

April 6, 2015

US Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460
Attention Docket ID No. EPA-HQ-OW-2012-0217

Submitted via electronic submission: www.regulations.gov

RE: Drinking Water Contaminant Candidate List 4—Draft, Docket ID No. EPA-HQ-OW-2012-0217, February 4, 2015, 80 Fed. Reg. 6076-6084

Dear Sir or Madam:

The American Chemistry Council (ACC), in a separate communication, has provided overarching comments related to the EPA's Notice of Drinking Water Contaminant Candidate List 4 (CCL4). The ACC Diisocyanates Panel (Panel)¹ herein submits specific comments relating to the inclusion of Toluene diisocyanate (TDI, CASRN 26471-62-5) among the substances included on the Draft CCL4. The Panel believes TDI is not an appropriate candidate for the Draft CCL4, and as explained further in these comments, should be removed from the Final CCL4.

The Panel understands that chemicals on the CCL may be brought into the domain of EPA's Endocrine Disruptor Screening Program (EDSP). In establishing EPA's EDSP List 2, EPA drew from three sources: National Primary Drinking Water Standards (NPDWS), pesticides on the reregistration schedule for 2007-2008, and CCL3. TDI was identified for inclusion on the Final EDSP List 2 solely because of its inclusion on the CCL3, and with no regard for the physical/chemical and reactive properties which preclude occurrence of the substance in drinking water sources. Therefore, the Panel has a strong interest in the CCL, the approach that EPA used to develop it, and if/how the CCL4 will interplay with EPA's EDSP and other potential future regulatory actions.

I. TDI'S OCCURRENCE AS A DRINKING WATER CONTAMINANT IS SCIENTIFICALLY IMPLAUSIBLE BY VIRTUE OF ITS PHYSICAL/CHEMICAL PROPERTIES

As is the case for most isocyanate substances, TDI hydrolyzes rapidly upon contact with water. Because each molecule of TDI possesses two reactive isocyanate functional groups, the hydrolysis of this hydrophobic substance is a heterogeneous reaction, which results in formation of insoluble cross-linked polyurea solids.^{2,3} The pseudo-first-order rate constant for hydrolysis of the

¹ The Panel includes U.S. manufacturers of MDI and/or TDI: BASF Corporation, Bayer Material Science, The Dow Chemical Company, and Huntsman Corporation.

² Yakabe Y., Henderson, K. M., Thompson, W. C., Pemberton, D., Tury, B. and Bailey, R. E. (1999). Fate of methylenediphenyl diisocyanate and toluene diisocyanate in the aquatic environment. *Environ. Sci. Technol.* 33(15): 2579-2583.

water-soluble analog, phenyl isocyanate, in water is reported to be $3.39 \times 10^{-2} \text{ sec.}^{-1}$ at 25°C, which corresponds to a half-life of 20 seconds at pH 7.⁴ Therefore, it can be concluded that hydrolysis of TDI occurs promptly upon its introduction to and dissolution in water. As such, the substance cannot persist and does not meet the Safe Drinking Water Act (SDWA) criteria that the substance “may be found in sources of drinking water” and to which a “substantial population” may be exposed.

In contact with water or humid air, TDI forms an insoluble polyurea with the concomitant release of CO₂. The insoluble polyurea can abrade and block orifices in pumps and metering equipment; the CO₂ can lead to dangerous pressure buildups in storage containers. Because of this known reactivity in water, environmental monitoring programs typically have not included TDI as a target contaminant. Consequently, any real or estimated occurrence of TDI in manufacturing or processing wastewaters is not expected to result in emission of the substance via treated effluents from production or processing sites. Because production is performed in closed systems, releases to soil and sediment are also expected to be negligible. The produced TDI is transported in road tankers, tank containers, rail tank cars or drums either from the production site, or, conveyed in pipelines to loading or using sites. Road tankers and tanks are pressurized with dry air or nitrogen to eliminate contact of TDI with moisture present in ambient air. Cleaning of road tankers and tank containers with water is rarely performed. Drums previously containing TDI are typically reclaimed and recycled through an approved drum reconditioner or metal recycling facility. Professional drum reclamation procedures employ neutralization and decontamination technologies to convert/destroy any TDI residues prior to further re-use or recycle of the drum metal in accordance with 40 CFR § 261.7(b)(1).

Although TDI is a target analyte of U.S. EPA analytical methods for solid wastes and water (e.g., SW-846, Method 8260), these and similar methods have been shown to be susceptible to generating false-positive detections of TDI. It has been shown that polyurethane and polyurea derivatives of TDI (which may be components or contaminants of common laboratory equipment), can be thermally decomposed in the heated injection port of various gas chromatographic analyses, and thereby result in formation of trace amounts of TDI during such analyses. Subsequently, any environmental monitoring results showing positive detections of TDI in water, sediment, or soil, should be critically evaluated, and perhaps validated using methods which avoid thermal decomposition such as cool-on-column injection/gas chromatography-mass spectrometry (COC-GC-MS) or liquid chromatography-mass spectrometry (LC-MS).

