similar to those made in the first period.

The process. While it is true that the SAB did not take a formal vote on TDI since placing it on the More Hazardous Chemicals list in 1999, no such vote was required by law. Nor was the Administrative Council deprived of relevant input concerning the matter before voting on designation. The Science Advisory Board was created by the statute "in association with the Institute" (TURI), and it is TURI that is required to advise the Council on High Hazard Substance designations, not the SAB. TURI is indeed required to consult with the Board on High Hazard Substance designations, and this occurred on more than one occasion. As set forth in the response to comments received during the first comment period:

- In December 12, 2013, the TURA program requested input from the Advisory Committee on chemicals to prioritize for HHS designation in 2014. One of the handouts at this meeting was a table of chemicals on the "More Hazardous Chemicals" list, including summary information on hazards for selected chemicals.
- In February 2014, TURA program staff shared the Advisory Committee's preliminary suggestions for prioritization of the "more hazardous chemicals" with the SAB. The information shared with the SAB at that meeting included notes regarding the key environmental, health and safety concerns for the substances emerging as higher priority based on Advisory Committee input, including TDI. The SAB did not choose to re-visit the science on TDI or any of the other more hazardous substances. *The SAB reaffirmed that all the chemicals on the list were appropriate candidates for designation as Higher Hazard Substances* (emphasis added).
- At the September 17, 2014 SAB meeting, TDI was not on the agenda, but members from ACC and the diisocyanates industry were in attendance for a separate diisocyanates agenda item. They voiced several concerns regarding TDI: the process (no full review of TDI by the SAB), the science (challenge to the IARC and NTP carcinogenicity classifications, and evidence of reduced impacts on workers in recent years) and the uses (not in spray foam insulation - California had agreed to remove reference to TDI from their description). Observations from SAB members during this discussion included the following:
    - Regarding TDI's carcinogenicity classification, a board member noted that the critical effect is pulmonary/sensitization, not carcinogenicity, and if the carcinogenicity classification changed, it would still be a 'more hazardous chemical.'
    - While discussing sensitization, an industry association representative noted increased medical surveillance. A board member inquired how that would reduce sensitization, and then speculated that if workers are removed from the workplace it could reduce the impact.
    - Board members reiterated the focus on inherent hazard, and noted that personal protective equipment, engineering controls and education of workers help reduce exposure, but do not change the inherent hazard of the substance.

Although the SAB has, on occasion, taken votes related to prioritizing chemicals on its More and Less Hazardous Chemicals lists for HHS designation, there is no requirement to do so. In the case of TDI, the SAB did review the question of whether or not it should remain on the list, and it unanimously confirmed its original decision to keep it on the More Hazardous Chemicals list. Industry representatives were present at the meeting and had ample opportunity to ensure that their perspectives were considered.

In its Response to Comments in November 2014, EOEEA noted that there were ample opportunities over a period of more than six months during which stakeholders knew that the TURA program was considering TDI as a priority, and could see a brief summary of the scientific information the TURA program was taking into account. In addition, stakeholders had an opportunity to submit information on the hazards and risks associated with TDI during the formal public comment period. In addition to these opportunities, the comment period for TDI had an additional 60-day comment period, during which the SAB reviewed the most recently submitted information.

The statute requires that TURI consult with the SAB in developing its advice for the Council. There has been a diligent effort to review relevant science and there has been ample opportunity for input from the public including the public meetings of the Advisory Committee. The SAB originally placed TDI on the More Hazardous Chemicals list primarily because of its impact on respiratory systems. The SAB has again confirmed its recommendation that TDI remain on the More Hazardous Chemicals list.

The statute requires that the Council "first consider" those substances designated by the SAB as Category 1/More Hazardous (Chapter 21I, Section 9(D)). This is the process that has occurred.

