BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	)	
PROPOSED AMENDMENTS TO GROUNDWATER QUALITY 35 ILL. ADM. CODE 620	)	**R22-18 (Rulemaking – Public Water Supplies)**

NOTICE OF FILING

To: ALL PARTIES ON THE ATTACHED SERVICE LIST

PLEASE TAKE NOTICE that today I have electronically filed with the Office of the Clerk of the Illinois Pollution Control Board the attached **3M Company's Post-Hearing Comment**, copies are which are herewith served upon you.

Dated: March 3, 2023

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One of its Attorneys

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CERTIFICATE OF SERVICE

I, the undersigned, certify that on this 3rd day of March, 2023, I have electronically served the attached **3M Company's Post-Hearing Comment** upon the individuals on the attached service list. I further certify that my email address is Sarah.Lode@afslaw.com, the number of pages in the email transmission is 21, and the email transmission took place before 5:00 p.m.

/s/ Sarah L. Lode
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PROPOSED AMENDMENTS TO GROUNDWATER QUALITY 35 ILL. ADM. CODE 620	)	**R22-18 (Rulemaking – Public Water Supplies)**

3M COMPANY'S POST-HEARING COMMENT

NOW COMES 3M Company ("3M") by their attorneys, pursuant to 35 Ill. Admin. Code 102.108 and the Hearing Officer's December 8, 2022 Order, and submits this Post-Hearing Comment on the Illinois Environmental Protection Agency's ("IEPA" or "Agency") proposed amendments to 35 Ill. Admin. Code Pt. 620 dated December 7, 2021, which include at Sections 620.410 and 620.420 the proposed addition of new Class I (potable resource) and Class II (general resource) groundwater quality standards for six per- and polyfluoroalkyl substances ("PFAS"): perfluorooctanoic acid ("PFOA"), perfluorooctanesulfonic acid ("PFOS"), perfluorohexanesulfonic acid ("PFHxS"), perfluorononanoic acid ("PFNA"), perfluorobutanesulfonic acid ("PFBS"), and hexafluoropropylene oxide dimer acid ("HFPO-DA") (collectively, the IEPA's "Proposed PFAS Standards").

For reasons explained below and in testimony by board-certified toxicologist, Dr. Robyn Prueitt of Gradient, and in testimony by Mr. Stephen Risotto of the American Chemistry Council, the Proposed PFAS Standards, as currently proposed, are not supported by evidence in the Board's administrative record and are inconsistent with the requirements of the Illinois Environmental Protection Act and Illinois Groundwater Protection Act. 3M therefore respectfully submits that

the Illinois Pollution Control Board (the "Board") decline to adopt or issue the Proposed PFAS Standards for first notice publication under 35 Ill. Admin. Code 102.604.

I. STANDARDS FOR BOARD GROUNDWATER RULEMAKINGS

An administrative body exceeds its rulemaking authority when it "(1) relies on factors which the legislature did not intend for the agency to consider; (2) entirely fails to consider an important aspect of the problem; or (3) offers an explanation for its decision which runs counter to the evidence before the agency, or which is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Greer v. Ill. Hous. Dev. Auth.*, 524 N.E.2d 561, 581 (Ill. 1988); *IEPA v. IPCB*, 721 N.E.2d 723, 730 (Ill. App Ct. 2d. Dist. 1999) (applying this standard to the Board); *Cnty. of Will v. IPCB*, 135 N.E.3d 49, 61 (Ill. 2019) (describing the *Greer* standard as a "useful rubric" in analyzing Board regulations).

Rulemakings regarding groundwater standards must also comply with the Illinois Environmental Protection Act (the "Act") and Illinois Groundwater Protection Act which respectively require the Board to (a) consider and take into account the "technical feasibility and economic reasonableness of measuring or reducing the particular type of pollution" that is proposed to be regulated and (b) consider "existing methods of detecting and quantifying contaminants with reasonable analytical certainty." 415 ILCS 5/27(a); *Granite City Div. of Nat'l Steel Co. v. IPCB*, 613 N.E.2d 719, 733-34 (Ill. 1993); 415 ILCS 55/8(b)(6).

