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**RESPONSE TO COMMENTS
ON PROPOSED AMENDMENTS TO 301 CMR 41.00 TOXIC OR HAZARDOUS
SUBSTANCE LIST TO DESIGNATE FIVE ADDITIONAL HIGHER HAZARD
SUBSTANCES**

Regulatory Authority:
M.G.L. Chapter 211

November 2014

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 1-Bromopropane (n-Propyl Bromide (CAS 106-94-5)), Hydrogen Fluoride (CAS 7664-39-3), Cyanide Compounds (*TURA #1016*), Toluene Diisocyanate (listed as CAS: 2,4-TDI [584-84-9]; 2,6-TDI [91-08-7]; and TDI mixed isomers [26471-62-5]), and Dimethylformamide (CAS 68-12-2) as Higher Hazard Substances. Designation as a HHS lowers the threshold for reporting and planning under TURA to 1,000 pounds (from either 10,000 or 25,000 pounds, depending on how the chemical is used at the facility).

Toxic chemicals pose a range of risks to the environment and public health. The Toxics Use Reduction Act (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. This law has been successful and, 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. Four of the letters (one with 31 organization/individual signatories) also supported the designation of 1-bromopropane, hydrogen fluoride, cyanide compounds, and dimethylformamide as Higher Hazard Substances. There were no written or oral comments in opposition to the designation of 1-bromopropane, hydrogen fluoride, cyanide compounds, and dimethylformamide as Higher Hazard Substances.

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. These comments were submitted by either a national chemical trade association or national chemical company that had interests in the manufacture of toluene diisocyanate (TDI). 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 are summarized below with EOEEA's response to each comment.

Despite the fact that the public has had opportunity to comment on the proposal and the designation has been the result of a science-based process conforming with the statute, the program has suggested that an extension of the comment period for one chemical TDI, and the opportunity for the SAB to review the most recently-submitted information would serve the public process. The program will finalize the four designations at this time, but is providing an additional 60 day comment period for TDI only, as it pertains to the proposal to designate as a Higher Hazard Substance.

The following people/organizations submitted comments:

Organizations and individuals submitting comments supporting the designation of five chemicals as Higher Hazard Substances

Letter of support for all five chemicals as HHS (31 signatories, Aftosmes-Tobio to Zimmerman below)

Alyssa Aftosmes-Tobio
Environmental Health Coordinator; Healthy Mothers, Healthy Babies Coalition of Massachusetts

Brent Baeslack
Bradford, MA

Julia Blatt
Executive Director, Massachusetts Rivers Alliance

Martha Dansdill
Executive Director, HealthLink

Susie Davidson
Coordinator, Boston Chapter of the Coalition on the Environment and Jewish Life

Janet Domenitz
Executive Director, MASSPIRG

Cheryl Durr Patry
Medfield Green

Tom Estabrook
University of Massachusetts Lowell, Massachusetts Teachers Association

The Rev. Laura E. Everett
Executive Director, Massachusetts Council of Churches

Dr. Daniel Faber
Director, Northeastern Environmental Justice Research Collaborative
(Institution for identification purposes only)

Debbie Fastino
Executive Director, Coalition for Social Justice

Steve Fisher
Director, Regional Environmental Council Worcester

Steve Gauthier
Local 201 IUE/CWA
North Shore Labor Council

Ellie Goldberg, M.Ed.
Healthy-Kids.info, Newton, MA

Marcy Goldstein-Gelb
Executive Director, Massachusetts Coalition for Occupational Safety and Health

Nancy Goodman
Vice President for Policy, Environmental League of Massachusetts

Ben Hellerstein
Environment Massachusetts

Ken Kipen
Director, Hilltown Anti-Herbicide Coalition, Ashfield

Alan Krentzel
Sustainable Sudbury

Joan Kulash
People for the Environment, North Andover

Rev. Bill Loesch
Codman Square Neighborhood Council

Claire Miller

Massachusetts State Director, Toxics Action Center

Deborah Moore, PhD
Executive Director, Second Look

Cheryl Osimo
Executive Director, Massachusetts Breast Cancer Coalition

David Ozonoff, MD, MPH
Professor of Environmental Health, Boston University School of Public Health
(Institution for identification purposes only)

Sue Phelan
GreenCAPE (Green Cape Alliance for Pesticide Education)

Bill Ravanese
Boston Regional Director, Health Care Without Harm

Leo V. Sarkissian
Executive Director, The Arc of Massachusetts

Elizabeth Saunders
Massachusetts Director, Clean Water Action
Coordinator, Alliance for a Healthy Tomorrow

Kimberly Wilson Verancio
Labor Extension Coordinator, Arnold M. Dubin Labor Education Center
UMass Dartmouth
(Institution for identification purposes only)

Robert L. Zimmerman
Executive Director, Charles River Watershed Association

Organizations and individuals submitting comments supporting the designation of toluene diisocyanate as a Higher Hazard Substance

Charlotte Brody, RN
Vice President for Health Initiatives, BlueGreen Alliance

Richard W. Clapp, D.Sc., MPH
Professor Emeritus, Boston University School of Public Health

Andrew Comai
Coordinator, United Auto Workers International Union

Peter Dooley, MS CIH, CSP
President, LaborSafe

Michael Ellenbecker, Sc.D., CIH
Professor Emeritus, Department of Work Environment
University of Massachusetts Lowell

Tolle Graham
Labor and Environment Coordinator, MassCOSH
USW Local 9358

Robert F. Herrick, Sc.D., CIH
Senior Lecturer
Harvard School of Public Health

Robert M. Park
National Institute for Occupational Safety and Health (NIOSH)

Elise Pechter MAT, MPH, CIH

Mark S. Rossi, PhD
Co-Director, Clean Production Action

David H. Wegman, MD, MSc
Professor Emeritus, Department of Work Environment
University of Massachusetts Lowell

Organizations and individuals submitting comments opposing the designation of toluene diisocyanate as a Higher Hazard Substance

Tim Feeley, Industrial Hygienist
Bayer Material Science (Bayer)

Robert Luedeka,
Executive Director, Polyurethane Foam Association (PFA)

Sahar Osman-Sypher
Director, Diisocyanates Panel of the American Chemistry Council (ACC Panel)

Ralph Parod, Toxicologist
BASF Corporation (BASF)

Steve Rosario
Senior Director Northeast Region, American Chemistry Council (ACC)

COMMENTS ON THE PUBLIC PROCESS

Comment: The process of bringing the recommendation to the Council was flawed. (ACC, ACC Panel, BASF, Bayer)

