



December 22, 2009

Via E-Mail

Dr. Jeffrey B. Frithsen
Chief, Exposure Analysis and Risk Characterization Group
National Center for Environmental Assessment
Mail Code: 8623P

Dr. Peter W. Preuss
Director, National Center for Environmental Assessment
Mail Code: 8601P

U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Comments of the American Chemistry Council's Chlorine Chemistry Division on NCEA's Review of the University of Michigan Dioxin Exposure Study

Dear Dr. Frithsen and Dr. Preuss:

The Chlorine Chemistry Division (C2) appreciates this opportunity to comment on the National Center for Environmental Assessment's (NCEA) September 2009 *Review of the University of Michigan Dioxin Exposure Study* (Review).¹ C2 is a business council of the American Chemistry Council, and strives to ensure appropriate product stewardship of chlorinated chemicals. As part of its mission, C2 addresses important science and public policy issues related to chlorine chemistry.

The University of Michigan Dioxin Exposure Study (UMDES or the Study) is one of the largest and most relevant studies concerning the impact of dioxin in soil and dust on human dioxin body burdens. The Study provides invaluable information for informing dioxin risk

¹ U.S. EPA. 2009. Review of the University of Michigan Dioxin Exposure Study. September 30, 2009. National Center for Environmental Assessment, Washington, D.C. <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=214244> (the "Review").

assessments and risk management decisions across the U.S. Overall, NCEA found the Study to be robust and of high quality. According to NCEA, however, the Study did not target highly exposed and/or sensitive populations, such as children or “people living on properties with very high dioxin soil levels and people consuming large amounts of possibly contaminated fish and game....”² NCEA, therefore, summarily dismissed the Study as having only “limited use in risk assessment to support management decisions.”³

As set forth in the appended comments, C2 believes NCEA’s Review is both scientifically and procedurally flawed. Contrary to NCEA’s conclusions, the UMDES is relevant to “EPA’s risk management mission.”⁴ Indeed, the UMDES offers a treasure trove of data to inform EPA’s ongoing dioxin reassessment, interim Preliminary Remediation Goals, and other dioxin related regulatory activities. Moreover, NCEA’s process for developing its Review skirts both the requirements of OMB and EPA Information Quality Guidelines, as well as OMB’s Final Information Quality Bulletin for Peer Review. NCEA’s process also was contrary to Administration and Agency commitments to transparency and scientific integrity. C2 urges NCEA to substantively revise the Review through a transparent process of external peer review and meaningful opportunity for public input.

C2 looks forward to NCEA’s response to the appended comments as well as other public comments. If you have any questions regarding this submission, please contact me at (703) 741-5230 or at david_fischer@americanchemistry.com.

Sincerely,

David Fischer

David B. Fischer
Assistant General Counsel

Attachment

² Review at 1.

³ Peter W. Preuss, *et al.*, *USEPA Review of the University of Michigan Dioxin Exposure Study (UMDES)*, Presentation, October 20, 2009, EPA ORD/NCEA, at 19. In a September 30, 2009 press release, EPA Region 5 announced “EPA reviews Univ. of Michigan dioxin study; finds limited application to Tittabawassee River and Saginaw River and Bay.” EPA Region 5, Press Release: *EPA reviews Univ. of Michigan dioxin study; finds limited application to Tittabawassee River and Saginaw River and Bay*, No-OPA186, September 30, 2009. <http://yosemite.epa.gov/opa/admpress.nsf/0/7B7F9676E27D0DB685257641007B482E>

⁴ EPA-ORD, Science in Action Fact Sheet, *U.S. EPA National Center for Environmental Assessment Review of the University of Michigan Dioxin Exposure Study*, September 30, 2009, at 2. Accessible through: <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=214244>

The Chlorine Chemistry Division's Comments on NCEA's Review of the University of Michigan Dioxin Exposure Study

The Chlorine Chemistry Division (C2)¹ appreciates this opportunity to comment on the National Center for Environmental Assessment's (NCEA) September 2009 *Review of the University of Michigan Dioxin Exposure Study* (Review).² The University of Michigan Dioxin Exposure Study (UMDES or the Study) is one of the largest and most relevant studies concerning the impact of dioxin in soil and dust on human dioxin body burdens. The Study provides invaluable information for informing dioxin risk assessments and risk management decisions across the U.S.