II. COMMENT

3M encourages the Board to decline to adopt or issue the Proposed PFAS Standards for first notice publication and instead modify and re-notice an updated version of the Proposed PFAS Standards that revises the proposed groundwater quality standards consistently with the substantial testimony provided by Dr. Prueitt and Mr. Risotto. Subparts A-I immediately below explain that, if the Board instead elects to adopt the Proposed PFAS Standards as currently proposed, the

adopted standards will be contrary to the Illinois Environmental Protection Act and Illinois Groundwater Protection Act. More specifically, the Proposed PFAS Standards are improperly predicated on US EPA's screening level hierarchy (Part II.A, *infra*) and various aspects of third-party studies inapposite to technically sound groundwater quality standards (Part II.B-H, *infra*). Finally, IEPA's process for selecting toxicity values resulted in proposed numeric standards that are not technically feasible and cannot be reliably or accurately measured with reasonable analytical certainty (Part II.I, *infra*).

A. *The Proposed PFAS Standards are improperly based on US EPA's Screening Level Hierarchy.*

Despite stating an intent to "[u]phold[] the policy of the Illinois Groundwater Protection Act" by "keeping groundwater quality standards current as scientific data and methods supporting the development of groundwater quality standards have evolved,"[1] IEPA did not follow a scientifically sound method in developing the Proposed PFAS Standards. This resulted in Proposed PFAS Standards that fail to consider an important aspect of the problem and are contrary to the evidence before the Board. *Greer v. Ill. Hous. Dev. Auth.*, 524 N.E.2d 561, 581 (Ill. 1988).

As Dr. Prueitt testified, there are several universally accepted human health risk assessment practices that the scientific community should follow to develop toxicity values for use in deriving regulatory standards, including "reviewing all available evidence to assess the weight of the evidence for a substance to cause health effects, evaluating the exposure levels at which those health effects are observed, and choosing the most sensitive adverse health effect . . . from reliable studies as a point of departure for deriving the toxicity value."[2]

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[1] IEPA, Statement of Reasons at p. 1 (Dec. 7, 2021) ("IEPA Statement of Reasons").

[2] Robyn Prueitt, Gradient, Pre-Filed Testimony of Robyn Prueitt, Ph.D., DABT Regarding the Illinois Environmental Protection Agency's Proposed Amendments to Illinois Administrative

The Proposed PFAS Standards do not follow these well-established and important risk assessment practices. The resulting Proposed PFAS Standards improperly rely upon toxicity values developed by other agencies and without any evaluation of the underlying work of those other agencies. (*See* Hearing Transcript at 48:17-49:1 (Dec. 7, 2022) ("Hearing Tr.")). The Proposed PFAS Standards for each PFAS use a toxicity value selected by IEPA via its rigid application of a toxicity value hierarchy framework that was developed by the U.S. Environmental Protection Agency ("US EPA") to guide its work in developing regional screening levels ("RSLs") for initial investigations of chemicals at contaminated sites (the "Screening Level Hierarchy"). (*See* Response to Pre-filed Questions to the American Chemistry Council's Pre-filed Testimony at p. 8, Answers 1 & 2 (Nov. 23, 2022) ("ACC Pre-filed Responses") ("IEPA's selection of toxicity values appears to be based solely on the [Screening Level Hierarchy]" which "has resulted in [IEPA's] failure to consider more recent data and more recent assessments."); Pre-filed Answers of Robyn Prueitt at p. 9, Answer 1 (Nov. 23, 2022) ("Prueitt Pre-filed Answers") ("The US EPA Screening Level Hierarchy is intended for use in the selection of toxicity values for the derivation of RSLs, which are screening levels for the initial evaluation of a contaminated site and the determination in that context as to which substances detected at the site warrant further investigation. . . RSLs are not intended to be legally enforceable standards, but instead are guidance values used for screening purposes.")).