- The SAB has not formally taken a position of the designation of TDI since 1999 nor formally voted on its designation as a HHS. (ACC, ACC Panel, BASF)
- The SAB statement at its February 2014 meeting that TDI is “worthy” of HHS designations, is not sufficient basis or justified for designation without a “hard look at the science” (ACC, ACC Panel, BASF, Bayer)
- There is no evidence that TDI was further reviewed since 1999 (ACC, ACC Panel)
- An objective summary of the TDI hazards reviewed by the SAB should be made available to the public for comment prior to the SAB finalizing its HHS recommendation (ACC, ACC Panel)
- There was insufficient opportunity for stakeholder review and input into the science (ACC, ACC Panel)
- The program did not follow the process as outlined in the Decision-Making Under TURA: Process Overview and Reference Guide (ACC, ACC Panel, BASF)
- EEA should table the process until new data have been reviewed (ACC)

Response:

Higher Hazard Substance Designation Process. The Higher Hazard Substance designation process was established by the 2006 Amendments to TURA (MGL Ch 21I). The Act authorizes the Administrative Council on Toxics Use Reduction (a board chaired by the Secretary of Energy and Environmental Affairs consisting of Secretariat and Agency representatives from EOEEA, the Executive Office of Housing and Economic Development, Executive Office of Labor and Workforce Development, the Executive Office of Public Safety, the Department of Public Health and Department of Environmental Protection) to designate listed TURA chemicals as Higher Hazard Substances, based on a recommendation from the Toxics Use Reduction Institute (TURI) in consultation with the Science Advisory Board. The Secretary of Energy and Environmental Affairs, as chair of the Council, promulgates into regulation the actions of the Council.

The statute states that TURI will advise the Council as to which substances from the list of toxic or hazardous substances should be designated as Higher Hazard Substances, and that advice is to be based on advice from the Science Advisory Board (SAB), taking into consideration the policy implications of the recommendation. The SAB is an eleven member board of experts in toxicology, environmental impacts and related scientific disciplines; members are nominated by TURI, Economic Affairs, Public Health or EOEEA, and are appointed by the governor. The Act also states that substances the SAB had categorized as “category 1/more hazardous” prior to the adoption of the amendments should be given first priority for consideration.

In addition, the Act authorized the chair of the Administrative Council to appoint a 15 member Advisory Committee with specified numbers of representatives from business, environmental, public health, labor groups as well as the Attorney General’s office and members of the toxics use reduction community.

The referenced document, “Decision-Making Under TURA: Process Overview and Reference Guide,” is a tool that was created to assist members of the Science Advisory Board, the Advisory Committee, and the Administrative Council. It does not constitute an official mandate on any policy question; the authoritative sources on all TURA program activities are the TURA statute and regulations. The document reviews the statutory roles of the TURA program agencies, Advisory Committee, Administrative Council, Science Advisory Board, and reviews technical and policy issues relevant to a range of TURA program decisions, including designation of Higher Hazard Substances. Based on stakeholder input, the TURA program will update this document, as well as its informational fact sheets, to further clarify the various processes.

The role of the Science Advisory Board is to provide scientific input into the inherent hazards of the substance, and it is up to the program to evaluate policy implications, including the order in which the “category 1/ more hazardous chemicals” should be considered for HHS designation; the program consults with its advisory bodies as needed.

TURI’s recommendations for Higher Hazard Substance designations are brought before the Advisory Committee first in the conceptual phase and then as a formal Policy Analysis for review and comment prior to bringing them to the Administrative Council, in order to bring a wide perspective to these decisions.

The SAB, Advisory Committee and Administrative Council meetings are public meetings with notification and agendas published in advance. They are open to and routinely attended by stakeholders. As shown below, the program appropriately followed the procedures outlined in the statute in developing its recommendation to designate these chemicals as Higher Hazard Substances, as well as the Administrative Council’s vote to designate. The public record shows there was ample opportunity for public input in addition to the formal opportunity afforded by the 21-day public notification and comment period mandated by the Administrative Procedures Act as a part of the process for promulgating regulations. The process was in accord with requirements and was not flawed.

- The Science Advisory Board categorized TDI as a category 1/more hazardous chemical in 1999 after a review of the science. This action made it a candidate for possible HHS designation and section 9(D) of the Act requires the Council to first consider the chemicals on that list under its authority to designate HHS.
- A summary of the categorization was published in Toxics Use Reduction Institute, *Methods and Policy Report No.18, “Categorization of the Toxics Use Reduction List of Toxic and Hazardous Substances”*, 1999. The reasons for TDI being categorized in the “more hazardous chemicals” list are listed as: “irritating to eyes, nose, skin and TLV 5 ppb, IARC 2b”. The ACGIH (American Conference of Governmental Industrial Hygienists) occupational exposure Threshold Limit Value (TLV) for TDI is particularly low because of the evidence of sensitization. These key decision points have not changed since 1999.
- 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.

- The Advisory Committee discussed the list of chemicals again on March 4, 2014. The TURA program included additional information on the chemicals, based on requests from the Committee.
- On May 7, 2014, the TURA program provided a more detailed table of ten substances (seven substances plus the three TDI CAS numbers - the TDI isomers were considered together, but are listed under TURA with three different CAS registry numbers) under consideration for possible HHS designation to the Advisory Committee. This table included summary hazard information. The Advisory Committee provided additional input at this time on ways to prioritize among these chemicals.
- On June 3, 2014, the Administrative Council considered the short list of ten chemicals prioritized based on the Advisory Committee's criteria. At this meeting, the Council expressed interest in avoiding adverse substitutions by acting on chemicals in groups based on either functional use or chemical structure; requested additional analysis to identify logical groupings, including by functional use; and requested additional background information on the Advisory Committee's prioritization criteria and process.
- On July 14, 2014, the TURA program provided summary information to the Administrative Council on the input provided to date by the Advisory Committee and SAB, including the criteria the Committee had proposed for prioritization within the larger list of "more hazardous chemicals." The TURA program provided Council members and attendees with a memo explaining the prioritization process to date and the key reasons for prioritizing each of the chemicals that had been selected as top priority for action in 2014. TDI was included in this list, and the key reasons for prioritizing it in 2014 were noted as: "EPCRA EHS and strong sensitizer (occupational hazard)." Both of these were criteria the Advisory Committee had asked the program to use in prioritizing chemicals. The summary table with hazard information was handed out at this meeting as well. A draft policy analysis of hydrogen fluoride (HF) was shared and the Council indicated that TURI should prepare full policy analyses for DMF, cyanide compounds, HF, and the 3 TDI CAS numbers.
- On August 5, 2014, the TURA program presented a full draft policy analysis to the Advisory Committee. Industry association representatives were present at this meeting; questions regarding the process were voiced and the process was reviewed. No comments on the science were received at this time.
- On August 19, 2014, the Council deliberated and voted (6 yes, 0 no) to move forward on the designations.
- 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.

In summary, 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 what scientific information the TURA program was taking into account. In addition, as discussed below, stakeholders have had an opportunity to submit information during the formal public comment period. Despite the fact that the public has had this opportunity, the program is providing an additional 60 day comment period (for TDI only), and the SAB will review the most recently submitted information.

