



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 10

1200 Sixth Avenue, Suite 900  
Seattle, WA 98101-3140

OFFICE OF  
WATER AND WATERSHEDS

January 20, 2015

Don Essig  
Idaho Department of Environmental Quality  
1410 N. Hilton  
Boise, Idaho 83706

RE: EPA comments on Idaho's Discussion Paper #7 Risk Management and Protection of Human Health

Dear Don:

EPA appreciates the opportunity to provide comments to the Idaho Department of Environmental Quality (DEQ) on the discussion paper, Risk Management and Protection of Human Health, which DEQ presented at the December 3, 2014 negotiated rulemaking meeting. The EPA is very appreciative of the challenging work that DEQ has undertaken thus far in consideration of revising its human health water quality criteria, which has included a robust public process and review of the factors used to derive human health criteria.

In general, EPA found DEQ's discussion paper to be well written. However, EPA has concerns about some of the statements included in the paper and the absence of discussion on some important issues. While we are providing more specific comments below, the EPA is available and interested in continuing discussions with DEQ about risk management considerations in the rulemaking process. As you know, EPA also has been very engaged in Washington's human health water quality rule development and has emphasized the importance of having states fully assess potential health risks to higher fish consumers, taking into consideration factors such as environmental justice and tribal treaty rights. These issues were not addressed in DEQ's issue paper and EPA believes it is important for DEQ to fully consider these and other issues noted below as it moves forward in the rulemaking process.

SPECIFIC COMMENTS

1. With regards to characterization of EPA's reference dose (pg. 1), it should be noted that the reference dose is currently based on the most sensitive toxic endpoint exhibited by the most sensitive species. EPA is moving towards a more complete description of all of the dose response relationships associated with exposures to non-carcinogens, not just the effect associated with the current reference dose methodology.
2. The paper cites recent work done by the State of Florida on relative source contribution. EPA is still evaluating their analysis.
3. The citation of the percentages of cancer associated with occupational and environmental causes in the American Cancer Society (ACS) publication (pg. 2) is not well documented in

the ACS publication. However, it appears that the percentages of cancers associated with these causes is from Doll and Peto (1981). If so, it is important to note that Doll and Peto's analysis has a number of weaknesses which are well characterized in the 2008-2009 report on the President's Panel on Cancer, "Reducing Environmental Cancer Risk, What We Can Do Now," [http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP\\_Report\\_08-09\\_508.pdf](http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf). Specifically, it is now recognized that the development of cancer depends on multiple factors and that the contribution of environmental factors is likely underestimated in Doll and Peto's work. Doll and Peto relied primarily on epidemiologic studies of workers in large industries and failed to include minorities, deaths among persons aged 65 and older, exposures in smaller workplaces, and the effects of indirect contact with carcinogens. Even if Doll and Peto's suggested percentages were deemed to be accurate, given the population of the United States, the general probability of getting cancer, and the costs of cancer treatment, occupational and environmental cancer exacts a staggering cost to the U.S., as well as costs in human suffering that are difficult to quantify.

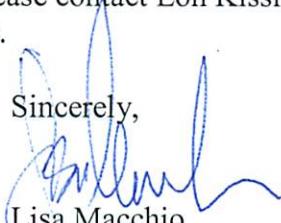
4. Though it is true that EPA generally assumes that there is no dose threshold associated with cancer risk (pg. 2), EPA's 2005 Cancer Guidelines, [http://www.epa.gov/raf/publications/pdfs/CANCER\\_GUIDELINES\\_FINAL\\_3-25-05.PDF](http://www.epa.gov/raf/publications/pdfs/CANCER_GUIDELINES_FINAL_3-25-05.PDF), clearly acknowledge that carcinogens may have a threshold mechanism of action. Chloroform and formaldehyde are examples of chemicals that utilize cancer risk assessment based on a non-linear mode of action.
5. In its discussion paper, DEQ identifies factors that might be considered in developing acceptable risk levels (pg. 3). DEQ also specifically states (pg. 8), "the concept of ALARA has some significance to the development of water quality criteria," and "the challenge is to develop "reasonably achievable" criteria." To clarify, EPA's standard of review under the Clean Water Act and EPA's implementing regulations at 131.11(a) is that water quality criteria must protect applicable designated uses and be based on sound scientific rationale. In developing 304(a) criteria and reviewing state water quality standards under CWA 303(c), EPA does not consider economic impacts or the technological feasibility of meeting the criteria in ambient water. Therefore, EPA believes the list of factors relevant to development of water quality criteria is narrower than the list presented in the discussion paper.
6. The Idaho paper discusses the origins of the use of one in a million risk (pg. 3). However, the origin is not as relevant as an analysis of the factors considered when selecting a risk level to use for developing risk-based water quality standards (e.g., What is the appropriate risk level associated with criteria for regulating involuntary exposure of U.S. citizens to chemicals in the Nation's waters?). The focus should be on evaluation and discussion of the issues covered in the Idaho paper as informed by the enabling statute, the Clean Water Act, and its implementing regulations not the historical origin of one in a million risk.
7. In considering risk levels used by other regulatory programs (pg. 4), DEQ should define how risk is considered as specified in the enabling statutes and associated implementation regulations. Further considerations include whether or not risk is involuntary (as is the case for exposure to contaminants in environmental media) or is voluntary (as is the case for some occupational exposures). Another consideration is the scope of the program of interest (e.g.

the limited geographic scope of CERCLA/RCRA cleanups, the national scope of ambient water quality criteria, or regulation of the workplace). A useful addition to the discussion paper would have been a discussion of how other entities have considered risk in setting water quality criteria as opposed to comparing risk levels across programs with varied regulatory objectives and mandates.

8. The discussion paper's section on flexibility in choice of risk level (pg. 7) does not fully describe the recommended risk range for setting AWQC. The language within the paper focuses on use of  $10^{-6}$  to  $10^{-5}$ . However, EPA's Human Health Methodology (EPA 2000) notes that States and Tribes can choose more stringent risk levels, such as  $10^{-7}$ .
9. The discussion of voluntary vs. involuntary risk (pg. 7) touches on the responsibility of government to reduce risks. However, the discussion paper does not address the important issue of environmental justice and how DEQ should consider those issues, recognizing that tribes and other low-income, minority populations have generally been well-documented to have exposures to contaminants in fish and shellfish exceeding those experienced by the general population. These issues, along with tribal trust responsibilities, including treaty rights, are important considerations. The conclusions section (pg. 8) should address these types of issues.

We look forward to continued work with DEQ on this effort and are available if you would like to discuss our comments further. Please contact Lon Kissinger (206-553-2115) or myself (206-553-1834) if you have any questions.

Sincerely,



Lisa Macchio

Water Quality Standards Coordinator