The mandated process of review and public comment was followed, and the Administrative Council was fully informed of the relevant science when it voted to designate TDI as a Higher Hazard Substance. The claim that the Administrative Council took its vote to designate prematurely is inaccurate. Further review of the process is unnecessary.

Testimony of Dr. Ellenbecker. In his letter submitting his comments, Dr. Ellenbecker stated "I am writing not as the Director of TURI but in my role as Professor Emeritus of Occupational and Environmental Hygiene at UMass Lowell and as a Certified Industrial Hygienist." Dr. Ellenbecker is a nationally recognized expert in industrial hygiene and occupational exposure, with particular expertise in respiratory effects from exposure to chemicals, nanomaterials, asbestos, and other substances. Dr. Ellenbecker reviewed factual information in his letter, including the various TDI occupational exposure limits, the American Conference of Industrial Hygienists' statement on sensitization, and the potential for overexposure due to TDI's vapor pressure. It is entirely appropriate for him to state his scientific opinions on this matter.

In terms of the roles of the SAB and TURI in making HHS recommendations, ACC questions the value and validity of the SAB given that they are not making the recommendation to the Council and asks for clarification of their role. The TURA statute created a Science Advisory Board (SAB) to work with the Institute. The SAB's primary role is to advise 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. Recommendations from TURI to the Council include policy and other considerations as well.

Staff and representatives from MassDEP and OTA regularly participate in SAB meetings and discussions, but do not vote. TURI's role is to provide recommendations to the Council, and in doing so seeks advice from the SAB. TURI is not a "neutral arbiter on subjects before the SAB" as stated by ACC, as there is no conflict between adversarial parties to settle; rather it is a careful, considered discussion among experts which bring a wide variety of backgrounds and expertise to the table. In its recommendations, TURI makes use of the discussion, expertise, opinions and background material provided by the SAB, as well as any consensus or votes that might be taken, and combines that with policy considerations.

We believe that no conflict of interest exists from Dr. Ellenbecker's testimony, that it does not border on unethical conduct" and is appropriate given his disclosure in the written testimony and his professional credentials.

Comment:

From The American Chemical Council's Diisocyanates Panel, Sahar Osman-Sypher, Director.

The commenter refers to a "purported" recommendation by the SAB to designate TDI as an HHS and states that key steps never occurred, no document containing scientific data on the hazards posed by TDI has been identified, and there is no record the SAB reviewed it prior to the vote by the Council to designate. The commenter acknowledges that EOEEA has stated that in fact notes and a detailed table of hazard information was provided to the SAB and the Council before the vote, but the commenter states that these documents were not provided to industry stakeholders. The commenter states that inaccurate and poorly referenced hazard data were in TURI's 2003 TDI Fact Sheet and its 2014 Final Policy Analysis. The commenter states that TURI has overstated the hazards posed by TDI, "which leaves industry with little confidence in the fundamental objectivity of the information contained in the 'notes' and 'detailed tables' provided by TURI to the SAB or in the scientific basis for the eventual designation of TDI as an HHS."

The commenter states that the SAB finalizes its recommendations with a vote, and the only vote by the SAB on TDI took place in 1999 when TDI was added to the More Hazardous Chemicals list. There is no record the SAB considered more recent data or recommended that TDI be designated as an HHS.

Although the commenter acknowledges that TURI staff raised the question of prioritizing the more hazardous list with the SAB in February, 2014, (including TDI), the commenter states that there was a lack of communication with the industry, which first became aware of the pending designation in August 2014.

The commenter states that important factors, such as exposure and impacts to business, have not been adequately considered. Claims made by the program that toxics use reduction efforts have led to financial savings for many companies are not substantiated.

The comments state that there are inaccuracies in the Fact Sheet and Policy Analysis. The commenter's also take issue with comments provided in support of the designation of TDI during the first comment period, and include several examples of what are alleged to be "biased and factually incorrect statements," and urges EOEEA to "challenge all stakeholder comments in an objective and balanced manner."

