Technical Comments of

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to the

Illinois Environmental Protection Agency

Re 35 III. Adm. Code 620; Groundwater Quality Pre-Filing Public Comment Period

June 25, 2021

To whom it concerns,

We the signers, applaud the efforts by the Illinois EPA to set enforceable groundwater standards for PFAS chemicals, which will be necessary for identifying and cleaning up contaminated groundwater resources in the state. We previously submitted comments on the original proposal for groundwater standards in February 2020. Since then we are glad to see the IEPA has used more protective exposure estimates which have resulted in stronger health guidelines especially for perfluorooctanoic acid (PFOA), perfluorooctanesulfonic acid (PFOS), and perfluorononanoic acid (PFNA). However, we are still very concerned that some of the proposed groundwater standards, specifically those for perfluorohexane sulfonic acid (PFHxS) and perfluorobutanesulfonic acid (PFBS) are still not strong enough to fully protect human health. Several states have set more protective water standards for PFAS by considering the special vulnerability to PFAS exposure during gestation and infancy, and by basing risk evaluations on the most sensitive health effects linked to a particular PFAS. Other states have used a transgenerational toxicokinetic model to estimate exposure over a lifetime, including the increased consumption of water by infants and very young children, which leads to an increased body burden of PFAS during the most sensitive period of life.

The following comments lay out our concerns over IEPA's overall risk assessment process, in addition to comments on the chemical specific risk assessments performed. We urge IEPA to ensure that Illinois groundwater be regulated at levels protective enough to ensure that women and children could safely drink this water without any risk of harmful effects from PFAS. Finally, we urge IEPA to move beyond a chemical-by-chemical approach, to acknowledge the risks posed by the entire class, including cumulative exposures to mixtures of PFAS.

General Comments on IEPA's Risk Assessment Process

Risk assessments should be based on the current best available science, including the use of any chemical specific parameters available, and should be protective of all populations. Federal and state agencies that conduct independent risk assessments can evaluate current data to determine the appropriate parameters that should be used to arrive at a final value that is protective of those populations most vulnerable to exposure to a specific chemical or group of chemicals.

In contrast, IEPA is proposing to use an *a priori* determined hierarchy to guide development of its risk assessments. This hierarchy consists of three tiers from which to choose an existing toxicity value: 1) Integrated Risk Information System, 2) Provisional Peer Reviewed Toxicity Values, and 3) other toxicity values from sources where the risk assessment has been peer-reviewed. On one hand, this is beneficial to the state agency in that it streamlines the development of water standards, thereby allowing for their more rapid development. On the other hand, it limits the agency from conducting its own independent review of the existing literature and may limit the agency from utilizing risk assessments conducted by other state agencies. We also note that the procedures outlined in Appendix A leave little room and flexibility to incorporate chemical specific parameters. Further it is unclear how the hierarchy

takes into consideration how up-to-date various toxicity values are, or how new information can be considered.

Given the constraints imposed by the process used by IEPA for setting groundwater standards, we support the use of a RSC of 20% (= 0.2) in the absence of chemical specific data, which was outlined in Appendix A, Section (a) Calculating the Human Threshold' Toxicant Advisory Concentration for NonCancer Effects. Further, we feel that this RSC was appropriately applied in the risk assessments for PFAS prepared by IEPA.

However, we do not support the use of W=Per capita daily water consumption for a child (0 to 6 years of age, equal to 0.782 liters per day ("L/d") (Appendix A, Section (a)). Several states have used the more protective drinking water exposure estimate for very young infants 0 to 1 year of age (0.142 L/kg/day), and we encourage IEPA to do the same. Infants are particularly susceptible to the harmful effects of environmental chemical exposures due to the rapid growth and development that occurs during early life. Infants also consume more water on a per body weight basis than adults (0.029 L/kg/day), lactating women (0.054 L/kg/day), and even children aged 0 to 6 years (0.052 L/kg/day). Note that the drinking water exposure estimate for infants 0 to 1 year of age is more than double the estimate for children 0 - 6 years old.

Further we point out that the requirement to use the methodology outlined in Appendix A, Section (a) precludes the use of more sophisticated toxicokinetic modeling for estimating exposure through drinking water. For example, the procedure for "Calculating the Human Threshold' Toxicant Advisory Concentration for NonCancer Effects" proposed in Administrative Code 620 does not allow for the use of the peer reviewed transgenerational toxicokinetic model developed by Minnesota Department of Health scientists that more accurately models serum levels of persistent chemicals, such as PFAS, over a lifetime of consumption.^{1, 2} Importantly, the transgenerational toxicokinetic model and supporting documentation highlight the need to protect the very young, as serum levels of PFOA and related chemicals spike (i.e. are elevated) in the first two years of life.