Comment: The program did not adequately consider the factors other than hazard in reaching the decision to designate TDI. (ACC)

- The Administrative Council in its decision making is allowed to consider issues such as quantities used in the Commonwealth, exposure, available alternatives, impacts to business and other information regarding substance use (TURAC, 2012)(ACC Panel)
- TDI use in Massachusetts is limited to a small number of facilities. The ACC Panel does not believe that the HHS designation is commensurate with the level of risk for exposure presented by TDI.

Response:

Higher Hazard Substance designations are based on a chemical’s inherent hazard. Factors such as quantity used, exposure, and available alternatives are taken into account as one factor helping the program to prioritize initiatives, given scarce resources; however, HHS designation does not depend exclusively on these factors. Business impacts are always considered.

The Advisory Committee considered these and other policy considerations over the course of more than six months as they worked on prioritizing the larger list of more hazardous substances from a policy standpoint. They suggested prioritizing substances that were 1) extremely acutely hazardous, with particular concern for workers; 2) used in significant quantities or by significant numbers of Massachusetts businesses; and 3) prioritized for regulatory action by other jurisdictions (e.g., EU). The final policy analysis outlines the quantities used in Massachusetts by TURA filers, available alternatives, and the impacts of Higher Hazard Designation on potential filers. In 2012, Massachusetts TURA filers reported using more than 7.3 million pounds of TDI isomers.

Comment: The TURA program’s approach to TDI is relevant for its approach to other diisocyanates.

- Given the stated intent to use the designation of TDI as a segue to a HHS designation of other diisocyanates, it is critical the scientific record concerning TDI be correct so that other diisocyanates receive a proper and complete review. The rationale for any

SAB/TURI HHS recommendation should be clearly delineated since other diisocyanates will have different characteristics. (ACC Panel, Bayer)

Response:

Both TDI and MDI are already on the “more hazardous chemicals” list. The SAB is in the process of reviewing the science on the other diisocyanates in the EPA TRI “Diisocyanates Category.”

The Administrative Council has advised TURI and the Board that it would like to designate substances that are potential hazardous replacements of Higher Hazard Substances, consistent with its effort to avoid adverse substitutions. In its policy analysis for TDI, TURI noted the importance of considering other diisocyanates. Industry representatives provided input on issues related to substituting one diisocyanate with another.

MDI is now listed as part of the EPA TRI Diisocyanates Category. This category did not exist at the time of the SAB’s original categorization of the TURA list. The Science Advisory Board has begun and will continue an in depth review to determine whether other substances in the Diisocyanates Category should be categorized on the “more hazardous chemicals” list. There will be ample opportunity to comment on this process.

Comment: With regard to the science review and TURI’s recommendation to designate TDI as a Higher Hazard Substance, the Administrative Council should conduct a review “to understand how such a procedural breakdown occurred” (ACC)

- The Administrative Council should “table” the designation and send it back to the SAB for further review. (ACC, ACC Panel, PFA)

Response: EOEEA, as chair of the Council, believes the correct regulatory procedures for designating Higher Hazard Substances were followed and that there was no procedural breakdown in the review of the science or the appropriateness of the recommendation to designate TDI as a HHS.

COMMENTS ON WHETHER THE FACTS SUPPORT DESIGNATION OF TDI AS A HIGHER HAZARD SUBSTANCE

SENSITIZATION AND ASTHMA

Comment: The program has overstated the risk of asthma from TDI exposure (ACC Panel, Bayer, BASF)

- Detailed reviews of occupational cohorts (Ott *et al.*, 2002, Ott *et al.*, 2003) examined exposure-response relationships for TDI, and showed an association between the declining incidence of diisocyanate asthma and the reduction in airborne TDI levels in the workplace (ACC Panel, PFA).
- An analysis performed by NIOSH, specifically in Massachusetts isocyanates ranked 10th among work related asthma cases between 1990-2008, falling to 16th place during the years 2009-2010 (ACC Panel).

- The decline in the incidence of TDI-induced asthma in Massachusetts over the past 20-years, particularly when evaluated against the increase in use of TDI's within the state does not support the recommendation of TDI as a HHS. (ACC Panel)
- The underlying reason for the reduction in isocyanate-related asthma is multifactorial, and is believed to include better compliance with exposure standards, use of less volatile isocyanate forms such as prepolymers, better medical surveillance program and improved work practices. It appears that control of exposures and compliance with current occupational exposure limits have shown that isocyanate asthma can be minimized. (PFA)
- It is scientifically and medically unnecessary to designate TDI as a Higher Hazard Substance to protect worker safety and environmental and public health. (PFA)

Comment: It is important to list TDI as a Higher Hazard Substance because of its impact on asthma, including new-onset asthma. (Pechter; Graham-MassCOSH; Comai)

- Diisocyanates are now recognized among the leading causes of work-related asthma in developed countries.^{i[i] i[iii]} (Pechter)
- Massachusetts and four other states are currently funded by the Centers for Disease Control and Prevention (CDC) to conduct surveillance of work-related asthma. Isocyanates were the ninth most frequently reported exposure among all cases of work-related asthma in Massachusetts, California, Michigan and New Jersey (1993-2008). Most of those cases from isocyanates were new-onset asthma among workers who never had asthma before.” (Pechter; Graham – MassCOSH)
- “UAW represents workers who are exposed to isocyanates at work in the State of Massachusetts. TDI is one of the leading causes of occupational asthma among workers.” (Comai)

Comment: TDI is a sensitizer, and this is an important reason to list it as a Higher Hazard Substance. (Wegman, Brody-BGA) **Sensitization is sufficient reason for HHS designation.** (Herrick, Ellenbecker)

- “In my opinion there is sufficient evidence for designating TDI as a high hazard substance, based primarily upon the ability of TDI to behave as a sensitizer.” (Herrick)
- “There is ample scientific, medical and public health evidence that TDI is a powerful respiratory sensitizer that initiates, among other conditions, asthma in a substantial number of persons who are exposed, *de novo*, as well as to dramatically exacerbate frequency and severity of asthma attacks in those who already have asthma. Once an individual is sensitized, he or she is at significant risk of experience severe respiratory symptoms on exposure to much lower levels, well below the current OSHA Permissible Exposure Level.” (Wegman)
- “Once an individual is sensitized to TDI, exposure extremely low levels are all that is needed to cause deliberately asthma attacks, resulting in workers having to change jobs and in some cases leave their place of employment altogether.” (Brody – Blue Green Alliance)
- “... [T]he sensitization potential of TDI is sufficient reason to list [TDIs], irrespective of their carcinogenic or other toxic properties.” ““[I]t is because of the extreme danger for sensitization at very low exposure levels, with subsequent respiratory

difficulty at even lower exposures once sensitized, that I strongly recommend that TDI be placed on the Higher Hazard Substance list.” (Ellenbecker)