No materials relied upon by IEPA in its Statement of Reasons suggests that US EPA's Screening Level Hierarchy should, or was intended to, be used by states to establish enforceable groundwater standards. Indeed, the contrary is true. As explained by Dr. Prueitt:

Code Title 35, Part 620: Groundwater Quality Standards at p. 4 (Sept. 15, 2022) ("Prueitt Pre-Filed Testimony").

> The US EPA Screening Level Hierarchy is not intended to be used for choosing a toxicity value upon which to base an enforceable groundwater standard, and it is not appropriate to use it for this purpose without a careful evaluation of the available toxicity values to ensure that standard practices were used in deriving those values and that the values represent appropriate health endpoints.

(*See* Prueitt Pre-Filed Testimony at p. 4). In other words, the Screening Level Hierarchy can be used to develop enforceable groundwater standards only if the underlying science behind each available toxicity value is carefully examined. No materials in the Board's administrative record suggests that the IEPA did such a careful examination. IEPA has acknowledged that it did not independently assess the third-party evaluations it relied upon, and it referred all public commenters with questions about these toxicity values to the specific agencies that derived the toxicity values. (*See* IEPA's Pre-filed Answers to Follow-up Questions (May 6, 2022) at Answer to ACC Question 3 ("Concerns regarding the basis for [Agency for Toxic Substances and Disease Registry's ("ATSDR")] development of its toxicity values are more appropriately directed to ATSDR."); *id.* at Answer to ACC Question 4 ("Concerns regarding the basis for California EPA's development of its toxicity values are more appropriately directed to California EPA."); *id.* at Answer to ACC Question 5 ("Concerns regarding the basis of IARC's carcinogen classification are more appropriately directed to IARC."); *see also* IEPA's Pre-filed Answers to the American Chemistry Council (Mar. 7, 2022) at Answer to ACC Question 7 ("Concerns regarding the basis for ATSDR's development of its toxicity values are more appropriately directed to ATSDR.") and *id.* at Answer to ACC Question 8 ("Concerns regarding the basis for OEHHA's development of its toxicity value are more appropriately directed to OEHHA.")).

Dr. Prueitt's testimony explained that, rather than deflecting questions regarding the ATSDR's development of toxicity values to the ATSDR:

> IEPA should have evaluated this issue to see if it agreed with ATSDR's interpretation of the underlying data, but instead, it chose to ignore the issue

> altogether. In short, IEPA has assumed no responsibility for ensuring that the toxicity values it chooses are based on sound science and appropriate methodologies, and indeed, IEPA has failed to investigate any criticisms of the various toxicity values it chose.

(*See* Prueitt Pre-Filed Testimony at p. 4). Instead of conducting a careful evaluation of available toxicity values, IEPA simply compared the available PFAS toxicity values from third-party evaluations against the Screening Level Hierarchy and chose the toxicity value for each PFAS based solely on whichever evaluation fell highest in the hierarchy. It did so without evaluating the validity or applicability of each value or whether more appropriate toxicity values for each PFAS existed lower in the hierarchy. (*See id.* at p. 5).

In sum, by relying upon toxicity values determined in other contexts in studies of non-Illinois agencies without any inquiry into those studies demonstrating that they are appropriate for use in the Proposed PFAS Standards, IEPA has failed to consider a very important aspect of PFAS standards (i.e., the validity and applicability of each chosen toxicity value for present circumstances).

B. ***The Proposed PFAS Standards failed to consider important available relative source contribution data contrary to the evidence***.

IEPA compounded its error by improperly calculating proposed groundwater standards for five PFAS (PFOS, PFHxS, PFNA, PFBS, and HFPO-DA) according to specific equations based on noncancer effects and on cancer effects (for PFOA). (*See* IEPA Statement of Reasons at Attachment 1G1). The proposed standards based on noncancer effects improperly incorporate a default relative source contribution ("RSC")[3] from drinking water of 20%, despite uncontroverted available data on PFAS exposure that supports a higher and less stringent RSC. (*See* Prueitt Pre-

[3] The RSC represents the percentage of a person's exposure to a particular chemical that comes from drinking water. (Prueitt Pre-Filed Testimony at p. 2).