Overall, NCEA found the Study to be robust and of high quality. According to NCEA, however, the Study did not target highly exposed and/or sensitive populations, such as children or "people living on properties with very high dioxin soil levels and people consuming large amounts of possibly contaminated fish and game...."³ NCEA, therefore, summarily dismissed the Study as having only "limited use in risk assessment to support management decisions."⁴

As set forth below, C2 believes the Review is both scientifically and procedurally flawed. Contrary to NCEA's conclusions, the UMDES is relevant to "EPA's risk management mission."⁵ Indeed, the UMDES offers a treasure trove of data to inform EPA's ongoing dioxin reassessment, interim Preliminary Remediation Goals, and other

¹ C2 is a business council of the American Chemistry Council and strives to ensure appropriate product stewardship of chlorinated chemicals. As part of its mission C2 addresses important science and public policy issues related to chlorine chemistry.

² U.S. EPA. 2009. Review of the University of Michigan Dioxin Exposure Study. September 30, 2009. National Center for Environmental Assessment, Washington, DC. <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=214244> (the "Review").

³ Review at 1.

⁴ Peter W. Preuss, *et al.*, *USEPA Review of the University of Michigan Dioxin Exposure Study (UMDES)*, Presentation, October 20, 2009, EPA ORD/NCEA, at 19. In a September 30, 2009 press release, EPA Region 5 announced "EPA reviews Univ. of Michigan dioxin study; finds limited application to Tittabawassee River and Saginaw River and Bay." EPA Region 5, Press Release: *EPA reviews Univ. of Michigan dioxin study; finds limited application to Tittabawassee River and Saginaw River and Bay*, No-OPA186, September 30, 2009. ("Region 5 Press Release") <http://yosemite.epa.gov/opa/admpress.nsf/0/7B7F9676E27D0DB685257641007B482E>

⁵ EPA-ORD, Science in Action Fact Sheet, *U.S. EPA National Center for Environmental Assessment Review of the University of Michigan Dioxin Exposure Study*, September 30, 2009, ("Fact Sheet") at 2. Accessible through: <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=214244>

dioxin related regulatory activities. NCEA's dismissal exemplifies the findings of a recent Government Accounting Office (GAO) report that noted deficiencies in EPA's ability to interpret and utilize exposure data in risk assessment. The GAO recommended that "EPA develop a comprehensive research strategy to improve its ability to use biomonitoring in its risk assessments."⁶

Moreover, NCEA's process for developing its Review skirts both the requirements of OMB and EPA Information Quality Guidelines, as well as OMB's Final Information Quality Bulletin for Peer Review. NCEA's process also was contrary to Administration and Agency commitments to transparency and scientific integrity. C2 urges NCEA to substantively revise the Review through a transparent process of external peer review and meaningful opportunity for public input.

The Review is “Influential” Information with Significant Impacts on Dioxin Risk Assessment and Management Decisions

The UMDES is one of the largest and most relevant studies concerning the impact of dioxin in soil and dust on human dioxin body burdens.⁷ The UMDES included 946 adult participants (695 from the study area and 251 from a reference area) and examined blood, soil, and household dust collected from study participants to understand the factors that contribute to dioxin body burdens. Although the Study was conducted in response to community concerns about dioxin contamination around Midland, Michigan, the findings of the Study are broadly applicable to other dioxin-contaminated sites.

NCEA issued the Review in September 2009. Its conclusions were discussed at subsequent public meeting held in the Midland-Saginaw area of Michigan. Importantly, the UMDES was not subject to independent peer review because as noted in the Review's disclaimer, the “document is itself a review....”⁸ OMB's Final Information Quality Bulletin for Peer Review, however, explicitly requires that each agency “subject

⁶ GAO 2009. *Biomonitoring: EPA needs to coordinate its research strategy and clarify its authority to obtain biomonitoring data.* GAO-09-353.

⁷ Independent scientists at the University of Michigan conducted the UMDES. To help ensure objectivity and scientific integrity, the study authors reported directly to an independent Science Advisory Board, comprised of Dr. Linda Birnbaum (Director of NIEH), Dr. Marie Haring-Sweeney (NIOSH), Dr. Paolo Boffetta (IARC) and now at NYU; and Dr. Ron Hites (University of Indiana), that oversaw all aspects of the study, including study design and implementation. Members of the SAB are highly respected and extremely knowledgeable concerning epidemiological design, sampling, and dioxin and dioxin exposures. <http://www.sph.umich.edu/dioxin/scientific-advisory-board.html>

⁸ Review at 1: Disclaimer.