- “Both inhalation and skin contact with isocyanates can contribute to respiratory disease.ⁱⁱⁱ” (Pechter)

Comment: TDI’s effects as a sensitizer have been recognized for decades. (Clapp; Brody - BGA; Pechter)

- “TDI has been recognized for over 40 years as a respiratory irritant and sensitizer” (Clapp)
- “TDI has been known for many years to be a potent asthmagen in both experimental animals and humans exposed at work” (Clapp)
- “It is well established that TDI is a “potent” sensitizer (a simple search in PubMed for “potent sensitizer” and “TDI” will reveal this statement to be true).” (Brody)
- “TDI, and other related diisocyanates, cause work-related asthma. Evidence about the relation between diisocyanates and asthma emerged in the 1950s and diisocyanates have been recognized as a cause of work-related asthma since the 1960s.”^{iv v vi vii viii ix x} (Pechter)

Comment: New science elucidates mechanisms of sensitization.

- “The mechanism of TDI-induced sensitization has recently been demonstrated to be post-transcriptional regulation by microRNAs in animal models (Anderson, et al., Journal of Immunotoxicology, Vol. 11, No. 3, July-September, 2014)” (Clapp)

Response:

Leading cause.” The statement that “exposure to diisocyanates, including TDI, is recognized as a leading cause of work related asthma” is a statement of a broadly accepted consensus. In challenging this view, the ACC Panel notes that “isocyanates ranked 10th among work related asthma cases between 1990-2008” in Massachusetts, with a lower value (16th) for 2009-2010. 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). It appears that the commenters for and against the designation do not disagree about the role of diisocyanates in causing work-related asthma, but rather, about whether it is still appropriate to refer to it as a “leading cause.”

Workplace protections. ACC’s and PFA’s comments suggest that TDI should not be designated as a Higher Hazard Substance because the incidence of asthma can be minimized by proper workplace practices and is declining in proportion to the reduction in ambient concentrations. TDI has inherently hazardous properties. TURA is designed to supplement existing regulatory programs by requiring companies to evaluate whether there are cost effective ways to reduce use, emissions, and discharges of hazardous and toxic chemicals in the workplace and the environment.

The occupational cohort studies referenced by the ACC Panel and PFA support the view that increased government and business attention to the hazards of TDI and other diisocyanates can play an important role in preventing or mitigating the development of work-related

asthma. A Higher Hazard Substance designation under TURA would help to ensure on-going focus on options for reducing hazard at every step of the relevant industrial processes.

Established science on sensitization. TDI has been recognized as a potent sensitizer since the 1960s. There is no data the program is aware of that contradicts the original decision that TDI is a potent respiratory sensitizer, and most commenters support this position. This long-established science on sensitization is a key basis for the proposed designation.

Contradiction of respiratory sensitization as a basis for designation of TDI as a HHS would require strong evidence that directly contradicts more than fifty years of scientific evidence supporting the proposition that TDI is a strong respiratory sensitizer. The program is aware of no such evidence that has been produced since the original “more hazardous” designation in 1999, and a majority of the commenters strongly support this position.

The MSDS for TDI from BASF Product Manager Jarrett Russell includes the following statements: “Pulmonary sensitization can occur in some individuals, leading to asthma-like spasms of the bronchial tubes and difficulty breathing. Individuals with a history of respiratory illness, asthmatic conditions, eye damage or TDI sensitization should not be exposed to this product. . . . Acute or chronic overexposure to isocyanates may cause sensitization in some individuals, resulting in allergic symptoms of the lower respiratory tract (asthma-like), including wheezing, shortness of breath and difficulty breathing. Subsequent reactions may occur at or substantially below the PEL and TLV. Asthma caused by isocyanates, including TDI, may persist in some individuals after removal from exposure and may be irreversible. Some isocyanate sensitized persons may experience asthma reactions upon exposure to non-isocyanate containing dusts or irritants. Cross sensitization to different isocyanates may occur.”

New science on mechanisms. The information on new science on mechanisms is of interest for educational materials the TURA program will develop on TDI.

Summary: EOEEA agrees with the commenters noted above that it is appropriate and important to designate TDI as a Higher Hazard Substance because of its sensitization effects.

SENSITIZATION AND ASTHMA: ADDITIONAL POINTS RELATED TO WORKER HEALTH

Comment: Rates of dermal and respiratory sensitization are low. These low rates argue against the designation of TDI as a Higher Hazard Substance. (ACC Panel, BASF, PFA)

- The low incidence of respiratory sensitization is supported by data from worker exposure and disease incidence programs in Finland, Canada, Germany, Belgium, and France over the past decade against a background of increasing production and use around the world. (ACC Panel)
- The low incidence of dermal and respiratory sensitization in current occupational settings demonstrates that these conditions can be effectively managed by good industrial hygiene practices. (ACC Panel, Bayer, PFA)

Comment: There is evidence of adverse effects on workers.

- In studies of workers producing TDI, the annual incidence of TDI-induced OA decreased as the TDI exposure levels have decreased in the workplace. Lowering TDI exposures to

0.001 ppm (1 ppb) will result in further reduction in the annual incidence of TDI-induced OA. (Herrick)

- “TDI causes respiratory and skin disease in workers directly exposed. TDI also poses a threat to communities that are exposed. I have been directly involved in evaluating many workplaces where TDI use resulted in severe health outcomes for exposed workers.” (Dooley)
- “Because of continuing worker illness reports, OSHA announced a special emphasis program on isocyanates, starting in June 2013 that is continuing currently.^{xii}” (Dooley)
- “OSHA has dozens of records of multiple companies in which they found exposures to TDI in Massachusetts.^{xiii} OSHA is only informed about a fraction of the exposures, since many workers do not know their OSHA rights or fear job loss. Exposure to TDI is a long standing and still present problem. OSHA announced a special emphasis program on isocyanates, starting in June 2013 that is continuing currently.^{xiii}” (Pechter)
- “Despite industries’ best effort to lower exposure levels, TDI and other diisocyanates continue to rank among the top 10 causes of occupational asthma nationally^{xiv} and these trends are consistent with sentinel cases reported to the Massachusetts Department of Public Health’s asthma surveillance system.^{xv}” (Brody)
- “New methods of sampling for exposure are currently available that reveal significantly higher exposures than previously monitored.” (Comai)

Comment: There is a significant likelihood of undercounting of worker health impacts.

- “Health effects may go unreported due to the inadequate quality control of Patch Test materials used in determining dermatitis.^{xvi}” (Comai)
- Healthy worker effect: “In reviewing the extensive literature we are seeing evidence of a strong healthy worker survivor effect, indicating the workers who develop sensitization to TDI do not remain long in the workforce, exiting increasingly rapidly with higher average exposure levels. If not accounted for in analyses of exposure-response, this effect of course would tend to cause underestimation of the response. Few published studies address this source of bias.” (Park - NIOSH)

Comment: There is a significant likelihood of harmful worker exposures.

