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Submitted Via E-Mail to: whiteld@niehs.nih.gov

Re: Draft Report on Carcinogens Concept: Di- and tri-haloacetic acids found as wáter disinfection by-products (March, 2016)

Dear Dr. White:

On behalf of the American Chemistry Council (ACC)[1], I submit these comments on the National Toxicology Program's (NTP's) "Draft Report on Carcinogens Concept: Di- and tri-haloacetic acids found as water disinfection by-products." The Draft Concept announces that the Office of the Report on Carcinogens plans to evaluate ten di- and tri-haloacetic acids identified in drinking water for possible listing in the Report on Carcinogens (RoC). However, the NTP does not provide adequate justification for prioritizing this planned use of public funds. We highlight our specific concerns regarding the Draft RoC Concept as follows:

- **The US Environmental Protection Agency's (EPA) 2006 Stage 2 Disinfection By-products (DBP) Rule regulated four trihalomethanes and five haloacetic acids and helped control not only those identified DBPs, but a host of unregulated contaminants. EPA's implementation of this rule and the resulting controls on DBP exposures in drinking water make further examination and regulation of DBPs unnecessary.**

Controlling DBP precursors has the effect of controlling not only regulated, but many unregulated, DBPs as well. According to the Final Stage 2 Disinfectants and Disinfection Byproducts Rule, "Installing certain advanced technologies to control DBPs has the added

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $801 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

benefit of controlling other drinking water contaminants in addition to those specifically targeted by the Stage 2 DBPR. For example, membrane technology installed to reduce DBP precursors can also reduce or eliminate many other drinking water contaminants (depending on pore size), including those that EPA may regulate in the future."[2] Thus, controls are already in place to limit formation of DBPs of many types. Further evaluation under the RoC, which may or may not change the cancer label, will have no further substantive impact on implementation of the existing rule, and is thus unnecessary.

- **Scientific evidence indicates two of the EPA-regulated DBPs, bromodichloromethane (BDCM) and chloroform, should not be listed as *reasonably anticipated to be a human carcinogen* in the NTP RoC.**

BDCM: A 2006 NTP bioassay found *no evidence of carcinogenic activity* of BDCM in male F344/N rats exposed to target concentrations of 175, 350, or 700 mg/l in drinking water. There was also no evidence of carcinogenic activity of BDCM in female $B6C3F_1$ mice, exposed to the same target concentrations in drinking water.[3]

A summary of a review subcommittee's comments (page 10 of the report) notes that a previous NTP study in which BDCM was given by gavage "was carcinogenic at multiple sites in rats and mice." Dr. R.L. Melnick (NIEHS) "attributed the difference in tumor response by the two routes to a variety of factors, including differences in organ dosimetry, diet, and body weight." A motion to accept the conclusion of *no evidence of carcinogenic activity* "was carried unanimously with nine votes."

Chloroform: The US Environmental Protection Agency Integrated Risk Information System lists chloroform as both "Likely to be carcinogenic to humans" and "Not likely to be carcinogenic to humans." It is likely to be carcinogenic to humans "by all routes of exposure under high-exposure conditions that lead to cytotoxicity and regenerative hyperplasia in susceptible tissues," according to the EPA IRIS website.[4] According to the same source, it "is not likely to be carcinogenic to humans by any route of exposure under exposure conditions that do not cause cytotoxicity and cell regeneration." The latter exposure scenario includes normal exposure to chlorinated drinking water. This distinction should be made clear in the RoC.

Chloroform is one of four EPA-regulated trihalomethanes. The Maximum Contaminant Level of the combined four regulated trihalomethanes must be less than 80 ppb, under the EPA Safe Drinking Water Act. According to the EPA website, health effects from exposure to levels

[2] 71 Fed. Reg. 387 (Janu. 4, 2006). Online, available: https://www.gpo.gov/fdsys/pkg/FR-2006-01-04/html/06-3.htm

[3] National Toxicology Program (2006). National Toxicology Program Technical Report 532 on the Toxicology and Carcinogenesis, Studies of Bromodichloromethane, in Male F344/N Rats and Female $B6C3F_1$ Mice. Online, available: https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr532.pdf

[4] https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=25

above [emphasis added] the Maximum Contaminant Level "over many years" may include "liver, kidney, or central nervous system problems and increased risk of cancer."[5]

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In closing, we question the need for additional, costly evaluation of DBPs at a time when there are many more urgent drinking water quality issues of public concern worthy of US public resources. These include controlling contaminants in drinking water delivered through aging infrastructure and addressing *Legionella*, currently the single drinking water contaminant responsible for the most waterborne disease outbreaks in the US, according to data from the US Centers for Disease Control and Prevention.[6]

Respectfully,

Judith Nordgren

[Redacted]

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[5] https://safewater.zendesk.com/hc/en-us/articles/211400928-1-What-disinfection-byproducts-does-EPA-regulate-like-TTHMs-how-are-they-formed-and-what-are-their-health-effects-in-drinking-water-at-levels-above-the-maximum-contaminant-level-

[6] U.S. Centers for Disease Control and Prevention (August 13, 2015). Morbidity and Mortality Weekly Report, 2011-2012 CDC Surveillance summaries: Surveillance for waterborne disease outbreaks—United States. Available: http://www.cdc.gov/healthywater/surveillance/drinking-surveillance-reports.html