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Submitted electronically via email: RegComments@pa.gov

April 27, 2022

Mr. Patrick McDonnell, Chair
Environmental Quality Board
Rachel Carson State Office Building, 16th Floor
400 Market Street
Harrisburg, PA 17101-2301

Re: Comments on the Safe Drinking Water PFAS MCL Rule

Dear Ms. Griffin:

The 3M Company ("3M") appreciates the opportunity to comment on the proposed Safe Drinking Water PFAS MCL Rule ("Proposed Rule"), relating to the promulgation of new drinking water maximum contaminant levels (MCLs) for per- and polyfluoroalkyl substances (PFAS) including Perfluorooctanesulfonic acid (PFOS) and Perfluorooctanoic acid (PFOA). 3M is a science-based company with substantial experience, expertise, and stewardship related to PFAS. It is with that background 3M offers comments on the Proposed Rule.

3M supports regulations based on sound science. These comments are offered to inform and improve upon the Proposed Rule. As the Pennsylvania Department of Environmental Protection (DEP) itself has acknowledged, the Proposed Rule is the first time DEP has ever undertaken setting its own maximum contaminant level (MCL). It is important, therefore, that DEP be on firm ground as it takes this unprecedented action. DEP recognizes that in promulgating the Proposed Rule, it must employ similar criteria and undergo an equally stringent process as the EPA is required to undertake when promulgating MCLs under the federal Safe Drinking Water Act (SDWA). There are several issues in DEP's Proposed Rule, however, that clearly do not meet this rigorous standard.

As detailed further below, 3M is concerned that the Proposed Rule is based on problematic studies that do not reflect the weight of scientific evidence regarding PFOS and PFOA. As a result, the proposed MCLs are overly conservative and technically flawed. The Proposed Rule is also based on no more than an assumption regarding the linearity of protection resulting from lowering the MCL as compared to EPA's current drinking water health advisories.

DEP's cost-benefit analysis inflates the number of water users that will allegedly benefit from the proposed MCLs and fails to quantify those purported benefits in any meaningful way. DEP must understand and describe both the purported benefits and costs of setting an MCL at a

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particular level in order to meet the SDWA's standards regarding cost-benefit analysis and feasibility.

I. THE CRITICAL STUDIES UNDERLYING THE PROPOSED RULE ARE DEEPLY FLAWED

The Drexel PFAS Advisory Group (DPAG) drew from existing work published by EPA, other states and the ATDSR. 3M has commented extensively on all of this work, including the critical studies and methods used by DPAG. DPAG excluded numerous relevant studies from its analysis without explanation and 3M is concerned that this exclusion precludes a full understanding of the relevant weight of evidence. Based on DPAG's review of the selected critical studies for each substance and its selection of methods used by other states, DPAG arrived at 8ppt for PFOA and 14 ppt for PFOS.

A. The methods and studies used to support the PFOA MCGL are flawed

DPAG selected Koskela (2016) and Onishchenko (2011) as the critical studies for PFOA.[1] DPAG also used the Goeden model to convert the reference dose to the MCGL, with some adjustments to account for the relative source contribution of an infant.

The "critical studies" – Onishchenko et al. (2011) and Kodkela et al. (2016) - lacked fundamental scientific rigor. The critical effects chosen were neurobehavioral activities and skeletal alteration in offspring in mice. These critical effects were not supported by the available animal data (described in detail below) and therefore do not provide a basis for the resulting PFOA MCLG recommended by DPAG. There are major technical concerns associated with these two published studies with respect to their use in any human risk assessment. They include:

1. A single dose experiment cannot address (any) dose-response relationship.

Albeit published five years apart, these two publications actually originated from one single study. From the same pregnant dams treated with a single dietary PFOA dose during gestation, the pups evaluated by Onishchenko et al. (2011) were litter-mates of the pups evaluated by Koskela et al. (2016). As such, it was really one study and the corresponding outcomes (from both studies) should be consolidated when discussed. In essence, there was only one PFOA dose group used in these two studies and it is impossible to interpret the experimental data reported by these authors in terms of any dose-response. Considering the inherent variations in biological responses in any animal study, the nature of a single-dose study simply does not allow any specific evaluation of any dose-and-effect responses or biological plausibility inference.

[1] Maximum Contaminant Level Goal Drinking Water Recommendations for Per- and Polyfluoroalkyl Substances (PFAS) in the Commonwealth of Pennsylvania, the Drexel PFAS Advisory Group (Jan. 2021), at p. 22.

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2. An uncertainty factor of 10 (LOAEL-to-NOAEL extrapolation) was not scientifically justified.

Given that there was only one PFOA dose group used, the study design did not follow the fundamental practice of toxicology testing such as evaluation of a dose-response relationship. Given the lack of any dose-response, it is scientifically impossible to establish a realistic NOAEL and/or LOAEL for the data reported. Therefore, an uncertainty factor of 10 was not scientifically justified. The Minnesota Department of Health made the same point in its comments to ATSDR.