filed Testimony at p. 5; Pre-filed Testimony of Stephen P. Risotto of the American Chemistry Council at p. 4 (Sept. 15, 2022) ("Risotto Pre-filed Testimony"); Hearing Tr. at 53:24-54:13). Recognizing that data, many other states have departed from the default RSC of 20% and derived a less stringent RSC value in setting groundwater standards for PFAS. (*See* ACC Pre-filed Responses at p. 8, Response 3 (testifying that the default RSC of 20% is no longer applicable to PFOA, PFOS, PFNA, and PFHxS because production of these substances have been phased out and levels in blood have declined)). In turn, other states have relied upon US EPA methodology[4] and publicly available data on background concentrations of PFAS in the blood of the general population in the United States to derive more scientifically supported, higher, and less stringent RSC values. (*See* Prueitt Pre-filed Testimony at p. 5). As Dr. Prueitt testified, states that have assumed higher and less stringent RSC values include Michigan (RSC value of 50% for PFOA, PFOS, PFHxS, and PFNA) and Minnesota (RSC value of 50% for PFOA, PFOS, and PFHxS). (*Id.*) For these reasons, 3M respectfully requests that the Board not adopt or issue IEPA's proposed standard for first notice.

C. *The Proposed PFAS Standards improperly use a toxicity value for PFOA based on cancer effects.*

The toxicity value used by the Proposed PFAS Standards for PFOA is further inappropriate in that it is predicated upon the (i) incorrect conclusion that PFOA meets the definition of a carcinogen based on the International Agency for Research on Cancer's ("IARC") classification of PFOA as "possibly carcinogenic to humans" and (ii) improper reliance on an oral cancer slope factor derived by the California Office of Environmental Health Hazard Assessment

[4] *See* US EPA, EPA-822-B-00-004, "Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)" (Oct. 2000).

("CalOEHHA") for its health-based advisory levels through the use of a linear dose-response model for carcinogenic effects of PFOA.[5]

First, the IARC classification of PFOA as "possibly carcinogenic to humans" is not an adequate basis for the Agency to conclude that PFOA causes cancer in humans. IARC acknowledges that its classification is based on limited evidence of carcinogenicity in humans and experimental animals and that it cannot rule out chance, bias, or confounding in the human studies with reasonable confidence. (*See* Prueitt Pre-filed Answers at p. 10, Answer 3). Indeed, based upon her review of the underlying data and studies, Dr. Prueitt has concluded that neither human nor animal data support the conclusion that PFOA is a human carcinogen. (*Id.*; Prueitt Pre-filed Testimony at p. 8 (collecting and discussing studies)). A groundwater standard for PFOA based on cancer effects is not appropriate.

Second, CalOEHHA's cancer slope factor was derived using a linear dose-response model, which is not appropriate for evaluating PFOA carcinogenicity. As Dr. Prueitt explained:

> Such [linear dose-response] models are used for carcinogens with a mutagenic mode of action or as a conservative default approach when the mode of action has not been ascertained. It is well-documented in the literature that PFOA is not genotoxic or mutagenic. Rather, the scientific literature indicates that the modes of action for tumors observed in rodents after exposures to high concentrations of PFOA are PPARα-mediated and/or involve sustained increases in CCK, and these modes of action involve a threshold (and are not relevant to humans). Use of a linear dose-response model for a threshold carcinogen is not appropriate, as US EPA cancer guidelines indicate that a non-linear approach should be used when data indicate a lack of linearity (*i.e.*, the presence of a threshold) at low doses and the chemical does not have mutagenic activity.