- “The potential for overexposure is great. The NIOSH guideline lists the vapor pressure of TDI as 0.05 mm Hg, which corresponds to a maximum airborne concentration of 66,000 ppb. Thus, the maximum airborne concentration is 66,000 times higher than the pending TLV and 13,000 times higher than the current TLV and REL.” (Ellenbecker)
- “New methods of sampling for isocyanates are finding higher levels of isocyanate in work place air than previously known.”^{xvii} (Comai)
- Exposures during hot work are a particular concern. “Where isocyanates are used in coating and sealers worker exposure risks continue even when the material is “cured”. Hot work (welding, grinding and cutting) release a host of debilitating chemicals including vapor phase TDI and its oligomers. Research found levels at 20 times the Occupational Exposure limit during hot work.” (Comai)
- “To quote from the ACGIH 2014 TLV booklet, “...after a person is sensitized, subsequent exposure may cause intense responses, even at low exposure concentrations (well below the TLV).” Thus, a sensitized worker could have a severe response at exposures well below 1 ppb - this seems to me to very clearly meet the definition of a Higher Hazard Substance.” (Ellenbecker)

Comment: Asthmagens and sensitizers are a key concern for Massachusetts workers.
(Pechter; Graham – MassCOSH)

- “Nearly 10% of Massachusetts adults have asthma; CDC estimates that 477,599 adults in Massachusetts currently have asthma.^{xviii} The rate in Massachusetts is higher than the US as a whole. Asthma that is caused or made worse by work may affect 40% of adults with asthma. Asthma that is related to work appears to become more severe, resulting in more symptoms, interrupted sleep, and trips to the doctor for treatment.^{xix}” (Pechter)
- “We have particular concern about TDI because it can cause work-related asthma and sensitization that goes beyond the workplace and can be career ending with a life altering disease. Occupational asthma has overtaken asbestosis as the leading cause of new work-related lung disease.” (Graham - MassCOSH)
- “MassCOSH and the other labor representative on the TURA Advisory Board, Steve Gauthier from IUE/CWA Local 201 Health and Safety Committee and General Electric Employee have repeatedly asked TURA to address sensitizers in their assessments for high hazard chemical designations.” (Graham - MassCOSH)
- OSHA is only informed about a fraction of on-the- job exposures since many workers do not know their OSHA rights or may not know the source of their work-related health problems. However, OSHA does have dozens of records from companies in which they found exposures to TDI in Massachusetts.^{xx} (Pechter)

Comment: TDI is a source of concern in other states. (Comai; Dooley; Pechter; Rossi; Letter of support – 31 signatories)

- “Asthma caused by isocyanates is the most common cause of work-related asthma in Michigan. Isocyanates are responsible for 21% of the cases of work-related asthma in Michigan.”^{xxi} (Comai)
- The Michigan SENSOR program has written about the deaths of two workers from exposure to isocyanates on the job. Resources related to studies done related to Isocyanates include the following:
<http://www.oem.msu.edu/userfiles/file/News/v24n2.pdf>
http://isocyanates2012.org/content/media/poster_pdf/OHS/OHS_Poster_30_KennethRos enman.pdf (Dooley)
- “The Michigan SENSOR program has written about the deaths of two workers from exposure to isocyanates on the job.^{xxii}” (Pechter)
- “2,4-TDI and 2,6-TDI are listed on the California Candidate Chemical List.” (Rossi)
- “TDI is regulated under California’s Proposition 65 due to its carcinogenicity.” (Letter of support – 31 signatories)

Response:

Risk vs. hazard. The comments above from ACC Panel, BASF, and PFA focus on reducing risk, whereas a HHS designation under TURA is based on inherent hazard. As discussed above, a HHS designation is designed to encourage companies to identify and adopt manufacturing techniques that reduce use and waste of hazardous and toxic chemicals. These approaches often improve the financial position of the business as well as improving environmental performance and worker health and safety.

Industrial hygiene. As shown in the points above related to industrial hygiene, good industrial hygiene practices can help to reduce risk of dermal and respiratory sensitization. Designating TDI as a HHS will bring users of smaller amounts of TDI into the program, helping to ensure that they are following best practices to reduce both their TDI use and the worker exposures.

Potential for undercounting. The information above related to the potential for undercounting may be useful in the TURA program's work to help educate businesses and TUR planners about hazards and safer alternatives.

Massachusetts worker concerns. The TURA program has endeavored to take into account the input that labor representatives have provided via the Advisory Committee regarding the importance of sensitizers. Prioritizing a key sensitizer for action in 2014 is one aspect of this effort.

Concern in other states. Information from other states may be useful to the TURA program as it updates its educational materials on TDI.

Summary. EEA agrees that there is a significant likelihood of harmful worker exposures. The worker safety information presented in all the comments above supports the preventive TUR approach, in which options that reduce or eliminate the use of the hazardous material are prioritized.

CARCINOGENICITY, MUTAGENICITY AND TERATOGENICITY

Comment: Chronic effects of TDI (carcinogenicity, mutagenicity and teratogenicity) are overstated.

- The IARC classification was selected by the SAB as one of the more important criteria it used to identify more hazardous substances in creating the initial 1999 list of substances from which higher hazard substances would be recommended. However recent publications have shown that TDI is not a human carcinogen. (ACC Panel)
- The classification of TDI as an IARC 2B carcinogen, possibly carcinogenic to humans is based on a flawed bioassay performed by NTP in 1986, when an increased tumor incidence was observed when TDI in corn oil was administered directly into the stomach of rodents by oral gavage. (ACC Panel, BASF)
- The fact that no other isocyanate substances are classified by IARC as possible human carcinogen adds to the further evidence of the flaws in the NTP study used as a basis for the IARC classification of TDI. (ACC Panel)
- Besides the flawed NTP study, there is no evidence that TDI is carcinogenic in humans or animals under physiological exposure conditions. (ACC Panel, BASF)

- The claim that TDI is a mutagen is false. As detailed by Prueitt et al., 2013, positive responses seen in mutagenicity assays are due to the transformation of TDI to TDA, a known mutagen, when TDI is suspended in a water-soluble organic solvent that typically contain low levels of water. (ACC Panel, BASF)
- The suggestion that TDI is teratogenic and a reproductive hazard is false. In fact, in a secondary reference provided in the TURI factsheet, USEPA (2000) states that while no information is available on reproductive or developmental effects of TDI in humans, these systems were not effected in rats exposed to TDI via inhalation in concentrations of 0, 20, 100, or 500 ppb for the 6h/day on gestation day 6-15 (Tyl, 1998). (ACC Panel, BASF)
- The Panel has submitted extensive comments related to technical inaccuracies on recent regulatory documents that TURI reference in the Policy Analysis. However while TURI had access to these industry comments, they were disregarded. (ACC Panel)
- TURI provides a selective compilation of potential acute and chronic hazards that ignore information supporting the contrary. (ACC Panel, BASF)

Comment: In vitro evidence supports mutagenicity of TDI. TDI is classified as Group 2B by IARC, “reasonably anticipated to be a human carcinogen” by NTP, and “Confirmed Animal Carcinogen with Unknown Relevance to Humans” by ACGIH. (Clapp, Herrick, Rossi)

Response:

Authoritative classifications. Neither the IARC nor the NTP classification of TDI’s carcinogenicity has changed. The IARC classification for TDI remains a 2B (possibly carcinogenic to humans based on sufficient animal evidence and inadequate human evidence), while the NTP classification remains “reasonably anticipated to be a human carcinogen.”

