BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	)	
	)	
PROPOSED AMENDMENTS TO	)	R2022-018
GROUNDWATER QUALITY	)	
(35 Ill Adm. Code 620)	)	(Rulemaking – Public Water Supply)

NOTICE OF FILING

PLEASE TAKE NOTICE that I have today electronically filed with the Office of the Clerk of the Illinois Pollution Control Board the AMERICAN CHEMISTRY COUNCIL'S PRE-FILED QUESTIONS to the Illinois Environmental Protection Agency, copies of which are served upon you.

Dated February 18, 2022

Respectfully Submitted,

AMERICAN CHEMISTRY COUNCIL

By: /s/ Stephen P. Risotto
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CERTIFICATE OF SERVICE

I, the undersigned, certify that I have today filed the attached NOTICE OF FILING and AMERICAN CHEMISTRY COUNCIL'S PRE-FILED QUESTIONS to the Illinois Environmental Protection Agency in PCB R2018-032 upon the below service list by electronic mail.

Dated: February 18, 2022

By: /s/ Stephen P. Risotto
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AMERICAN CHEMISTRY COUNCIL PRE-FILED QUESTIONS TO THE ILLINOIS ENVIRONMENTAL PROTECTION AGENCY

Questions on IEPA Proposal to Amend Groundwater Quality Standards

1. The definitions for LOAEL and NOAEL in Section 620.110 specify a statistically significant increase in frequency or severity of adverse effects. However, many of the values proposed by IEPA are based on benchmark dose modeling.
   - Does IEPA also require statistical significance when considering data derived from benchmark dose modeling?
   - Does IEPA require evidence of a dose response to identify a hazard, or is a statistically significant response at any dose sufficient?

2. Section 620.125 lists several standard test methods for analyzing PFAS, including ASTM D7979-20. However, USEPA has not yet developed a validated laboratory method for analyzing PFAS in water other than drinking water. In September 2021, the Office of Water released draft method 1633 for the measurement of certain PFAS in aqueous samples but has not yet finalized the method.
   - Has IEPA validated ASTM D7979-20 for analyzing for PFAS in aqueous sources that are not drinking water?
   - How will IEPA assure that the data collected are accurate?

3. Section 620.310(3) of the proposal requires that the regulatory agency determine whether preventive response shall be undertaken if a statistically significant increase occurs above background for the identified substances.
   - How does IEPA define background?
   - How does IEPA determine statistical significance?

4. The proposed regulation would establish ground water standards for 22 substances (3 inorganic chemicals and 19 organic chemicals) and revise existing standards for 30 chemicals.
   - How were these substances selected?
   - Was there a public review process for their selection?

5. IEPA's selection of RfD sources for the PFAS substances appears arbitrary and inconsistent with its stated hierarchy.
   - Why did IEPA select toxicity values from ATSDR, a Tier 3 source, for PFOS when a toxicity value was developed by USEPA's Office of Water in setting its 2016 Lifetime Health Advisory (LHA) for the substance?
   - Similarly, why does IEPA use the Notification Level recommended by California's EPA, a Tier 3 source, for PFOA when the EPA Water Office conducted a toxicity assessment in setting the LHA?

6. The revised standard for 1,4-dioxane is based on an analysis conducted by USEPA for its Integrated Risk Information System (IRIS) in 2013. Considerable information has been generated on this chemical since then supporting a threshold mode of action (MOA) for carcinogenicity in laboratory animals, included an analysis by Health Canada completed in 2021. As a result, government bodies around the world have concluded that 1,4-dioxane does not present a cancer risk below a threshold exposure, including the World Health Organization, the European Union, and Health Canada.
   - Did IEPA consider the evidence for a threshold cancer MOA in considering revision of the groundwater standard for 1,4-dioxane?
   - What steps does IEPA take to ensure that its standards are based on the most current science?

7. In the key study used in its analysis of PFOS, the Agency for Toxic Substances and Disease Registry (ATSDR) ignores the conclusions of the study authors regarding the relevant dose resulting in adverse effects in the laboratory animals. The study authors identify 0.4 milligrams per kilogram (mg/kg) as a no-observed-adverse-effect level (NOAEL) and 1.6 mg/kg as a lowest-observable-adverse-effect level (LOAEL). ATSDR, in contrast, inappropriately considers the LOAEL to be 0.4 mg/kg without explanation which has a significant impact on its calculation.
   - Has IEPA reviewed the conclusions of the study authors and evaluated the appropriateness of using 0.4 mg/kg as a LOAEL.