The comments also contain recommendations concerning how the designation process should be conducted in the future. The ACC panel recommends that all designations should be based on a document summarizing the science, and that this document should be prepared by an independent consultant with clients in both public and private sector, it should be provided to the SAB and other stakeholders for comments, the SAB consultant should "critically examine" the references for all stakeholder comments before producing a final document, the final document should form the sole basis for designation, the vote of the SAB members should be recorded, and the document should serve as the basis for any reconsideration and be publicly available.

Response:

Claims of flawed process result from mistaken assumptions by the commenter about what the law requires. Industry submitted new information in the second comment period that questioned the program's description of TDI's carcinogenicity, but this has not been the primary reason for designation; and claimed that TDI's effect on the respiratory system was exaggerated, but the available scientific evidence strongly supports TDI as a strong respiratory sensitizer.

The process: documentation. It is standard process for TURI to conduct a literature search, with the input from SAB members, and to share the results with the SAB. Either each SAB member reviews each document or the members divide up the work of reading documents and then share with each other what they have learned. This is the manner in which the SAB has performed its work since the beginning. Scientists on the SAB help TURI to identify existing information and scientists on the SAB conduct the review of original information. There is no requirement for a single summary document under the law. However, TURI does produce many such documents and correctly notes that it does so in the *Decision-making under TURA: Process Overview and Reference Guide* document that describes how the work is conducted. The documents that TURI provides are not mandatory, but facilitative to the process of deliberation by the expert members.

The comments of the ACC panel acknowledge that in fact TURI did provide materials, in the form of "notes and a detailed table of hazard information" to the SAB before the vote. These materials summarized what the SAB had considered when placing TDI on the More Hazardous Chemicals list in 1999. As noted above, there is no requirement for an additional vote by the SAB once they have placed a substance on the More Hazardous Chemicals list. At this time, the question was before the SAB as to whether it wished to change its recommendation and it did not do so. It was clear that the discussion concerned whether TDI ought to be one of the first candidates for HHS listing. The recommendation for designation therefore was not a "purported"

recommendation but a previous recommendation that the chemical be considered for an HHS listing, that the SAB affirmed with full awareness that TDI would be a priority candidate for an HHS listing.

The claims that the process required documentation in a specific form, and a formal vote, were also addressed in EOEEA's response to the first comment period. Repetition of these claims continues despite their refutation in the responses to comments already received. The industry's claims of a flawed process are not consistent with statute or regulation, and assertions of bias are not substantiated. The SAB is a group of professional volunteer scientists who do their work as an act of public service. They review the original documentation for themselves, and discuss them in public, where bias can be identified by observers, and are not likely to be mislead by TURI.

All meetings were public and industry representatives have always had the opportunity to participate. Actions were taken to ensure that the industry knew of the pending Council vote before the date and were invited to provide written and oral comments prior to the Council's vote. Many written and oral comments were provided by industry prior to the Council's vote. The industry then had the same opportunity as any other member of the public to provide comments during the comment period, and at the public hearing. There have been several meetings, of the Advisory Committee, the SAB Committee, and the Council, where industry has had the opportunity to provide comments, and where comments were received. The panel may feel that more efforts could have been made, and more time could have been provided. But the program provided more than what is required under law. During this process, significant time has been provided at several meetings to hear from representatives of industry.

Furthermore, an extraordinary second comment period was provided in order to ensure that industry has been fully heard. The SAB has reviewed all of the information submitted by industry. TURI has made changes to its fact sheet and policy analysis. None of the issues cited by industry have changed whether TDI should remain as a candidate for HHS (the SAB's role) or actually be listed (the Council's role).