In 2000, NTP declined to review TDI’s classification: “Toluene Diisocyanate (TDI) was nominated by the Diisocyanates Panel of the Chemical Manufacturers Association for review and delisting from the RoC [Report on Carcinogens]. As outlined in the published listing/delisting procedures for the RoC, the RG1 reviewed the nomination and data provided by the Diisocyanates Panel. Based on its review of the available information concerning the carcinogenicity of TDI, the RG1 determined that there is no new, relevant data to support the delisting of TDI from the RoC. RG1 recommended that the nomination to delist TDI from the RoC not proceed any further through the review process.”¹

If IARC or NTP changes its classification, the TURA program and SAB will review that decision, consider whether it changes the TURA classification of TDI, and the TURA program will update fact sheets and information pieces. In the meantime, the basis for TDI’s listing as IARC 2B will be clearly described in fact sheets and other educational documents the TURA program will prepare if TDI is designated as HHS.

ACC has provided information indicating carcinogenicity via ingestion but not via inhalation (which is the primary route of exposure). We agree that human epidemiological studies do not show that TDI is a carcinogen, and that the animal studies showing carcinogenicity dosed animals via “gavage” - insertion of the chemical directly into the stomach, not via inhalation.

¹ January 2000 National Toxicology Program Board of Scientific Counselors' Meeting, available at <http://ntp.niehs.nih.gov/about/presscenter/frndocs/1999/janrocmgt/index.html>

Relevance of mutagenicity and teratogenicity data. With respect to the comments about mutagenicity and teratogenicity it is important to note that the Policy Analysis does not discuss either effect and neither was a factor in the designation decision. Both are cited in a previous 2003 TURI fact sheet, but not in the current policy proposal. The 2003 fact sheet refers to “limited evidence that 2,4-TDI may be a reproductive hazard.”

Carcinogenicity vs. other health effects – role in categorization. While carcinogenicity and other chronic effects were important considerations in the SAB’s decision to categorize chemicals as “category 1: more hazardous chemicals” or “category 2: less hazardous chemicals,” they were not the only consideration. For example, MDI (methylene diphenyl diisocyanate) is categorized by the SAB as a more hazardous chemical although it is not classified as a carcinogen.

Edits to 2003 fact sheet. Edits and updates to the 2003 fact sheet are welcome for use in future information pieces, but are not relevant to the present policy proposal, which is based on the information presented in the 2014 policy analysis.

AVAILABILITY OF SAFER ALTERNATIVES

Comment: It is unreasonable to expect reductions since there are no known substitutes for certain uses

- There is currently no known substitute for isocyanates that provide the unique qualities required for polyurethane applications. Non-isocyanate polyurethanes are not known to exhibit the qualities and range of performance attributes, nor has it been shown to be commercially viable. The public could be misled or given the impression that TURI has conducted an analysis and determined the alternate materials provide for comparable performance, availability, and better environmental and health impacts to isocyanate-based polyurethane. (ACC Panel, PFA)
- Attempts to reduce TDI are unreasonable because there are no alternatives to TDI in the manufacture of flexible polyurethane foam, a ubiquitous, well known safe and effective product. As such the Polyurethane Foam Association respectfully suggests that there is no scientific or medical basis for designating as a Higher Hazard Substance. (PFA)

Comment: Safer alternatives are available for many uses of TDI.

- “We believe that substitution of other non-isocyanate based systems are available for many applications. These include non-isocyanate based maritime paints used on oil platforms in the North Sea. These paints were developed when European Labor Unions documented the high rates of asthma for maintenance workers who were grinding and welding on cured paints.” (Comai)

Response:

The existence or lack of alternatives does not preclude designation as HHS. A Higher Hazard Substance designation is made based on hazard information. Difficulties related to identifying safer alternatives for a specific application may, in fact, be a basis for greater urgency in moving forward with a HHS designation. One of the key activities under the TURA program is to encourage research and development activities to identify practical, safer alternatives for existing uses of the HHS. Such designation may also lead companies to change their production processes to reduce but not eliminate their use of TDI through process improvements and/or improved operations and maintenance.

TURI has not conducted a detailed analysis of the technical, economic, and EH&S aspects of alternatives to isocyanate-based polyurethane. Such an analysis may, however, be within the scope of the TURA program's work going forward, if the HHS designation is adopted. The policy analysis provides a preview of themes that may be worthy of consideration in a larger alternatives assessment.

Information about safer alternatives provided by commenters will be useful to the TURA program as it develops training, educational materials, and other resources to help businesses investigate the possibility of adopting safer alternatives to TDI in the specific applications relevant for them.

COMMENTS ABOUT THE POTENTIAL IMPACT OF HHS DESIGNATION

Comment: The proposed designation of TDI will have a negative impact on industries in Massachusetts. (AAC Panel)

Comment: HHS designation will create benefits, including: greater attention to hazards; encouragement of reductions; education; and additional work on identification and adoption of safer alternatives.

- “The designation of TDI as a higher hazard substance will help bring attention to the associated health hazards associated, will encourage reductions in total use and the extra caution that use of a hazardous substance requires. This serves an important education function also, providing information about hazardous chemicals which must be controlled.” (Dooley)
- “The BlueGreen Alliance supports listing TDI as a higher-hazard chemical, which will help your program prioritize toxic use reduction activities on this isocyanate. In particular, we urge TURA to incentivize research to identify safer substitutes for TDI – the best form of protection to keep workers healthy, and jobs secure and safe.” (Brody – Blue Green Alliance)
- “Despite the attention of OSHA and NIOSH, and the historical information about the health hazards of TDI, use of TDI and exposure to TDI continues. TDI causes work-related asthma, which may be a career ending and life altering disease.” (Pechter)
- Moving forward on a HHS designation for TDI is consistent with recommendations made in recent years to TURA, including considering additional asthmagens for listing on the “more hazardous chemicals” list. (Graham - MassCOSH)

Comment: The Toxics Use Reduction approach is well suited to address on-going hazards associated with TDI use.