8. CalEPA bases its analysis of PFOA on reports of liver and pancreatic tumors in a laboratory animal study. Available studies suggest that these tumors are associated with a mode of action that is of less relevance to humans.
   - Has IEPA assessed the relevance of the tumors reported in the animal study to human exposure?

9. USEPA's Drinking Water Treatability Database indicates that available treatment technologies can remove up to 99 percent of concentrations of HFPO-DA, PFBS, PFHxS, PFNA, PFOA, and PFOS in water.
   - Why are the standards for Class II (Ground Resource) Groundwater for these substances in Section 620.420 not adjusted by a treatment factor of 10 as is done for other substances for which >90 percent removal efficiency can be achieved?

10. Section 620.605 indicates that a health advisory for a substance for which a threshold dose exists should be based on the lower of the HTTAC or HNTAC if an MCL Goal does not exist.
    - What is the basis for calculating a HNTAC for a substance for which a threshold exists?

11. Under USEPA's voluntary stewardship program, manufacture of PFOA, PFOS, and other long-chain PFAS was phased out in the early 2000s in the United States, Europe, and Japan, As a result, data from the Center for Disease Control and Prevention indicates that blood serum levels of PFOA and PFOS have declined by 60 and 85 percent, respectively. Based on this decline, several states have assumed a relative source contribution (RSC) of 50 percent or more for these two substances.
    - What is the basis for IEPA's decision to use the default RSC of 20 percent in deriving the groundwater quality standards for these two substances?
    - What chemical-specific data are considered for determining the appropriate RSC for a substance?

12. There is compelling and robust scientific evidence that mechanisms of carcinogenicity which operate in adults also operate in children, and that to the extent children may be more, less, or equally sensitive to some substances, current cancer assessment methodology is sufficiently conservative to protect children. In its guidance for assessing early life exposures, moreover, EPA indicates that even if the data indicate a mutagenic mode of action, available chemical specific data should be considered before applying the age-dependent adjustment factors
    - How will IEPA consider chemical-specific data when assessing whether to add an adjustment factor for early life exposures for substances determined by USEPA to be mutagenic carcinogens?

13. Under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA, or Superfund), USEPA conducts a screening assessment for all substances affecting the same organ system. However, the Agency only assumes dose additivity for substances acting by a common mode of action when conducting a more refined assessment. Appendix C of the proposal appears to suggest that dose addition will be applied to substances affecting the same organ system, regardless of mode of action.
    - Under what circumstances does IEPA assume dose additivity when assessing exposures to multiple substances?
    - Does IEPA require that both criteria listed in paragraph (a) of Appendix C be met to consider substances to be similar-acting?

14. Appendix C indicates that nervous system depression and liver toxicity are "modes of action" when they are actually health endpoints that can result from a variety of modes of action?
    - How does IEPA define a "mode of toxic action"?
    - Why is IEPA using a different definition for "mode of action" than that used by USEPA and the scientific community?

15. Appendix C lists decreased body weight and developmental effects as separate health endpoints, when body weight decrease in offspring is very often the basis for identifying a developmental effect.

- What is the basis for considering the two separately?
- What body weight effects is IEPA considering, if not those observed in offspring of exposed mothers?

16. The following organ systems have not been identified as targets for the specified chemical in the source cited by IEPA's for its toxicity assessment of the chemical: HFPO-DA – kidney (USEPA), PFBS – reproductive (USEPA), PFOS – reproductive (ATSDR)
    - What is the basis for listing these targets in Appendix E?

17. Although several of the substances are listed to affect multiple target organs, the reference dose (RfD) for each substance is based on effects in a single organ.
    - How will IEPA assess dose additivity for a health endpoint if that endpoint is not the basis of the toxicity value calculation for the identified substances?
    - Has IEPA conducted additional analysis to derive toxicity values for each of the endpoints for which a substance is identified? If not, how can IEPA consider adding doses from multiple health endpoints?