(*Id.* at Answer 4 (internal citations omitted); *see also* Prueitt Pre-filed Testimony at pp. 7-8). IEPA neither addressed nor mentioned these issues in its Statement of Reasons. In addition, in setting

[5] *See* CalOEHHA, "Notification Level Recommendations for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS) in Drinking Water" (Aug. 2019).

the proposed standard for PFOA, IEPA failed to consider that several other agencies, including the U.S. Department of Health and Human Services' National Toxicology Program ("NTP"), have not classified PFOA as a known human carcinogen. For example, the NTP did not include PFOA on its 2021 list of substances that are known or reasonably anticipated to cause cancer in humans. (Prueitt Pre-filed Testimony at p. 8). IEPA failed to independently evaluate the evidence, improperly relied on a designation of PFOA as a possible human carcinogen, and on that basis applied an incorrect cancer slope factor, compounding the Agency's error. Therefore, 3M respectfully requests that the Board not adopt or issue IEPA's proposed standard for PFOA for first notice.

D. ***The Proposed PFAS Standards improperly use a toxicity value for PFOS based on non-adverse effects.***

In its Proposed PFAS Standards, IEPA based its groundwater standard for PFOS on the ATSDR intermediate MRL for PFOS of 0.000002 mg/kg-day. (Prueitt Pre-filed Testimony at p. 9; ATSDR, "Toxicological Profile for Perfluoroalkyls" (May 2021)). This toxicity value is based on a 2005 study that reported delayed eye opening and transient decreased body weight in rat pups that were exposed to 0.4 mg/kg-day. While ATSDR considered 0.4 mg/kg-day to be the lowest observed adverse effect level ("LOAEL") and 0.1 mg/kg-day to be the no observed adverse effect level ("NOAEL") in the study, the 2005 study considered 0.4 mg/kg-day—not 0.1 mg/kg-day—to be the NOAEL. The 2005 study did not consider the delay in eye opening to be an adverse effect and did not consider the transient decrease in body weight to be toxicologically significant. In other words, "IEPA based its groundwater standard for PFOS on a toxicity value that ignores the conclusions of the authors of the underlying study and is based on nonadverse effects." (Prueitt Pre-filed Testimony at p. 9; Prueitt Pre-filed Answers at p. 12, Answer 6). IEPA neither identified nor discussed this issue in the Statement of Reasons.

Reliance on the ATSDR's PFOS MRL also is incorrect because ATSDR "used an unnecessary extra modifying factor of 10 to reduce the MRL 10-fold based on the concern that immunotoxicity may be a more sensitive endpoint than developmental toxicity. This modifying factor is inappropriate and results in an overly conservative MRL, as the occurrence of immunological effects at such low doses of PFOS is not supported by the science." (Prueitt Pre-filed Testimony at p. 9; *see also* Prueitt Pre-filed Answers at p. 14, Answer 8). In addition, ATSDR chose a half-life for PFOS that is not supported by the science and resulted in an overly conservative MRL. (Prueitt Pre-filed Testimony at p. 9). While IEPA purported to justify its choosing of the toxicity value for PFOS because ATSDR relies on more recent toxicity studies than the US EPA's PFOS toxicity value derived in 2016, a newer study "does not necessarily mean it is more scientifically sound or a better choice for an endpoint on which to derive a toxicity value." (Hearing Tr. at 51:22-52:6). Indeed, as Dr. Prueitt has testified, ATSDR's MRL is neither scientifically sound nor a better basis from which to derive a toxicity value. (*See* Prueitt Pre-filed Testimony at pp. 8-9). IEPA did not independently evaluate the ATSDR MRL and the underlying 2005 study and consequently chose an overly conservative toxicity value for PFOS that is based on non-adverse effects. Therefore, 3M respectfully requests that the Board not adopt or issue the IEPA's proposed standard for PFOS for first notice.

E. ***The Proposed PFAS Standards improperly use a toxicity value for PFHxS based on uncertain science.***

The groundwater standard for PFHxS contemplated by the Proposed PFAS Standards improperly relies on the ATSDR intermediate MRL for PFHxS of 0.00002 mg/kg-day for its toxicity value. (ATSDR, "Toxicological Profile for Perfluoroalkyls" (May 2021)). As Dr. Prueitt testified, the ATSDR MRL is based on a single study that reported thyroid follicular cell hyperplasia without measuring thyroid hormones and runs counter to the findings of several other