II. EPA’S APPROACH TO CARRY FORWARD CCL3 CONTAMINANTS TO THE DRAFT CCL4 IS NOT APPROPRIATE

The SDWA requires EPA to publish a list every five years of currently unregulated contaminants that pose risks for drinking water, referred to as the Contaminant Candidate List or CCL. The SDWA specifies that the list must include contaminants that are not subject to any

³ Seel K, Walber U, Herbold B, Kopp R. (1999). Chemical behavior of seven aromatic diisocyanates (toluenediisocyanates and diphenylmethanediisocyanates) under in vitro conditions in relationship to their results in the Salmonella/microsome test. *Mut Res.*438:109–23.

⁴ Castro, E. A., Moodie, R. B. and Sansom, P. J. (1985). The kinetics of hydrolysis of methyl and phenyl isocyanates, *J. Chem. Soc. Perkin Trans. II*, 737-742.

proposed or promulgated NPDWS, are known or anticipated to occur in public water systems, and may require regulation under the SDWA. The SDWA directs the Agency to consider the health effects and occurrence information for unregulated contaminants to identify those contaminants that present the greatest public health concern related to exposure from drinking water.

In establishing the Draft CCL4, EPA is proposing an abbreviated evaluation and selection process which involves carrying forward all substances listed on CCL3 (except those with regulatory determinations). While the Panel understands that the carry forward process is consistent with that previously used in CCL2, we do not believe simply carrying forward is an appropriate approach for all future CCLs. Instead, the Panel believes it critical that the Agency also evaluate the latest science available regarding physical/chemical properties, reactivity, and routes/magnitudes of potential emissions on those potential drinking water contaminants at every five year interval to ensure their continued listing is still warranted. In fact, the Draft CCL3 was published in February 2008 and the final was published in October 2009; therefore the data relied upon for placing substances on the draft CCL4 is now more than seven years old. EPA must avoid a wholesale carry forward approach and consider the most current scientific evidence to justify the continued inclusion of a substance on the CCL.

III. EPA HAS INAPPROPRIATELY RELIED ON THE TOXICS RELEASE INVENTORY (TRI) DATABASE FOR IDENTIFYING DRINKING WATER CONTAMINANTS

EPA has explained that it “interprets the criterion that contaminants are known or anticipated to occur in public water systems broadly” and acknowledged that it had listed chemicals on the CCL3 if one of the following types of data was available: 1) “finished water occurrence data;” 2) “limited public water system monitoring data;” or 3) “ambient monitoring data, *environmental release data*, or modeled data.” (emphasis added).⁵ While the first two types of data relate directly to drinking water exposure, the term “environmental release data” does not, but instead refers to listing on TRI, established under another unrelated statutory program.⁶ The TRI includes chemicals for which there has been any reportable release in any form (i.e., solid, liquid, or gas) to any environmental medium (*e.g.*, air, soil) anywhere in the country (*i.e.*, whether close to or remote from drinking water sources) down to quantities as small as a pound.

For many chemicals, including TDI, EPA placed chemicals on the CCL3 based solely on TRI data and despite having no water data available. In most cases, TRI reporting of releases to surface water are overly conservative estimates, not measured releases. The TRI reporting of releases does not assess whether any exposure to humans has or may occur, let alone that a “substantial population may be exposed.”

For certain substances, including TDI, the CCL3 listing process used information from the TRI and production data as indicators of “prevalence” in drinking water. In such cases, EPA clearly acknowledged “[t]he relationship between production or even environmental release data and the

⁵ Notice, Drinking Water Contaminant Candidate List 3—Final (“Final CCL3 List”), 74 Fed. Reg. 51,859 (Oct. 8, 2009)

⁶ EPA (2009). Final Contaminant Candidate List 3 Chemicals: Classification of the PCCL to CCL EPA-HQ-OW-2007-1189-0187. Page A-12.

actual occurrence in drinking water is complex.”⁷ The Agency explains that many times the correlation between a CCL3 prevalence score based on actual measurements in potable water samples and a CCL3 prevalence score based on production or TRI data “was not good.” Nonetheless, TRI data appears to be the sole source relied upon for inclusion of TDI on the CCL3, and its subsequent inclusion on the draft CCL4.