Consideration of economic impacts. The panel states that impacts to business have not been adequately considered. This is incorrect. The regulatory promulgation process requires that a business impact statement be developed, and this was done as part of the process and it was provided to all interested parties with the notice of the comment period. The impact on Massachusetts businesses was considered and characterized as required by law. The panel claimed that TURI states that because of scarce resources it has not been able to adequately assess economic impacts. TURI's mention of scarce resources does not refer to economic impacts specifically, but simply notes that its analysis is limited to what its resources allow. TURI's role is to make a policy recommendation to the Council, which can direct it to continue its analysis if it thinks it is not adequate. The Council made no such direction to TURI.

The panel claims that the program's statements that toxics use reduction efforts have led to financial savings for many companies are not substantiated. These statements were not substantiated in the documents cited. However, they are amply substantiated elsewhere. The TURA literature is replete with instances and several surveys have been conducted that have

firmly established the basis for these statements. Many companies have published case studies of the benefits they have experienced and many companies have also spoken at public conferences. Toxics use reduction data show significant reductions in toxics use by companies within the program. No company has been required to reduce chemical use, so reductions are undertaken when they make good business sense. Reducing the use of a toxic chemical usually means that management costs of the hazardous chemical will be reduced as well as liabilities and risks. Experience has shown that the examination of alternatives often leads to improvements in process because people become more aware of their options.

Comments on health effects. The panel urges EOEEA to evaluate all comments in an objective and balanced manner. The panel claims that there are inaccuracies concerning TDI's cancer classification. The panel notes that while it is appropriate to consider IARC designations, the SAB "can consider overall weight-of-evidence," and that this is important when there is new information. The panel states that some new information was not provided to the SAB in its review, and argues that the IARC classification may be faulty. It is important to note that NIOSH's recommended exposure level is "lowest feasible concentration" (based on carcinogenicity). Though our understanding of carcinogenicity may not be complete, authoritative bodies have not changed their classification of TDI with regard to carcinogenicity. Moreover, as noted above, the SAB affirmed in 2014 and again in 2015 that its concern was primarily with TDI's respiratory and/or sensitization effects rather than carcinogenicity. Therefore, the available evidence supports Higher Hazard Substance designation based solely on TDI's strong respiratory and sensitization effects.

The panel claims that there are inaccuracies concerning TDI-induced asthma, in that terming TDI as a "leading cause of work-related asthma" is an overstatement and a "disservice" to the public. The panel states that in fact, TDI is ranked 9th among asthma-causing agents in a study of four states. As noted in EOEEA's first Response to Comments, while "leading" cause does not have a formal definition that we are aware of, government agencies have applied it up to the 10th place (e.g. CDC National Vital Statistics Reports, "Deaths: Leading Causes for 2010" available at http://www.cdc.gov/nchs/data/nvsr/nvsr62/nvsr62_06.pdf). The panel also states that TDI has fallen to 20th in recent years in those four states. (See the comments of Elise Pechter disputing the accuracy this statement.) The panel also describes a trend in various states where TDI-induced asthma has recently fallen substantially. (Again, see comments of Elise Pechter regarding these trends.) These points do not support the assertion that the term "leading cause" is inappropriate.

Literature supports the characterization of TDI as a leading cause of asthma. The Centers for Disease Control lists diisocyanates as one of the "most frequently reported agents associated with work-related asthma cases". As far as Massachusetts is concerned, the Massachusetts Department of Public Health's 2010 SENSOR report states that isocyanates were the 8th leading cause of work-related asthma in the commonwealth. Pechter points out that "all cases were new-onset," which is evidence of sensitization, as opposed to exacerbation. Concerning the national trend, reductions in cases can be attributed to many causes, such as failure to obtain care, failure of surveillance, discouragement of reporting, or improved use of protective measures. The reduction in cases does not support a conclusion that assessments of the chemical's hazards are incorrect.

