

Oral Comments
American Chemistry Council Diisocyanates Panel
Before
U.S. Environmental Protection Agency
Science Advisory Board Drinking Water Committee
Regarding Removal of Toluene Diisocyanate
From Draft Fourth Candidate Contaminant List
Public Teleconference, August 3, 2015

Members of the Science Advisory Board (SAB) Drinking Water Committee, my name is Robert West, and I am an Environmental Scientist with The Dow Chemical Company speaking on behalf of the American Chemistry Council's (ACC) Diisocyanates Panel (Panel). I am providing comments relating to the SAB's draft report of its review of EPA's Draft Fourth Contaminant Candidate List (CCL4) and the procedures and supporting documents leading to derivation of the listed chemical and microbial contaminants.

The Panel finds the draft report to be well-written and comprehensive in its contents, conclusions, and recommendations. The SAB review appears to have clearly met the objectives for this review as stated by the EPA Office of Water. The Panel is in general agreement with the SAB's conclusions that:

1. More detailed information is needed to understand how the EPA arrived at each individual chemical or microbial contaminant included in the proposed CCL4.
2. Specific details are lacking to understand and follow the decision-making process for each proposed contaminant listed.

The Panel also supports SAB recommendations for further action which EPA should take to improve the clarity and transparency of the listing process, including:

1. Presenting the results of the CCL4 screening and classification process in a manner that explicitly outlines the scoring schemes used in applying the selection criteria;
2. Providing examples for both microbial and chemical contaminants that display the process of how contaminants were included on or eliminated from the draft CCL4 list; and
3. Clearly describing and improving the process for removing contaminants from prior CCL lists.

With regards to the proposed listing of Toluene Diisocyanate (TDI, CAS RN 26471-62-5), we would like to particularly emphasize the importance of the recommendation to present "the results of the CCL4 screening and classification process in a manner that explicitly outlines the scoring schemes used in applying the

selection criteria.” As previously noted in public comments made to the SAB on April 29, 2015, the Panel here again objects to the inclusion of TDI among the substances on EPA’s draft CCL4.

The information previously compiled and summarized in the August 2009 Third Contaminant Candidate List (CCL3) Contaminant Information Sheet (CIS) includes information which has incorrectly characterized the emission and physical/chemical properties which directly relate to characterization of prevalence and magnitude at which TDI may occur as a drinking water contaminant. With regards to prevalence, we know of no reported detections of TDI substances in drinking water or in potential drinking water sources. The potential for occurrence of TDI in drinking water is therefore presumed to be based on reported TRI emission information, which in the CCL3 CIS indicates only 1 pound of estimated TDI emission to surface waters at a single state. It should be noted that the most current TRI reporting year 2013 data indicates no emission of TDI to surface water; and that total reported estimated emissions to other media (air, land) would have no known or expected pathways for introduction of the substance to drinking water sources.

The TDI CCL3 CIS has indicated that the (presumed long) half-life for TDI in the environment is associated with its predicted slow biodegradation by acclimated microorganisms. In fact, TDI has been shown to not be inherently biodegradable with or without acclimation, but rather is known and is publically reported to rapidly hydrolyze in water and soil with a half-life in the order of seconds to minutes. This fact then directly contradicts the (presumed estimated) water solubility value of 37.6 mg/L included in the CCL3 CIS, as TDI cannot persist in a dissolved state in water for any meaningful period of time.

With this example for TDI, we illustrate the importance of SAB’s recommendation that EPA present the results of the CCL4 screening and classification process in a manner that explicitly outlines the scoring schemes used in applying the selection criteria. Where correct and current data are used in characterizing the emission and physical/chemical parameters for this proposed contaminant, a transparent classification process and scoring scheme would result in low scores for both prevalence and magnitude, and thus, removal of TDI from the draft CCL 4.

One of the charge questions for the SAB review is to determine whether there are any contaminants currently on the draft CCL4 that do not merit inclusion on the list. On behalf of the Panel, we urge the SAB and EPA to review the scientific information available on this and all proposed CCL4 substances, and to consider relevant physical, chemical, and reactivity properties which would preclude occurrence and persistence in drinking water sources.

The Panel wishes to thank the SAB for its excellent work in review of the draft CCL4 and associated processes, and for this opportunity to provide public comment.

My name is Ralph Parod and I am a Senior Toxicologist with BASF Corporation, also speaking on behalf of the American Chemistry Council's Diisocyanates Panel. As you know, contaminants on the CCL are selected based on two major criteria: (a) their potential to occur in public water supplies, and (b) the potential for these occurrences to result in a public health concern. Mr. West just spoke to you on the physical-chemical properties of TDI that preclude its occurrence in public water supplies; I would like to focus on the potential health effects associated with exposure to TDI in water. Whereas TDI has well-characterized toxicological hazards for dermal and respiratory contact, there are no known or expected hazards from TDI exposure via drinking water, partially because exposure to the substance does not occur by this route for the reasons explained by Mr. West.

When you inspect the Third Contaminant Candidate List (CCL3) Contaminant Information Sheet (CIS), you will note that TDI has a total health effects score for potency and severity of 13 points out of a possible maximum score of 19. This relatively high score was derived from a single study, an NTP bioassay of TDI performed about 30 years ago. In that study, rats were gavaged with TDI in corn oil because, according to NTP, it was too unstable in water or feed to be administered by a drinking water or dietary routes. Indeed, NTP even acknowledged in its report that TDI was also unstable in corn oil due in part to the trace levels of water (0.05%) present. In the subsequent publication of this study, the NTP investigators commented that the tumor pattern observed with TDI was likely due, not to TDI, but to the transformation of TDI to a rodent carcinogen, either before test substance administration or due to the placement of TDI directly into the low pH environment of the stomach which favors this transformation.

Now you may be thinking to yourselves, as the NTP investigators did, that this issue is of little import because such transformation will occur *in vivo* anyway. However, subsequent investigations have shown that the rodent carcinogen is not detected in biological fluids of animals and humans exposed to TDI via physiologically-relevant routes of exposure such as inhalation and dermal contact, where the relatively neutral pH conditions favor the reaction of TDI with macromolecules at (e.g., proteins), and non-carcinogenic effects (e.g., sensitization) at the point of body contact, which for TDI are the lungs and skin. The plausible modes of physiological exposures to TDI do not result in systemic toxicity.

So in conclusion, it appears that TDI has been inappropriately placed on the CCL due (in part) to the high scores it received for potential occurrence in drinking water and the health effects these occurrences may cause. In the case of health effects, TDI does not exist in water long enough to be toxic. Toxicity by the oral route has only been demonstrated when TDI is placed in a non-aqueous medium and subsequently given under aphysiological exposure conditions that irritate the gastrointestinal tract or facilitate its transformation to another chemical, a chemical that is not detected in biological fluids under relevant exposure conditions. Where current and reliable data are appropriately applied and interpreted in characterizing the potential to occur in public water supplies, and the potential for these occurrences to result in a public health concern, a transparent classification process and scoring scheme would result in removal of TDI from the draft CCL4.

The Panel wishes to thank the SAB for its thorough review of the draft CCL4 and its associated contaminant selection process, and for this opportunity to provide specific public comments.