



September 10, 2002

W-99-18 NODA Comment Clerk  
Water Docket (MC – 4101)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20036

Re: Chlorine Chemistry Council Comments on *Standards for the Use or Disposal of Sewage Sludge; Notice of Data Availability*

Dear Sir or Madam:

The Chlorine Chemistry Council (“CCC”) is pleased to comment on the U.S. Environmental Protection Agency’s (EPA’s) *Standards for the Use or Disposal of Sewage Sludge; Notice of Data Availability*; 67 Fed. Reg. 40554 (June 12, 2002) (the “NODA”). The NODA raises important issues concerning the management of dioxin. CCC, a business council of the American Chemistry Council, represents manufacturers and users of chlorine and has been actively following issues concerning the assessment of dioxin risks, including EPA’s Dioxin Reassessment process. CCC believes that the NODA should (1) incorporate the world-wide convergence on an acceptable dioxin exposure of 1 to 4 pg/kg/day, and (2) fully consider the impact of dramatically decreasing emissions and exposures to dioxin on the need for regulating biosolids.

#### EPA’s Conservative Assessment of Dioxin Cancer Risks

EPA has staked out a highly conservative position on dioxin’s potential cancer risks. EPA has relied solely on a conservative linear default model to quantify those risks. This approach differs from other world bodies (e.g., the European Commission Scientific Committee on Foods (EC), the Joint FAO/WHO Expert Committee on Food Additives (JECFA)) that have concluded a threshold model is more consistent with the science concerning dioxin’s carcinogenic action.

Those bodies have based their determination on the weight of the evidence that dioxin is a nongenotoxic carcinogen. According to the Agency for Toxic Substances and Disease Registry (ATSDR), this has led to a “world-wide convergence” on an acceptable dioxin exposure of 1 to 4 pg/kg/day.<sup>1</sup> This is in contrast to EPA’s determination that a one in one million cancer risk exists at approximately 0.001 pg/kg/day. ATSDR observed that EPA’s dioxin reassessment “may place too much confidence in the ability to accurately predict cancer risks at low doses. This approach dramatically increases cancer risk estimates that are not based on compelling new data but rather on the application of statistical models . . . [that] are not yet fully validated . . . .”<sup>2</sup>

ATSDR also noted that “USEPA’s model of the dose response for cancer is inconsistent with the recommendations of the President’s Committee on Risk Assessment and Management for cancers thought to be elicited by nongenotoxic mechanisms (CRARM 1996).”<sup>3</sup> Moreover, as noted in a recent GAO report, the threshold model is in stark contrast to EPA’s non-threshold determination and conclusion that “the upper bound on the general population’s lifetime risk for all cancers from dioxins might be on the order of 1 in 1,000 or more (i.e., people might experience a 1 in 1,000 increased chance of developing cancer over their lifetime because of exposure to dioxins).”<sup>4</sup>

A threshold approach is also consistent with animal studies addressing carcinogenicity of dioxin. For example, in a recent review article by Dragan and Schrenk,<sup>5</sup> the authors conclude that “While the mechanism of carcinogenicity induced by TCDD is unknown, the processes involved have a no-effect level. . . .” With regard to human studies it has been shown that a threshold model applied to the combined occupational cohort data provides a much better fit of this human data than EPA’s linear no threshold model, which lacks biologic plausibility.<sup>6</sup>

In addition, authors of the dose-response chapter of the draft Dioxin Reassessment expressed concern that EPA’s dioxin risk characterization failed to “adequately reflect the weight-of-

---

<sup>1</sup> Pohl, H.R., *et al.*, 2002. Public Health Perspectives on Dioxin Risks: Two Decades of Evaluations. *Hum. Ecol. Risk Assess.* 8(2):233-250.

<sup>2</sup> Pohl, 2002.

<sup>3</sup> *Id.*

<sup>4</sup> U.S. General Accounting Office, April 2002, “Environmental Health Risks, Information on EPA’s Draft Reassessment of Dioxins,” GAO-02-515, at 31.

<sup>5</sup> Dragan and Schrenk, *Animal Studies Addressing the Carcinogenicity of TCDD (or related compounds) with an Emphasis on Tumor Promotion, Food Additives and Contaminants*, 2000, Vol. 7, No. 4, 289-302.