studies. (Prueitt Pre-filed Testimony at pp. 9-10). Moreover, IEPA did not independently consider the study underlying the ATSDR MRL or the other studies of PFHxS toxicity but rather uncritically chose the ATSDR MRL as the toxicity value. Finally, ATSDR chose an overly conservative half-life for PFHxS that resulted in an unnecessarily low MRL. (*Id.* at p. 10). Again, IEPA did not consider the appropriateness of the half-life that ATSDR chose in deriving the MRL for PFHxS, nor did it identify that the half-life ATSDR used was higher than that found in other studies. Thus, 3M respectfully requests that the Board not adopt or issue IEPA's proposed standard for PFHxS for first notice because IEPA failed to consider the important evidence before it in selecting a toxicity value for PFHxS.

F. The Proposed PFAS Standards improperly use a toxicity value for PFNA based on an effect with limited to no relevance to humans.

IEPA based its groundwater standard for PFNA on the ATSDR intermediate MRL for PFNA of 0.00002 mg/kg-day. (ATSDR, "Toxicological Profile for Perfluoroalkyls" (May 2021)). The study underlying the MRL has limited relevance to humans. That is, the ATSDR based its MRL on a 2015 study that reported decreased body weight and developmental delays in mouse pups exposed to PFNA at 3 mg/kg-day. However, the studies demonstrate that PFNA activates PPARα and induces PPARα-dependent gene expression, which are less relevant to humans than to rodents, if relevant at all. Thus, Dr. Prueitt testified that the uncertainty factor ("UF") of three for interspecies differences that ATSDR included in its derivation of an MRL for PFNA, which decreased the MRL value three-fold, is overly conservative:

> An interspecies UF is generally applied when a toxicity value is based on an animal experiment, as an added protection in case humans are more sensitive than the test animals to the adverse effect. Because PPARα-mediated processes are less active in humans than in mice, it is likely that humans are *less* sensitive than mice to the effects of PFNA, making the interspecies UF unnecessary. Thus, the MRL could be higher and still be protective of human health.

(Prueitt Pre-filed Testimony at p. 10). IEPA neither considered these issues nor independently evaluated whether the ATSDR's MRL was appropriate. Because the Proposed PFAS Standards completely fail to consider this information regarding PNFA, the proposed standard for PFNA should not be adopted or issued for first notice.

G. ***The Proposed PFAS Standards use a toxicity value for PFBS based on an effect of uncertain adversity and relevance to humans.***

The groundwater standard for PFBS posited by the Proposed PFAS Standards is based on the Provisional Peer-Reviewed Toxicity Value ("PPRTV")/reference dose ("RfD") of 0.0003 mg/kg-day for chronic exposure to PFBS.[6] For two independent reasons, that RfD for PFBS should not be relied upon by here. (*See* Prueitt Pre-filed Testimony at pp. 10-11; Prueitt Pre-filed Answers at p. 14). First, the RfD is based on a 2017 study, which observed decreased serum thyroid hormone levels in mouse pups exposed to PFBS at doses above 50 mg/kg-day. However, the study also indicates that the decrease in serum levels after PFBS exposure was not a specific developmental effect, and uncertainty exists as to whether the decrease in levels was a toxicologically relevant, adverse effect in the study.

Second, the RfD is less relevant to humans because rodents are vastly more susceptible to thyroid hormone disturbances than humans due to their smaller reserve capacity of thyroid hormones. (Prueitt Pre-filed Testimony at p. 11 (citing relevant studies)). As Dr. Prueitt explained, "[t]his suggests that the UF of 3 for interspecies differences that US EPA . . . included in its derivation of the RfD for PFBS is unnecessary, and that the RfD could be higher and still protective

[6] *See* US EPA, EPA/600/R-20/345F, "Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3)" (Apr. 2021), https://www.epa.gov/pfas/learn-about-human-healthtoxicity-assessment-pfbs.

of human health." (*Id.*) Therefore, 3M respectfully requests that the Board not adopt or issue IEPA's proposed standard for PFBS for first notice.