OSHA is sufficiently concerned about TDI to post a limit value of 0.02 parts per million (ppm) and to note the Health Factors and Target Organs as: "allergic sensitization of respiratory tract; asthma".[2] The ACGIH recommends an even lower Time Weighted Average of 0.005 ppm, and cites the same Health Factors and Target Organs. OSHA notes that "Death from severe asthma in sensitized workers has been reported," that "once sensitized, workers may continue to exhibit the health effects of TDI several years after exposure has ended," and that "individuals sensitized to TDI may develop a chronic asthma-like syndrome that includes coughing, wheezing, tightness or congestion in the chest, and shortness of breath." TURI's characterization is consistent with government agencies charged with evaluation of the chemical's hazard, and with the ACGIH, a private group of professionals that includes industry representatives. The panel comments that its calculations of low levels of prevalence provide "no support for TURI's claim that isocyanates are a leading cause of work-related asthma." However, the panel's calculations are at variance with those of recognized authorities and peer-reviewed studies, as well as the surveillance data, all of which do provide extensive support.

The panel asserts that TURI's statement that "TDI is a potent dermal and respiratory sensitizer" is "inconsistent with human experience" and that only a small fraction of individuals present skin reactions. This statement denies the potency of TDI as a sensitizer in humans but acknowledges that it occurs and actually only contests the estimation of how many people are affected. The panel states that the statement should be qualified to include that only some individuals may have such reaction, and to state that the reaction would occur in the absence of rudimentary controls and that the problem can be managed with appropriate industrial hygiene practices.

It is important to understand that the approach of TURA is to identify chemicals that have inherent hazards. For the purpose of designation, the program does not need to add these qualifications. They apply to all chemicals in the TURA program. Discussion of protective equipment is appropriate for fact sheets, guidance, educational documents, but they are not appropriate for the purpose of considering a hazard-based designation. The strategy of TURA is to cause those who use such chemicals to pay increased attention to the issues arising from their use. Higher Hazard Substance designation is intended to prompt greater use of controls because users are more conscious of their need.

In addition, the program is required to serve every citizen of Massachusetts equally, and not to discount the importance of protecting a member of the public simply because they are in a group that is not as great in number as another group. If TDI sensitizes only a few individuals and not many, the few merit the protection that greater awareness might prompt.

The panel's recommendation that EOEEA carefully examine the comments submitted by others is reasonable. As discussed above, Master of Public Health and Certified Industrial Hygienist Elise Pechter submitted a comment relevant to the panel's argument that the data shows TURI's characterization is an overstatement and a disservice to the public. Pechter cited several peer-reviewed sources, that have confirmed TURI's characterization, some very recent (such as Tarlo

[2] https://www.osha.gov/dts/chemicalsampling/data/CH_272400.html.

and Lemiere, 2014[3], which refers to diisocyanates as "important sensitizers" and "the most common cause of occupational asthma in many industrialized areas"). Pechter notes that the "BRFSS, a population based telephone interview system documented that, in Massachusetts, 40.2% of adults with current asthma report that work caused or exacerbated their asthma. Approximately 496,700 adults in Massachusetts had a current diagnosis of asthma (2007). As many as 198,680 Massachusetts adults may have work-related asthma. Only 10% of adults with current asthma reported that their healthcare provider diagnosed their work issues or heard the patients' work concerns. See "Burden of Asthma in Massachusetts" April 2009. Pechter also makes the point that many workers do not know what chemicals they are exposed to.

Another commenter, Master of Public Health and Registered Respiratory Therapist Rachel Wilson cites numerous reputable sources (peer-reviewed, literature reviews, official government findings) that support the characterization of TDI as a potent sensitizer, and explains that "upon inhalation TDI reacts with glutathione (GSH), a non-protein thiol located in the epithelial fluid lining the lungs. GSH has a protective functionality responsible for xenobiotic metabolism, free radical elimination and gene expression regulation." TDI is known to be highly reactive. This account may explain how oxidative damage, cell death and other problems occur, that account for the asthmatic effect. Reviewing these comments, which included references to the original sources, and reviewing those sources, did not support the claim that many of the comments received in support were "biased and factually incorrect."