- “[T]he other ‘tools’ workers have to protect themselves in the workplace such as OSHA do not address safer substitution or much primary prevention.” (Graham - MassCOSH)
- “[A]ccording to the hierarchy of controls the improved strategy for the choice of surface coatings would include product substitution.” (Comai)

Comment: Action on TDI is overdue

- “Control of TDI exposures to a lower level of human exposure is long overdue and it would greatly benefit the population of workers and other individuals in Massachusetts to designate TDI as a Higher Hazard Substance under Massachusetts Toxic Use Reduction authority.” (Wegman)

Response:

EOEEA agrees with commenters that the HHS designation, by placing additional emphasis on TDI and bringing additional businesses into the TURA program, will further the goals noted above, including improved attention to hazards, encouragement of toxics use reduction, education of businesses and others, and progress in identifying and adopting safer alternatives.

No comments were received from Massachusetts companies regarding expected impact. No comments opposing the HHS designation were received from Massachusetts businesses.

MISCELLANEOUS COMMENTS

Comment: Federal government agencies have prioritized TDI for development of guidance values and a variety of regulatory actions.

- “At NIOSH we are developing a new document on TDI which will propose a new Recommended Exposure limit (REL).” NIOSH looks forward to collaboration with Massachusetts on TDI. (Park - NIOSH)
- “The National Institute for Occupational Safety and Health has provided warnings about these hazardous chemicals and guidance about necessary protection.^{xxiii} NIOSH recommends protection beyond what is required by OSHA.” (Pechter)
- “Because of continuing worker illness reports, OSHA announced a special emphasis program on isocyanates, starting in June 2013 that is continuing currently.²” (Dooley)
- “It has been known for many years that TDI is a very potent respiratory sensitizer. For this reason, NIOSH has established an REL of 5 ppb for TDI on an 8-hour TWA (see **attached NIOSH guideline**) and the ACGIH has established a TLV for TDI of 5 ppb on an 8-hour TWA, with a current Notice of Intended Change to lower this to 1 ppb. The listing includes a designation as both a dermal and respiratory sensitizer. Both NIOSH and ACGIH have a ceiling value (10 minute exposure) of 20 ppb, and the ACGIH intends to decrease this to only 3 ppb.” (Ellenbecker)
- “The federal government has acknowledged the danger of TDI diisocyanates; regulated under the Clean Air Act as a hazardous air pollutant and designated as an Extremely Hazardous Substance under the Toxic Release Inventory compiled by the EPA.” (Letter of support – 31 signatories)

Response:

EOEEA agrees that the proposed designation is consistent with, and complements efforts undertaken at the federal level.

² OSHA https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=24273

Comment: The policy analysis includes an out-of-date reference to spray polyurethane foam.

- TURI references the California Department of Toxic Substances Control (CDTSC) SPF Priority Product Profile to state that TDI may be contained in spray polyurethane foam (SPF). CDTSC has removed this reference in response to extensive comments provided by the ACC Panel. (ACC Panel, Bayer)

Response:

TURI made use of the California DTSC literature that was available at the time. The commenter is correct that the DTSC documentation no longer makes reference to the presence of TDI in SPF products.

The DTSC documentation that TURI cited made reference to TDI as a possible “minor component or residual constituent” of some spray foam insulation. TURI included this information for the sake of completeness but did not cite it as a basis for its recommendation to designate TDI as an HHS.

This information will be updated in future materials.

Comment: Improvements and corrections should be made to the 2003 TURI fact sheet on TDI.

- TURI incorrectly states that one of the primary end uses for TDI-based polyurethane adhesives and sealants are in wood binders. TDI is not used in wood binding applications, MDI is. (ACC Panel, Bayer)
- The 2003 TURI factsheet is poorly referenced and overstates the hazards posed by TDI. Endnote #1 is simply a laundry list of secondary sources the reader must individually scrutinize in the hope of identifying the basis for the listed hazard. (ACC Panel, BASF)

Response:

Wood binders. The policy analysis does not reference wood binders as an application. However, TURI’s 2003 fact sheet makes reference to wood binders. This information will be changed when the fact sheet is updated.

TURI welcomes additional information from stakeholders on specific uses of TDI. This information will be valuable in reaching out to Massachusetts businesses, developing an updated fact sheet on TDI, and identifying areas for additional research on safer alternatives.

Comment: In their factsheet and policy analysis, TURI provides a select compilation of potential acute and chronic hazards that ignores information supporting the insignificance of the stated hazards. The current documents clearly overstate the hazards of TDI and as such are not objective reviews of the available hazard data. (ACC Panel, BASF)

Response:

While the information in the 2003 TURI fact sheet was not used for the SAB, Advisory Committee or Council review, it was cited in the policy analysis as the source for two statements.

The first statement is: “Exposure to high levels of 2,4-TDI can cause pulmonary edema (fluid build-up in the lungs) and at 2.5 parts per million (ppm) 2,4-TDI is immediately dangerous to life and health.”

The commenters are correct that other resources may be preferable sources to cite for this statement. However, the statement is accurate and current. The *NIOSH Pocket Guide to Chemical Hazards* lists the IDLH value for 2,4-TDI as 2.5 ppm, and includes pulmonary edema as a symptom of exposure (<http://www.cdc.gov/niosh/npg/npgd0621.html>, viewed November 24, 2014).

The second statement is: “End-uses for flexible polyurethane foams include transportation, furniture, bedding, carpet underlay, packaging, and textile applications, among others.” Again, this information is accurate and current, and is also available in many other locations in addition to the 2003 TURI fact sheet.

TURI’s brief (one page) review of the science in the policy analysis is a high-level review of well-known TDI hazards. Specifically, the review covers the following, uncontested information: dermal and respiratory sensitization; additional target organ systems (gastrointestinal, CNS); IDLH value; association with other respiratory diseases; IARC and NTP classifications.

Regarding TDI and respiratory sensitization, the program is aware of no data or organization, including (based on its comments reviewed here) the ACC, that supports the proposition that this hazard is “insignificant.” All data we are aware of supports the proposition that respiratory sensitization is sufficient in and of itself to categorize TDI as a HHS.

Comment: The 2003 TURI fact sheet should be taken off TURI’s website until it is updated. (ACC Panel)

Response: TURI will review and update the 2003 TDI fact sheet as appropriate and will add notes to the webpage to clarify these points.