H. *The Proposed PFAS Standards use a toxicity value for HFPO-DA based on uncertain science.*

The Proposed PFAS Standard for HFPO-DA uses US EPA's chronic RfD of 0.000003 mg/kg-day as the toxicity value.[7] There is significant uncertainty in the science underlying this RfD, and there is no evidence in the record indicating that IEPA evaluated that uncertainty. In particular, US EPA's RfD for HFPO-DA is based on an unpublished reproductive and developmental study in mice that was submitted to US EPA under a consent order. (Prueitt Pre-filed Testimony at p. 11). The critical effect chosen for derivation of the RfD was a "constellation of liver lesions," not a single liver effect, and these different effects were not consistently observed for each animal evaluated. In addition, some of these observed liver effects are not adverse but rather are adaptive changes (e.g., enlargement of liver cells) or of unclear adversity (e.g., alterations in the cytoplasm of liver cells). (*Id.*) As Dr. Prueitt testified, other scientists evaluated this study and found that even the purportedly adverse liver effects observed in mice by US EPA were actually not considered to be adverse and was likely mediated by PPARα, a pathway of limited relevance in humans. (*Id.*). Moreover, several other mouse and rat studies did not observe the same "constellation of liver lesions" at the same low dose as US EPA observed in its study. (*Id.* at 12 (citing and discussing the other studies)). There is no evidence in the record indicating that IEPA took these uncertainties into account in choosing the US EPA's RfD as its toxicity value

[7] *See* US EPA, 822R-21-010, "Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3), Also Known as 'GenX Chemicals'" (Oct. 2021), https://nepis.epa.gov/Exe/ZyPDF.cgi/P1013DI0.PDF?Dockey=P1013DI0.PDF.

for HFPO-DA. Thus, 3M respectfully requests that the Board not adopt or issue the Proposed PFAS Standard for HFPO-DA for first notice.

I. *The Proposed PFAS Standards are not technically feasible and contrary to the Illinois Groundwater Protection Act.*

The Proposed PFAS Standards also should not be adopted or issued for first notice because IEPA's process for selecting toxicity values resulted in proposed standards set at levels that are not technically feasible and cannot be reliably or accurately measured with reasonable analytical certainty for several reasons. First, IEPA identifies US EPA SW-846 Method 8327 as a validated test method for PFAS in groundwater. (IEPA's Pre-filed Answers to the PFAS Regulatory Coalition's Questions at Answer 11 (Mar. 7, 2022)). Under Method 8327, the lower limits of quantification ("LLOQs")[8] for PFOA, PFOS, PFBS, and PFNA are 10 ng/L, and the LLOQ for PFHxS is 40 ng/L, which means that concentrations of these PFAS below the corresponding LLOQ cannot be reliably measured by this method. (Prueitt Pre-filed Testimony at pp. 5-6). Moreover, U.S. EPA acknowledges that its LLOQ values are based on an acceptance criteria of +/-50%, meaning that U.S. EPA's LLOQ values entail an uncertainty of 50%.[9] Nevertheless, IEPA's Proposed PFAS Standards for PFOA and PFOS (2 and 7.7 ng/L, respectively) are below their

[8] LLOQ is defined by US EPA as "the lowest concentration at which the laboratory has demonstrated target analytes can be reliably measured and reported with a certain degree of confidence." (US EPA, "EPA Method 8327: Per- and Polyfluoroalkyl Substances (PFAS) By Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)" at p. 8327-18 (July 2021), https://www.epa.gov/system/files/documents/2021-07/8327.pdf ("US EPA Method 8327")). That degree of confidence "must be ≥ the lowest point in the calibration curve" and requires recovery of target analytes in the LLOQ verification to be between 50-150% to demonstrate acceptable method performance at the LLOQ. (*Id.* at 8327-19).

[9] US EPA, Docket No. EPA-HQ-OLEM-2018-0846, "Additional Performance Data Associated with Multi-Laboratory Validation of SW-846 Methods 3512 and 8327," at PDF p. 10 (July 15, 2021), https://www.epa.gov/system/files/documents/2021-07/additional-peformance-data-from-validation-study-for-methods-3512-and-8327.pdf ("US EPA Additional Performance Data").