We also note that the hierarchy of sources of toxicity values described in Appendix A, section (b), subsection (2) does not allow for needed flexibility in responding to the rapidly evolving science related to PFAS. It is unclear how IEPA will make use of the hierarchy of toxicity values when new information becomes available, especially given that some of the listed agencies in Subsection (2), parts A-C are not required to regularly update their assessments. It is possible that these resources could become out of date as new scientific literature becomes available. Without the option to conduct its own risk assessment or to make use of risk assessments conducted by other state agencies IEPA risks developing standards that are out of date and not health protective.

As noted in an EPA memorandum from December 1993 entitled "Use of IRIS Values in Superfund Risk Assessment" (OSWER Directive 9285.7-16, December 21, 1993):

"...IRIS is not the only source of toxicology information, and in some cases more recent, credible and relevant data may come to the Agency's attention. In particular, toxicological information other than that in IRIS may be brought to the Agency by outside parties. Such information should be considered along with the data in IRIS in selecting toxicological values; ultimately, the Agency should evaluate risk based upon its best scientific judgement and consider all credible and relevant information available to it."³

However, it is unclear if IEPA has always followed the above cited guidance and how IEPA will do so moving forward. For example, in an earlier draft of the groundwater standard for PFBS, IEPA had relied upon Tier II data - a PPRTV from EPA from 2014, which was already considered out of date by other state and federal agencies conducting risk assessment on PFBS. At the time of IEPA's draft there was already an existing draft human health toxicity value derived by US EPA⁴, and toxicity values derived by Michigan's Science Advisory Workgroup⁵ and Minnesota's Department of Health⁶. We are pleased to see that IEPA is now relying on the new human health toxicity value for PFBS released by US EPA on April 28, 2021, but it remains unclear in Administrative Code 620 how the age of the data is considered when deciding which toxicity value to use and/or when to update existing standards.

Chemical-specific Comments

We support IEPA's decision to set the groundwater quality standard for PFOA at 2 ppt, as this value is health protective based on current evidence. We generally support IEPA's decision to set the groundwater quality standards for PFOS at 7.7 ppt, and PFNA at 12 ppt.⁷ Although our own analysis suggests that these values could be slightly more health protective, they are in line with values derived by other reputable states and agencies.



However, as discussed in detail below, we do not agree with IEPA that the values for PFHxS (77 ppt) and PFBS (1,200 ppt) are health protective groundwater standards, thus highlighting the need to make further changes to the Administrative Code as described above.

PFBS



IEPA used the reference dose (RfD) of 300 ng/kg/day derived by the US EPA. The RfD was also used by Michigan and Washington in setting health-based values in those states. California also based it's RfD on the same critical study, yet calculated a RfD of 500 ng/kg/day. Michigan and California, each arrived at more health protective final values than IEPA: 420 ppt in Michigan and 500 ppt in California compared to IEPA's 1,200 ppt. The nearly two- to three-fold difference in final values is the result of choosing to protect very young infants who are most vulnerable.

Michigan used a drinking water ingestion estimate specific for infants (birth to <1 year old) of 0.142 L/kg/day based on the 95th percentile of water intake for consumers only (direct and indirect consumption) per Table 3-1 in USEPA Exposure Factors Handbook, 2019. Similarly, California used a drinking water ingestion estimate specific for infants 0-6 months old of 0.237 L/kg/day. In contrast, IEPA has chosen to use a drinking water ingestion estimate for children up to 6 years old of 0.052 L/kg/day. While this drinking water estimate is significantly more protective than drinking water ingestion estimated for adults (0.029 L/kd/day), it is not as protective as drinking water ingestion estimates for infants or for nursing and lactating women (0.054 to 0.055 L/kg/day), both of which have often been used by agencies engaged in PFAS risk assessment.

IEPA has chosen to base its risk assessment for PFBS on the critical effect of decreased total serum T4 in newborn animals. However, by using a drinking water ingestion estimate for children of an older age, it is questionable if the final value achieved will actually be protective of this effect or not. We encourage IEPA to acknowledge that infants 1 year of age and younger are a particularly vulnerable and sensitive population when it comes to PFAS exposure by choosing to use a drinking water ingestion estimate for infants 0 to 1 years old in all of it's PFAS risk assessments unless there is strong evidence that an effect is more sensitive in another population. We note above that this should be addressed by updating Appendix A, Section (a).