‘influential’ scientific information to peer review prior to dissemination.”⁹ There is little doubt that the Review is “influential information” because its dissemination “will have or does have a clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions.”¹⁰ For example, in dismissing the UMDES, the NCEA incorrectly concluded that “The UMDES does not appear to be relevant to EPA’s risk management mission.... [T]he study does not provide sufficient information to inform the development of preliminary remediation goals for soil, which are set using national default exposure and toxicity values and not site-specific data.”¹¹ By not subjecting the Review to formal, independent, external peer review, NCEA has also failed to adhere to a rigorous standard of quality as required by OMB’s Information Quality Guidelines.¹²

The Review is Scientifically Flawed

The UMDES provides invaluable insight into the contribution of soil dioxin to dioxin body burden levels. Overall, NCEA found the UMDES robust and of high quality. As summarized in the EPA Region 5 Press Release, “EPA found the study was conducted well and provided useful, scientifically credible information” and that “the UMDES has produced a credible and valuable source of data on dioxin levels in adults.” EPA acknowledges that the statistical analysis of data in the Study supports a finding that there is not a meaningful relationship between blood serum dioxin and soil dioxin.¹³ As noted elsewhere in the Review, “had a strong correlation been found ... EPA’s own evaluations suggesting a small impact from soil exposure compared to all other exposures, particularly food exposures, would need to be reassessed.”¹⁴ Even EPA’s pharmacokinetic modeling “indicates that direct ingestion of soil and dust would not be

⁹ OMB, Final Information Quality Bulletin for Peer Review, December 16, 2004, p. 12.

¹⁰ U.S. EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, October 2002, at 19.

¹¹ Fact Sheet at 2. NCEA also concluded that the Study has “limited use in risk assessment to support management decisions,” including pending decision regarding the Tittabawassee River and Saginaw River and Bay. Peter W. Preuss, *et al.*, *USEPA Review of the University of Michigan Dioxin Exposure Study (UMDES)*, Presentation, October 20, 2009, EPA ORD/NCEA, at 19.

¹² 67 Federal Register 8452, 8459, Feb. 22, 2002.

¹³ EPA Exposure Review at 8.

¹⁴ Review at 43.

expected to contribute significantly to adult serum levels except at relatively high soil and dust concentrations (i.e., over 1000 ppt TEQ).”¹⁵

Despite the Study’s strengths, NCEA identified three “significant limitations” including the following:

- The study did not include children, who tend to have higher exposures to contaminants because they have more contact with, and ingestion, of soils and dusts.
- It is unclear if the study included a sufficient number of properties with highly contaminated soils. Such properties can be found in the Midland-Saginaw area.
- It is uncertain how well the study represented people who participate in activities that could lead to elevated dioxin exposures, such as eating local fish and game with elevated dioxin levels.

Based on these perceived limitations, NCEA summarily dismissed the Study as having only “limited use in risk assessment to support management decisions.”¹⁶

At the December 14, 2009 meeting of the UMDES Science Advisory Board, in which Dr. Jeff Frithsen of NCEA was present, the UMDES researchers presented a summary of their findings, based in part on analyses requested by NCEA and the State of Michigan, that address NCEA’s criticisms above.

In particular, the UMDES researchers reported the following:

- It is important that this study detected clear associations between serum PCDD levels and historic exposures that occurred more than 25 years previously.
- There was little evidence of ongoing exposure even though the soils on some properties in Midland and Saginaw are highly contaminated. Historic reservoirs of dioxins in soils and sediments may have little importance if there is no completed exposure pathway.¹⁷

Although the UMDES study design did not specifically include a direct assessment of children’s dioxin levels (for practical and ethical reasons it was not possible to draw enough blood from children to detect dioxin congeners), this did not lead to a significant data gap. In light of dioxin’s relatively long half-life, current body burden levels of young adults in both the study and reference populations do provide a window into childhood exposures to soil dioxin. Because dioxin body burdens of young adults in the study and reference populations are strikingly similar, it is highly unlikely

¹⁵ *Id.* at 45. 1000 ppt = 1 ppb, the current PRG for dioxin in residential soil.

¹⁶ Peter W. Preuss, *et al.*, *USEPA Review of the University of Michigan Dioxin Exposure Study (UMDES)*, Presentation, October 20, 2009, EPA ORD/NCEA, at 19.