LLOQ of 10 ng/L. In addition, the proposed standard for PFNA (12 ng/L) is nearly identical to its LLOQ of 10 ng/L, below the point at which the LLOQ carries a 95% high confidence interval (20 ng/L). (US EPA Additional Performance Data). The consequence is that the Proposed PFAS Standards for these compounds are not technically feasible and will result in "[u]nreliable measurements of PFAS concentrations in groundwater samples [that] cannot be used with any certainty to evaluate compliance with health-based groundwater standards." (Prueitt Pre-filed Testimony at p. 6). This is why US EPA has specifically advised that "[o]ptimally, LLOQs should be less than the desired decision levels or regulatory action levels" for the intended application and the data quality objectives established for a particular method. (US EPA Method 8327 at p. 8327-19).

Second, the Proposed PFAS Standards are not technically feasible in that they are incorrectly relying on lowest concentration minimum reporting levels ("LCMRLs") for the PFAS compounds rather than minimum reporting levels ("MRLs"). MRLs are the "minimum quantitation level that, with 95 percent confidence, can be achieved by a capable analyst at 75 percent or more of the laboratories using the specific analytical method." (ACC Pre-filed Answers at pp. 13-14, Answer 9.b. (relying upon US EPA definition)). By contrast, LCMRLs are "used primarily during analytical method development" and is defined as "the lowest *spiking* concentration such that the probability of spike recovery in the 50% to 150% range is at least 99%."[10] US EPA has specifically advised that the LCMRLs "enable the development of scientifically defensible MRL values for guidance and regulatory use." (*Id.*) That is, "the MRL

[10] US EPA, Lowest Concentration Minimum Reporting Level (LCMRL) Calculator (last updated Feb. 23, 2023), https://www.epa.gov/dwanalyticalmethods/lowest-concentration-minimum-reporting-level-lcmrl-calculator.

indicates the level above which the substance can be reliably measured," and LCMRLs do not. (ACC Pre-filed Answers at p. 14, Answer 10).

In its proposal, the PFAS analytical methods cited by IEPA are US EPA Methods 533 and 537.1. Methods 533 and 537.1 are validated methods for analyzing PFAS in drinking water from groundwater sources. (Prueitt Pre-filed Answers at p. 5, Answer 18). However, Methods 533 and 537.1 do *not* provide MRLs that can be achieved for each of the six PFAS compounds at issue in this rulemaking. The methods only state LCMRLs. (*Id.*; *see also* ACC Pre-filed Answers at p. 14, Answer 11). Under Method 537.1, the LCMRLs for the six PFAS compounds at issue are between 0.82 and 6.3 ng/L, which are all below the numeric limitations of the Proposed PFAS Standards. (ACC Pre-filed Answers at p. 14, Answer 11). Moreover, Method 533, which US EPA will use to measure PFAS in drinking water for the Fifth Unregulated Contaminant Monitoring Rule, states an LCMRL for PFOA (3.4 ng/L) that is higher than the IEPA proposed PFOA groundwater standard of 2 ng/L. (Prueitt Pre-filed Answers at p. 5, Answer 18).

The Proposed PFAS Standards are so low that PFAS concentrations in groundwater samples cannot be reliably measured with any degree of reasonable analytical certainty to evaluate compliance with the proposed groundwater standards. Nothing in the administrative record suggests otherwise. For the above reasons, the Proposed PFAS Standards are not technically feasible and are contrary to the Illinois Groundwater Protection Act, and 3M respectfully submits they should not be adopted or issued as proposed for first notice.

III. Conclusion

For the reasons stated in this Comment and in testimony by board-certified toxicologist, Dr. Robyn Prueitt of Gradient, and in testimony by Mr. Stephen Risotto of the American Chemistry Council, 3M Company respectfully submits that the Board should not adopt or issue the IEPA's

Proposed PFAS Standards for first notice because those proposed standards are not technically feasible and are contrary to the Illinois Groundwater Protection Act.

Respectfully submitted,

3M Company

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