TURI fact sheet. The commenter asks that TURI's TDI fact sheet be removed from TURI's website because it is not a "credible source of information for the SAB, the regulated community, or the public." The commenter recommends changes related to cancer classification, asthma and sensitivity potency; a reference to phosgene; a discussion of respiratory protection and medical response to exposure; and information about exposure from products. TURI has updated its TDI fact sheet, taking account of ACC's comments. Consistent with standard practice, TURI has retained references to authoritative classifications such as those available from IARC and NTP. EOEEA notes that the reference to phosgene as an intermediary in the production process is relevant, as TDI manufacturing could occur in Massachusetts, and Massachusetts fact sheets are used outside of the state and this could be helpful information.

The commenter states that the discussion of exposure from products is misleading because TURI refers to unreacted TDI. The ACC's comments assume that all TDI is reacted. TURI qualifies its statement as that unreacted TDI "may" be present. The ACC provides no information to support the idea that there is no possibility of unreacted TDI exposure from consumer products. EOEEA asks TURI to examine this question and to ensure that its statements reflect what is known about exposure from products. However, EOEEA notes that the EPA, in January, 2015, issued a proposed Significant New Use Rule pertaining to TDI in consumer products. The rule applies to any use in a consumer product, (with a proposed exception for use of certain chemical substances in coatings, elastomers, adhesives, binders, and sealants that results in less than or equal to 0.1 percent by weight of TDI in a consumer product). EPA notes that "TDI and related compounds are volatile and as such could migrate out of articles that contain them. For instance, studies of

[3] "Occupational Asthma", Susan M. Tarlo, M.B., B.S., and Catherine Lemiere, M.D., *N Engl J Med* 2014; 370:640-649, February 13, 2014, DOI: 10.1056/NEJMra1301758.

TDI in polyurethane products reported that after the reaction between an isocyanate and an alcohol to form polyurethane products, residual levels of isocyanates were detected on the surface of the products, (e.g. flexible foams), which if used could lead to exposure." EPA also states that "TDI and related compounds are known to be volatile chemical substances, have been reported to migrate from products, are sensitizers, and would be expected to present a higher potential for exposure if the TDI in the article were a consumer product…" (Federal Register Volume 80, Number 10 (Thursday, January 15, 2015), [Pages 2068-2077]).

Role of the SAB. The ACC panel charges that TURI has attempted to diminish the role of the SAB. The ACC claims that its actions have caused concern in the industry that the evaluation of TDI is not science-based. The ACC describes documents that TURI provided to the SAB that lack a rationale for the relevance, and claims that this eliminates any public discussion on TURI's interpretation of their significance. EOEEA has found no substantiation for the assertion that TURI has either biased the SAB's discussions or eliminated any public discussion, and TURI may provide information to the SAB without a discussion of its relevance to designation because the SAB judges that relevance for itself.

Dr. Ellenbecker created an erroneous perspective in summarizing a recent study of workers in Europe. A review of the article shows that Dr. Ellenbecker quoted it accurately. Dr. Ellenbecker commented at the January 2015 SAB meeting regarding the article "Inception Cohort Study of Workers Exposed to Toluene Diisocyanate at a Polyurethane Foam Factory: Initial One-Year Follow-up" by Gui, et al., published in the American Journal of Industrial Medicine in November 2014. ACC states "at the time [of the SAB meeting], industry objected to this unqualified statement because it had not been given an opportunity to evaluate the publication." The article had been published in a widely respected and available journal two months before the SAB meeting and, given its subject matter, it seems unlikely that the ACC panel members had not read it prior to the SAB meeting, and there was no requirement that TURI alert industry attendees concerning it.

At the meeting, Dr. Ellenbecker spoke extemporaneously about the article, pointing out that even in a "modern polyurethane production plant" worker exposures were occurring at a level sufficient to induce new adverse health effects in 14.2% of the workers. The Gui paper found that "seven of the 49 original workers (14.2%) developed either new asthma symptoms (N=3), TDI-specific IgG (N=1), new airflow obstruction (N=1) and/or a decline in FEV1≥ 15% (N=3), findings that could indicate TDI-related health effects….The findings suggest possible early TDI-related health effects in a modern polyurethane production plant." His comment was accurate.

