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EPA Docket Center
Environmental Protection Agency
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Washington, DC 20460
E-mail: OSWER.Docket@epa.gov. Or <http://www.regulations.gov>.

RE: EPA Draft Recommended Interim Preliminary Remediation Goals for Dioxin In Soil at CERCLA and RCRA Sites: Docket ID Number: EPA-HQ-SFUND-2009-0907

Dear Administrator Jackson:

The American Nurses Association (ANA) welcomes the opportunity to provide comments regarding the "Draft Recommended Interim Preliminary Remediation Goals for Dioxin in Soil at CERCLA and RCRA Sites."

ANA is the only full-service professional organization representing the interests of the nation's 2.9 million registered nurses through its constituent member associations (CMA's), its organizational affiliates, and its workforce advocacy affiliate. ANA advances the nursing profession by fostering high standards of nursing practice, promoting the rights of nurses in the workplace, projecting a positive and realistic view of nursing, and by lobbying the Congress and regulatory agencies on health care issues affecting nurses and the public.

Nursing leaders, including Florence Nightingale and Lillian Wald have recognized that nurses play a major role in controlling the influence of environmental factors (air and water quality, food, sanitation, cleanliness, chemicals, pesticides, waste products) on health. ANA has adopted the precautionary approach which includes reducing risks before full proof of harm is available if the effects could be serious or irreversible when evidence suggests a possible toxic relationship between chemical exposure and health effects.

The Environmental Protection Agency (EPA) is commended for its focus on dioxin assessment over the past decade including the EPA's Science Advisory Board (SAB), the Interagency Working Group (IWG) and the National Academy of Sciences, review of Health Risks from Dioxin and Related Compounds Evaluation of the EPA Reassessment, published in 2006. However, there is concern for the proposed Preliminary Remediation Goals (PRGs).

Dioxins are categorized into three primary classifications, as follows: 2, 3, 7, 8-tetrachlorodibenzo-p-dioxin (TCDD), dioxin-like compounds (DLCs) and other dioxins. TCDD

is recognized as the most hazardous, but all three produce toxic effects in humans and animals

Toxicity Values

The National Contingency Plan requires the agency to use the one-in-a- million cancer risk value as the point of departure for determining cancer PRGs. Using this recommended point of departure, the calculated PRGs for dioxins are 3.7 ppt Total Dioxin Equivalents (TEQ) for residential and 17 ppt (TEQ) for commercial/industrial use. However, according to the draft, EPA's proposed PRGs level is 72 parts per trillion (ppt) TEQ for residential use and 950 ppt TEQ for commercial/industrial use and are based on classifications for non-cancer PRGs.

EPA's proposal not only fails to provide scientific evidence to justify utilizing non-cancer values, it contradicts the EPA's own evidence and classification of dioxins. According to the National Academy of Sciences, EPA concluded that TCDD was best characterized as carcinogenic to humans and the National Toxicology Program (NTP, 2001) also classified TCDD as known-to-be a human carcinogen. The review further determines the appropriate classification of other dioxins. DLCs are likely to be carcinogenic to humans. An earlier study on The EPA's Technology Transfer Network, revised in 2000, states: "EPA has classified 2, 3, 7, 8-TCDD as a probable human carcinogen (Group B2)." The National Academy of Sciences stated the "classification of dioxin as carcinogenic to humans" versus "likely to be carcinogenic to humans" depends greatly on the definition and interpretation of the specific criteria used for classification." Despite this recent information, EPA admits, "The currently recommended PRGs are based on an EPA dioxin toxicity value adopted by the Agency in 1985," thus ignoring the agency's own evidence.

Inhalation Exposure of Dioxin

Site remediation including In Vitro remediation, such as excavation and construction and "off gassing" of dioxin contaminants will pose an inhalation hazard to workers and subsequent occupants.

According to the Federal Register, EPA has established these PRGs based on consideration of oral and dermal exposures to dioxin. According to the draft, inhalation was not considered because "there is no available inhalation unit risk value for dioxin" and "inhalation exposure to dioxin (particulates and vapor) is expected to be low (< 2.4%) compared to oral exposure in most cases." These statements contradict the U.S. Department of Health and Human Services, which states inhalation is 88% higher than oral and 40% higher than absorption. According to EPA's Technology Transfer Network, TCDD is listed on the "Air Toxics Web Site," and states, "Human studies, primarily of workers occupationally exposed to 2, 3, 7, 8-TCDD by inhalation, have found an association between 2, 3, 7, 8-TCDD and lung cancer, soft-tissue sarcomas, lymphomas, and stomach carcinomas..." EPA has also calculated an inhalation cancer slope factor of $1.5 \times 10^5 \text{ (mg/kg/d)}^{-1}$ and an inhalation unit risk estimate of $3.3 \times 10^{-5} \text{ (pg/m}^3\text{)}^{-1}$ for 2, 3, 7, 8-TCDD. According to the National Academy of Sciences review, atmospheric transport and deposition of DLCs are the primary means of their dispersal throughout the environment.

EPA Risk Estimates

The EPA report “Health Risks from Dioxin and Related Compounds” included studies on several exposures: cancer, immune function, reproductive and developmental and non-cancer endpoints. The study indicated dioxin caused adverse effects to humans and animals in all exposure areas. However, inaccuracies noted by the National Academy of Sciences concerning the EPA’s Risk Estimates pose a concern that the proposed PRGs are based on biased information minimizing the negative health effects of dioxins.

The assessment included several comments by the National Academy of Sciences concerning uncertainty of risk assessments. One comment pertaining to EPA’s discussion of epidemiological studies stated it “tended to focus on positive findings without fully considering the strengths and limitations of both positive and negative findings.” It also stated the 1% response above background is at the low end of the observed range, and the EPA’s risk assessment was “slanted” toward positive findings. The National Academy of Sciences recommended that EPA conduct a reassessment, specifically the risk characterization chapter of the Reassessment. Recommendations suggest the chapter should describe concisely and clearly the following aspects:

1. The effects seen at the lowest body burdens that are the primary focus for any risk assessment—the “critical effects.”
2. Consideration of individuals in susceptible life stages or groups (e.g., children, women of childbearing age, and nursing infants).
3. The precision and uncertainties associated with the body burden estimates for the critical effects at the point of comparison on the dose-response relationship, including the use of total body burden rather than modeling steady-state concentrations for the relevant tissue.
4. Distributions that provide clear insights about the uncertainty in the risk assessments, along with discussion about the key contributors to the uncertainty.

Conclusion

While ANA supports the EPA’s decision to place limitations on dioxins, the PRGs should be established at the one-in-a- million cancer risk value, 3.7 ppt for residential use and 17 ppt, for commercial/industrial. The PRGs revisions are necessary because:

- The Preliminary Remediation Goals (PRGs) are based on “non-cancer toxicity values” when dioxin is recognized as a carcinogen by numerous agencies including the EPA.
- When establishing the RPGs, EPA ignored inhalation, a primary route of exposure.
- EPA’s assessment of health risk of dioxins was biased toward positive findings and ignored potential adverse health effects. Promulgating inadequate PRGs will exacerbate the problem.

Again, thank you for the opportunity to submit comments on this important issue.

Sincerely,

A handwritten signature in cursive script that reads "Mary Jean Schumann". The ink is dark and the signature is fluid, with a large initial 'M' and a long, sweeping underline.

Mary Jean Schumann, MSN, MBA, RN, CPNP
Chief Programs Officer