PFHxS



IEPA used the RfD originally derived by ATSDR in June 2018,8 which qualifies as a Tier 3 Toxicity Value in the proposed hierarchy described in Appendix A, Section (b), Subsection (2) of Administrative Code 620. This RfD of 20 ng/kg/day is based on thyroid follicular cell damage in adult rats, and was finalized without any updates in May 2021.9 Other state agencies, namely Michigan, Minnesota, and Washington, that conducted risk assessment for PFHxS subsequent to the publication of the ATSDR Draft Toxicological Profile did not base their assessments on the same endpoint.^{5, 9, 11} Rather, these state agencies based the risk assessment on decreased free T4 observed in adult male rats in the National Toxicology Program's (NTP) TOX96 Report from 2018.¹² The resulting RfD for this endpoint used by Michigan, Minnesota, and Washington is 9.7 ng/kg/day. New Hampshire also conducted risk assessment for PFHxS subsequent to publication of the ATSDR Draft Toxicological Profile and chose a critical effect of impaired female reproduction, specifically reduced litter size in

exposed mice, resulting in a RfD of 4.0 ng/kg/day.¹³ Importantly, the work utilized by New Hampshire was published in a peer reviewed document,¹⁴ which would qualify it for use as a Tier 3 Toxicity Value according to the hierarchy described in Appendix A, Section (b), Subsection (2) of Administrative Code 620. It is unclear if these newer toxicity values could be used by IEPA given the hierarchy of toxicity values outlined in Appendix A.

Further, nearly all state agencies that have conducted risk assessment for PFHxS have relied upon the peer reviewed transgenerational toxicokinetic model¹ for estimating exposure to PFHxS.^{5, 9, 11,13} As noted in Figure 3 from the risk assessment document provided by Minnesota,¹⁰ serum levels of PFHxS are expected to spike in breastfed infants within the first two years of life, further highlighting the deficiency of the drinking water exposure estimate for children 0 to 6 years of age proposed for use by IEPA.



We recognize that the IEPA has strengthened its proposed groundwater quality standards for most of the PFAS chemicals however considering the above information, Illinois should lower its groundwater quality standard for perfluorohexane sulfonic acid (PFHxS) and perfluorobutanesulfonic acid (PFBS) to be on par with those set by Michigan and California in order to protect the most vulnerable populations to PFAS exposure. This can be accomplished by using the most up to date toxicity values and drinking water exposure estimates that are protective of the most vulnerable and susceptible populations.

Moving Beyond a Chemical by Chemical Approach

Perhaps more importantly, the structure of the fluorine-carbon bond and the hazards documented for PFAS support concern over the environmental and health impacts of the entire class. It is important to note that all of these individual risk assessments do not account for cummulative exposures to mixtures of PFAS, and thus could be vastly underestimating the risk posed by PFAS exposures. Yet, virtually all people living in the US have multiple PFAS in their bodies.¹⁵ The magnitude of this problem demands a more efficient and effective approach, which is why prominent scientists and medical organizations from around the world are urging a class-based approach for managing PFAS.^{16,17} A goal of zero PFAS in drinking water is needed to provide an adequate margin of safety to protect public health from a class of chemicals that is characterized by extreme persistence, high mobility, and is associated with a multitude of different types of toxicity at very low levels of exposure.⁷

Multiple resources are available to guide IEPA in developing class-based approaches for regulating PFAS. In previous technical comments we have outlined a hierarchy of class-based

approaches for regulating PFAS in ground and drinking water, from most health protective to least, that should be further considered by IEPA to protect Illinois residents from undo PFAS exposure.¹⁸ The most health protective approach being regulating the full class based on persistence, or the "P-sufficiency" approach, and setting a treatment technique for the class. We therefore urge Illinois to explore in the near future the establishment of a treatment technique for PFAS - a minimum treatment requirement or a necessary methodology or technology that a public water supply must follow to ensure control of a contaminant.

Thank you for considering these important ways to ensure greater protection for Illinois residents. Please take these urgent and defensible actions to strengthen groundwater protections from PFAS to ensure that Illinois groundwater resources remain safe and clean.

Sincerely,

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