The article also states the following: "A second notable finding from this study was the potential for exposure to TDI, despite the modern facilities and intensive industrial hygiene efforts, including ventilation, automated, enclosed production machinery, and continuous real-time monitoring of airborne concentrations."

The article is not consistent with the ACC statement that "the authors stated that there were no cases of isocyanate–related allergy or asthma reported." Although the ACC correctly quotes the

article as stating that no "significant associations were observed between the assigned risk group, based on job category, and new asthma-like symptoms, new eye irritation, baseline lung function, change in lung function over the year of follow-up or workers lost to follow-up," the authors also reported that "three workers (7.1%) reported new asthma-like symptoms during the study." The study authors did not find an association between job category and asthma induction. That is not the same as not finding asthma induction. The Gui article therefore supports significant TDI exposures and resulting adverse health effects among workers even at a "modern polyurethane production plant."

Comment

From Carol S. Eicher, President and CEO, Innocor Foam Technologies

Innocor, which has been engaged for over 16 years in the manufacture and fabrication of flexible polyurethane foam, and uses "between 5.5 and 6.5 million pounds of TDI annually" and "strongly objects" to the designation proposal, as "there is, to our knowledge, no commercially viable alternative to TDI." User fees associated with HHS designations would "potentially increase" product pricing and would have a "detrimental effect on our business," which currently employs approximately 45 workers.

The commenter states that "Innocor safety systems and pollution control devices capture and reduce the release inside and outside of the facility such that our total emissions of TDI are less than 200 pounds per year. Since 1999 our Newburyport facility has had two workers compensation claims relating to exposure to TDI. Based on the number of workers at our Newburyport facility who have worked with TDI processes, these incidences represent less than 2% of the total number of those workers that reported asthma-like symptoms over a 16 year period." The commenter notes that TDI vapor monitoring is conducted and documented frequently, and industrial hygiene testing is conducted by outside groups. Clean Air Act requirements are being met, and relevant workers receive pulmonary function tests and are respirator fit-tested initially and annually, and received extensive training. Innocor is always exploring the availability of alternative chemicals and ways to reduce potential hazards.

"Innocor believes that because there are no readily available non-isocyanate alternatives, designating TDI as a HHS would unfairly penalize our business. Imposing additional record-keeping, reports and fees could result in significant disadvantage for our company and may threaten the viability of the Newburyport operation, its workforce and the jobs of hundreds of workers employed in related industries that are dependent upon continued supply of competitively-priced Innocor flexible foam products."

Response

EOEEA commends the company for the actions it is taking and for its commitment to safe operations and to the continuous investigation of potential improvements. EOEEA is also appreciative of the fact that Innocor is operating in Massachusetts and providing jobs for Massachusetts workers.

However, Innocor's contentions concerning the impact of Higher Hazard Substance designation are not accurate. Higher Hazard Substance designation will impose no additional fees, no additional reporting, and no additional record-keeping requirements for Innocor. Innocor is already paying TURA fees, already supplying the required reports, and already conducting the required record-keeping. The effect of Higher Hazard Substance designation is to lower the reporting threshold to 1,000 pounds per year. Innocor is already using far in excess of the reporting threshold and its costs will not increase because of Higher Hazard Substance designation.

EOEEA also notes that a TURA listing and/or a Higher Hazard Substance designation, serves to focus attention on the inherent hazard of a material, which helps to ensure adherence to best practices and caution (as well as the continuous search for alternatives). While Innocor is to be commended for its record, it is likely that designation will heighten attention to the scrupulous implementation of safe practices, and perhaps the already low rate of exposures at the facility can be reduced to zero.