<sup>6</sup> Starr, T.B., *Significant Shortcomings of the U.S. Environmental Protection Agency’s Latest Draft Risk Characterization for Dioxin-Like Compounds*, *Toxicological Sciences*, Vol. 64, 7-13, 2001.

evidence interpretation of various mechanistic hypotheses” related to dioxin carcinogenicity. Those authors stated that the data “strongly support non-linear relationships for enzyme induction and liver cancer. For us this is not just a plausible alternative, but also a preferred hypothesis with extensive experimental support.”<sup>7</sup> This is consistent with a peer-review report of EPA’s dioxin reassessment conducted by EPA’s Science Advisory Board which concluded that the “majority of panel members have concerns about Agency cancer risk estimates associated with current population exposures and feel that it was not appropriate for the agency to characterize the risks in such a quantitative manner without providing a similar qualitative estimate of uncertainty.”<sup>8</sup>

In sum, the above discussion demonstrates that EPA’s assessment of dioxin cancer risk is neither in step with the conclusions of other federal and international bodies nor with a number of EPA’s peer reviewers and other scientists.<sup>9</sup> We believe that EPA should integrate in its dioxin reassessment the less conservative cancer estimates derived by federal and international bodies, which are consistent with the available science and that those estimates should be utilized to estimate cancer risks posed by biosolids.

#### Emissions and Exposures to Dioxins Have Been Declining Dramatically

The attached paper by Aylward and Hays demonstrates that the U.S. general population’s exposures to dioxins have been declining dramatically since the early 1970s. A recent paper by Matthew Lorber<sup>10</sup> of EPA mirrors the conclusions reached by Hays and Aylward. Lorber’s paper makes some fairly profound conclusions. For instance, Lorber states that, “body burdens of TEQs [among the general U.S. population] during the 1970s, 80s, and 90s could be modeled by assuming a historical dose which began the century at low levels of about 0.5 pg TEQ/kg-day, rose during the middle decades of the 20<sup>th</sup> century to over 6 pg TEQ/kg-day, and declined to current levels of about 0.5 pg TEQ/kg-day.” Therefore, by the estimates of an EPA scientist, body burdens today in the United States are consistent with exposures today that are

---

<sup>7</sup> See letter to William Farland from R. Conelly and M. Anderson, July 7, 2000 (available in the EPA dioxin reassessment docket).

<sup>8</sup> Science Advisory Board, Dioxin Reassessment – An SAB Review of the Office of Research and Development’s Reassessment of Dioxin, May 2001, p. 6. There was also a lack of consensus among the SAB Panel regarding the strength of weight of evidence for supporting the classification of TCDD as a human carcinogen and disagreement as to whether effects observed in the laboratory would be observed in humans at lower levels of exposure. Further, some SAB members did not consider it appropriate to apply the standard default assumptions recommended by EPA’s cancer guidelines, and “particularly the use of a linear response model . . .” SAB Report at 2.

<sup>9</sup> See, for example, Proceedings, EPA’s Characterization of Dioxin Risks: Do Background Dioxin Exposures Pose a Human Health Threat? International Society of Regulatory Toxicology and Pharmacology Conference, October 6, 2000. (The Proceedings can be found at [www.ISRTP.org](http://www.ISRTP.org).)

<sup>10</sup> Lorber, M., 2002. A Pharmacokinetic Model for Estimating Exposure of Americans to Dioxin-Like Compounds in the Past, Present, and Future. *The Science of the Total Environment*. 288:81-95.

likely to be as low as they were before the advent of the modern chemical and industrial revolution.

The dramatic decline in dioxin exposures raises the question of whether further reductions in exposures are necessary or cost effective. EPA failed to address that issue in the NODA. In the case of dioxin in biosolids it appears from the analysis in the NODA that decreases of dioxin in biosolids will likely have a minimal effect, if any on dioxin body burdens. EPA should consider the limited benefit to human health and the environment of regulating biosolids (any benefit will likely diminish as environmental levels of dioxins decrease).

We appreciate this opportunity to comment on the NODA. If you have any questions concerning our comments or if we can provide further information, please do not hesitate to call David Fischer at (703) 741-5179.

Sincerely,

A handwritten signature in black ink that reads "Kip Howlett". The signature is written in a cursive, slightly slanted style.

Clifford T. "Kip" Howlett, Jr.  
Executive Director,  
American Chemistry Council,  
Vice President