For TDI (mixed isomers, CASRN 26471-62-5), TRI surface water releases for reporting year 2013 were at zero pounds, further supporting the removal of TDI from the CCL4. Past TRI reporting years indicate a single point of potential surface water release associated with a single outfall of The Dow Chemical Company at Freeport, Texas. Production of TDI and the reported TRI emissions related to this production no longer occur for this location. The surface water outfall associated with the previously reported TRI emissions at Freeport, TX occurs on the Brazos River at a location where treated wastewater effluent is mixed with seawater prior to discharge, and is also influenced by tidal influx of seawater from the Gulf of Mexico. The surface water occurring at or downstream of this outfall would contain salinity and other water quality attributes which prevent its use as a drinking water source. This past example of potential TDI release occurring at a single outfall, which is not associated with public drinking water sources due to naturally-occurring water quality issues (among other factors), would therefore not have constituted a source of drinking water to which a substantial population may have been exposed. Furthermore, even if there was a release, TDI hydrolyzes rapidly upon contact with water which results in formation of insoluble polyurea solids.

The Panel is also concerned that EPA has not sufficiently accounted for data quality by relying on the TRI database in its assertion that substances on the CCL3 automatically satisfy the SDWA endocrine statutory requirements that a substance “may be found in sources of drinking water” to which a “substantial population” may be exposed. When utilizing any data source, EPA should analyze data strengths and weaknesses and applicability prior to using that data in regulatory programs and decision-making. EPA’s assertion that a chemical’s occurrence on the CCL *per se* meets the 1996 endocrine amendments to the SDWA that a substance “may be found in sources of drinking water” to which a “substantial population” may be exposed is an erroneous statutory interpretation. In particular, its mere presence on the CCL does not provide a rational basis for a determination that a substantial population may be exposed to TDI. Absent a transparent and comprehensive demonstration of significant correlation, there is no reason to assume that TRI data represents contamination of a source of drinking water to which a “substantial population” may be exposed.

IV. EPA SHOULD NOT RELY ON THE CCL4 AS THE SOLE BASIS FOR THE IDENTIFICATION/ PRIORITIZATION OF CHEMICALS FOR FUTURE REGULATORY PROGRAMS

The inclusion of TDI on the Agency’s EDSP List 2 serves as an example of how the occurrence of a substance on the CCL, and associated reporting of TRI emissions, were used to identify that substance for potential inclusion in costly and unnecessary regulatory testing without regard for the exposure characteristics and physical/chemical properties of the substance. The CCL and EDSP were authorized under separate sections of the SDWA. The listing criteria for the

⁷ EPA (2009). Final Contaminant Candidate List 3 Chemicals: Classification of the PCCL to CCL EPA-HQ-OW-2007-1189-0187. Pages 23-24.

regulations are clearly and purposefully different, with the EDSP criteria stating a more narrow and stringent standard. The mere inclusion of a substance on the CCL3 is not sufficient to satisfy the requirements for testing under the EDSP. Therefore, the wholesale import of CCL chemicals into the EDSP is not appropriate - and TDI in particular should not have been included on the Final EDSP List. Nonetheless, the Final EDSP List 2 includes chemicals, including TDI, for which EPA appears to have no drinking water monitoring data; chemicals that, due to their basic properties and use patterns, are unlikely ever to be detected in the drinking water of a substantial number of people; and chemicals that are fundamentally incompatible with EPA's testing protocols. Future use of the CCL in similar manners may, as in the case of TDI or those substances which were eventually removed from EDSP List 2, result in unnecessary expenditure of public and private resources.

Rather than applying the EDSP language of the SDWA to determine which chemicals to include in the EDSP, EPA has chosen to rely on existing lists of chemicals. While reliance on those existing lists provides an easy method for EPA to generate a list of potential substances for EDSP screening, those lists do not necessarily identify substances that "may be found in sources of drinking water" and to which "a substantial population may be exposed." EPA has asserted that chemicals on its CCL3 were within the scope of its SDWA EDSP authority. The CCL3, however, was not developed to identify chemicals that meet the SDWA requirement for testing substances that "may be found in sources of drinking water" to which a "substantial population may be exposed." Indeed, and as stated above, many substances - including TDI - on the CCL3 are not necessarily found in public drinking water sources to which a substantial population is exposed.

V. TDI SHOULD BE REMOVED FROM THE FINAL CCL4

In conclusion, EPA should remove TDI from the Final CCL4 because TDI cannot plausibly occur in drinking water due to its physiochemical properties. The Panel appreciates the opportunity to provide comments to the Agency and would be happy to further discuss these issues in more detail. Please do not hesitate to contact me at (202) 249-6721 or Sahar_Osman-Sypher@americanchemistry.com should you require additional information/clarification on any of the provided comments.

Sincerely,

Sahar Osman-Sypher
Director, Diisocyanates Panel