¹⁷ Slide 14, December 14, 2009 UMDES SAB meeting.

that any substantial elevations in serum levels occurred in these individuals as children, strongly indicating that dioxin soil ingestion contributes little to body burden levels.

Similarly, NCEA mistakenly asserted that the UMDES did not adequately represent people engaged in activities that could lead to higher dioxin exposures, such as eating local fish and game. Again, the inclusion of highly exposed individuals in the UMDES was part of a carefully considered and peer reviewed study design. At the SAB Meeting, the UMDES researchers shared the following conclusions and recommendations with the SAB and stakeholders about the particular food related exposures:

- Public health agencies should examine historic dioxin contamination sites carefully to look for plausible exposure pathways. The presence of dioxins in soils in and of itself appears not to be an exposure pathway.
- Fish, game, and home-raised animals from contaminated areas should be assessed in conjunction with consumption patterns to see whether contaminated food is a completed exposure pathway, and to judge its impact on the population.
- The UMDES indicates that home-raised meat can be a substantial source of PCDF intake.
- On the other hand, it does not suggest that current patterns of consumption of fish and game from the TR/SR/SB contribute measurably to serum PCDD or PCDF concentrations.

Moreover, the UMDES did identify elevated serum levels in the farmer who raised cattle along the Tittabawassee River and consumed the beef.¹⁸ UMDES researchers continue to analyze these highly exposed individuals. It is premature and inappropriate, therefore, for NCEA to dismiss the UMDES based, in part, on a portion of the Study that has not yet been completed.

NCEA also asserts that the UMDES failed to include an adequate number of properties with a high level of soil contamination. The UMDES, however, reported results for 23 highly contaminated properties. The decision to examine these properties was part of a carefully considered and peer reviewed study design. C2 believes these 23 properties provide an adequate data set for meaningful statistical evaluation. In particular, UMDES researchers found no relationship between soil contamination and dioxin blood levels - even at the highly contaminated properties. As noted by the UMDES researchers at the recent SAB meeting:

¹⁸ Slide 10, December 14, 2009 SAB Meeting.

- We found no reliable relationships between contaminated soil and blood dioxin concentrations. We had 923 subjects who had soil concentrations under 1000 ppt whose data is directly relevant to whether soil contamination in this range contributes to serum dioxins.¹⁹

In sum, C2 believes NCEA has summarily dismissed the UMDES based on scientifically unsupportable Study “limitations.” C2 urges NCEA to revise its Review to correct the scientific flaws described above.

NCEA Failed to Provide Adequate Notice and Opportunity for Public Comment

Given the significance of the Review, NCEA should have provided meaningful opportunities for public comment. Instead, NCEA discourages public input. For example, the only reference to public comment on the Review is found in a single sentence in the Review’s disclaimer: “EPA will consider any significant technical comments it receives.”²⁰ The word “draft” does not appear anywhere in the document. Thus, the Review appears on its face to be final. Moreover, it is unclear how NCEA defines “significant” and “technical” to warrant NCEA consideration. Even assuming public comments are submitted, (e.g., C2 comments), NCEA has not indicated whether it will revise the Review based on public comment.

C2 believes NCEA’s process for its Review is conspicuously contrary to Administration and EPA commitments to transparency and scientific integrity. Transparency was a key feature of the President’s March 9, 2009 *Memorandum on Scientific Integrity*, in which he underscored that the “public must be able to trust the science and scientific process informing public policy decisions.”²¹ Similarly, in her June 9, 2009, Senate testimony the Administrator re-emphasized her commitment to transparency.²² C2 urges NCEA to establish a public docket to receive public comments on the Review, and ensure those comments are addressed and incorporated in NCEA’s revisions to the Review.

¹⁹ Slide 12, December 14, 2009 SAB Meeting.

²⁰ Review at 2.

²¹ http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/.

²² In her June 9, 2009 testimony to the Senate Environment and Public Works Committee hearing on Scientific Integrity, EPA Administrator Jackson pledged "to uphold values of scientific integrity every day." The Administrator further pledged that "the Agency's scientific process [would] meet the highest standards of quality and integrity."

Conclusion

As discussed, C2 urges NCEA to revise the Review by correcting the numerous scientific flaws, subjecting the Review to external peer review and providing an opportunity for adequate public input. Had NCEA utilized a more open and transparent process that included adequate external peer review and public input, NCEA may have been able to avoid the scientific errors that led it to dismiss an important study that can better inform the management of dioxin-contaminated soil.