Comment:

- Based on toxicological data provided to the public by Federal and state regulatory agencies, as well as other information provided with these comments, the key hazards posed by TDI should be prioritized to state:
 - o Exposure to TDI can cause irritation to the skin, eyes, and respiratory tract
 - o Exposure to TDI can cause acute and contact dermatitis and asthma in some individuals.
- Although TDI is the only diisocyanate listed by IARC as a possible human carcinogen (2B), recent publications do not support this classification and indicate that TDI is an unlikely human carcinogen (ACC Panel)

Response:

Regarding the suggested language above, the first bullet point is similar to language already present in TURA program documents. The second bullet point is not justified, as both IARC and NTP list TDI as a possible human carcinogen. As noted above, if the authoritative bodies noted here update their classifications, or limit them to certain routes of exposure, then the TURA program will take this into account as appropriate.

Comment: EOEEA should consider other chemicals associated with diisocyanate use

“The Agency should consider that in the manufacture, use and end processing of polyurethane other chemicals are generated and released. Of particular concern are the amines that result during curing, hotwork and cutting. . . . Several of these aromatic amines are listed as suspected or possible human carcinogens. These include 2,4-TDA; 4,4AMOCA and 4,4A-MDA.”^{xxiv} (Comai)

Response:

This comment is not directly relevant for the question of designating TDI as HHS, but may be valuable information for consideration by the TURA program related to carcinogens going forward.

ⁱⁱ Redlich CA, Bello D, Wisniewski AV. Isocyanate exposures and health effects. In: Rom WN and Markowitz S, ed. *Environmental and Occupational Medicine*, 4th Edition. Philadelphia, PA: Lippincott Williams & Wilkins; 2006:502–516.

ⁱⁱⁱ Meredith SK, Bugler J, Clark RL. Isocyanate exposure and occupational asthma: A case-referent study. *Occup Environ Med*. 2000;57:830–836.

ⁱⁱⁱ Vandenplas O, Cartier A, Ghezzi H, Cloutier Y, Malo J-L. Response to isocyanates: Effects of concentration, duration of exposure and dose. *Am Rev Resp Dis*. 1993;147:1287–1290.

^{iv} Brugsch HG, Elkins HB. Toluene di-isocyanate (TDI) toxicity. *N Engl J Med*. 1963;268:353–357.

^v Elkins HB, McCarl GW, Brugsch HG, Fahy JP. Massachusetts experience with toluene di-isocyanate. *Am Ind Hyg Assoc J*. 1962;23:265–272.

^{vi} Longley EO. Methane diisocyanate; a respiratory hazard? *Arch Environ Health*. 1964;8:898.

^{vii} Gandevia B. Studies of ventilator capacity and histamine response during exposure to isocyanate vapour in polyurethane foam manufacture. *Brit J Industr Med*. 1963;20:204–209.

^{viii} Hama G. Symptoms in workers exposed to isocyanates; suggested exposure concentrations. *AMA Arch Ind Health*. 1957;16:232–233.

^{ix} Woodbury J. Asthmatic syndrome following exposure to tolylene diisocyanate. *Ind Med Surg*. 1956;25:540–543.

^x Walworth H, Virchow W. Industrial hygiene experiences with toluene diisocyanate. *Am Ind Hyg Assoc J*. 1959;20:205–210.

^{xi} OSHA https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=24273

^{xii} OSHA Chemical Exposure Health Data establishment search for TDI https://www.osha.gov/pls/samp/sampling_search.search?establishment=&city=&state=MA&zip=&startyear=&endyear=&sic=&naics=&substance=TDI&imis=&beginresult=&endresult=&p_start=&p_finish=80&p_sort=&p_desc=sc&p_direction=Next&p_show=20

^{xiii} OSHA https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=24273

^{xiv} National Institute for Occupational Safety and Health (NIOSH) WoRLD Data: Work-Related Lung Disease Surveillance System (eWoRLD). Section 9: Asthma. Work-Related Asthma: Most frequently Reported Agent Categories Associated with Cases of Work-Related Asthma, 1993–2002. Ref No. 2008F09-01. Available at: <http://www2a.cdc.gov/drds/WorldReportData> (accessed November 2014)

^{xv} Massachusetts Department of Public Health, Occupational Health Surveillance Program. SENSOR Occupational Lung Disease Bulletin. August 2010.

^{xvi} “In Scandanavian reports reports, patients reacted to their isocyanate-based work materials but not to commercial patch-test preparations of isocyanates. Therefore, we suspected that the low frequency of reported ACD from isocyanates was partly due to inadequate commercial preparations. A past study also showed the concentrations of diphenylmethane-4,4V-diisocyanate (4,4V-MDI) in petrolatum preparations to be much lower than declared. In one study, 2,4-toluene diisocyanate (2,4-TDI), 1,6-hexamethylene diisocyanate (1,6-HDI), and isophorone diisocyanate (IPDI) were investigated in a similar fashion.” Source: Malin Frick-Engfeldt, Erik Zimerson, Daniel Karlsson, A ° sa Marand, Gunnar Skarping, Marlene Isaksson, and Magnus Bruze Chemical Analysis of 2,4-Toluene Diisocyanate, 1,6-Hexamethylene Diisocyanate, and Isophorone Diisocyanate in Petrolatum Patch-Test Preparations

^{xvii} Jakob B Riddar **Isocyanates, Amines and Alkanolamines Sampling, Chromatography and Detection.** Doctoral Thesis in Analytical Chemistry at Stockholm University, Sweden 2013.

^{xviii} CDC http://www.cdc.gov/asthma/stateprofiles/asthma_in_ma.pdf

^{xix} Breton CV, Zhang Z, Hunt PR, Pechter E, Davis L. Characteristics of work related asthma: Results from a population based survey. *Occup Environ Med* 2006;63:411-5.

^{xx} OSHA Chemical Exposure Health Data establishment search for TDI
https://www.osha.gov/pls/samp/sampling_search.search?establishment=&city=&state=MA&zip=&startyear=&endyear=&sic=&naics=&substance=TDI&imis=&beginresult=&endresult=&p_start=&p_finish=80&p_sort=&p_desc=asc&p_direction=Next&p_show=20

^{xxi} Additional information from this commenter: “Although MDI is less volatile than TDI, because of widespread use MDI is as common a cause of work-related asthma as TDI in Michigan. Of the 218 reports of isocyanate-induced asthma in Michigan, 81 were from exposure to TDI, 64 were from exposure to MDI, 6 were from exposure to NDI, 14 were from exposure to HDI, and 53 were from exposure to an unknown type or combination of isocyanates. An additional 5 confirmed asthma cases had a primary exposure to a substance other than an isocyanate, and a secondary exposure to an isocyanate (one was from exposure to MDI and 4 were from exposure to an unknown type of isocyanate).” Source: Project Sensor News, Michigan State University-College of Human Medicine Volume 8 No. 2 Page 1

^{xxii} Michigan SENSOR <http://www.oem.msu.edu/userfiles/file/News/v19n3.pdf>

^{xxiii} NIOSH <http://www.cdc.gov/niosh/topics/isocyanates/>

^{xxiv} Ibid