In addition to the flawed experimental designs, there are major technical concerns associated with these two studies which preclude meaningful scientific interpretation of the results. These include limited sample size, lack of reproduction and developmental outcome information, pup litter selection bias, questionable dietary preparation, inadequate timing for behavior assessments, non-standard behavior assessment procedures, and absence of background data for bone morphology and bone density (see Attachment B, 3M's comments to ATSDR, for further details). Overall, the studies by Onishchenko et al. (2011) and Koskela et al. (2016) lack the scientific rigor to properly address the selected developmental endpoints and they should not be used for any human risk assessment.

3. The Goeden Model should not be relied on.

The Minnesota Department of Health (MDH) model (Goeden et al. 2019) relied on by DPAG has also never been validated with external data. It is unclear how well the model actually describes real-life situations. In addition, the model ignores correlations among inputs (e.g., between body weight and intake rate).

Assuming exclusive breastfeeding duration through 1 year, as done by the MDH model (Goeden et al. 2019), does not represent a "reasonable maximum exposure", especially since this goes against the recommendation by American Academy of Pediatrics that solid foods should begin to be introduced to the infant at 6 months. In addition, a 90^{th} percentile of water intake ingestion is more appropriate for chronic intake of water by adults than using the 95^{th} percentile ingestion rate from the US EPA handbook, as was done in MDH model.

B. The methods and studies used to support the PFOS MCGL are flawed

DPAG selected the study by Dong I (2011) over other immunotoxicity studies because it idenfied the highest NOEL for immunotoxicity and the longest exposure duration. 3M discusses the weaknesses in this approach below.

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1. There is a technical omission by Dong et al. (2011) as it relates to incomplete data presented in the manuscript.

In reviewing the data from Dong et al. (2011), 3M made a request to Dr. Dong (the corresponding author for the study) for the actual numerical source data for IL-4 in order to conduct benchmark dose modeling. The IL-4 data (which was the critical endpoints chosen by MDH for its PFOS derivation) were only provided as a bar graph as Figure 1b in the paper by Dong et al.(2011) and it is excerpted below for the purpose of illustration.

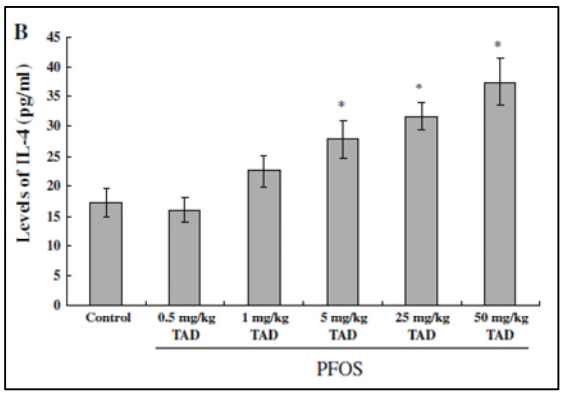

Figure 1B from Dong et al. 2011

(Arch Toxicol 85 1235-1244)

Dr. Dong graciously provided 3M with the IL-4 numerical data (as mean ± SEM), which are shown below. However, upon receiving the data for the six dose groups that were published in the paper (control, 0.5, 1, 5, 25, and 50 mg/kg TAD), there was an extra dose group (125 mg/kg TAD) that Dr. Dong provided to 3M but was not part of the published paper. When asked about the inconsistency of the dataset, Dr. Dong disclosed to 3M that one of the journal reviewers requested not to include the highest dose group data in the publication, which Dr. Dong agreed not to do. This extra dose group (125 mg/kg TAD) is provided in the table below.

Numerical Data for Serum PFOS and IL-4 Values

Total Administered Dose (TAD), mg/kg	Serum [PFOS], ug/mL		Serum [IL-4], pg/mL*	
	Mean	SEM	Mean	SEM
0 (Control)	0.05	0.01	17.25	2.32
0.5	1.07	0.11	16.04	2.07
1	2.36	0.47	22.53	2.58
5	10.75	0.82	27.89	3.11
25	22.64	2.29	31.67	2.25
50	51.71	3.81	37.42	3.94
125*	98.43*	6.70*	43.98	4.13

** Numerical data provided to 3M by Dr. G. Dong, personal communication (June 2019)*

DPAG's analysis therefore derived a serum dose using incomplete data, undermining its conclusion. 3M recommends including the missing data and recalculating the serum dose accordingly.

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2. Evidence of immune suppression was not supported by Dong et al. (2011) data.

From a fundamental immunology perspective, there were several important technical aspects that Dong et al. (2011) did not address, and that study also lacked overall scientific validity to support the conclusion that PFOS causes immune suppression. Specifically:

- In a standard immunology study, it is imperative to assess the total number of immune cell populations among primary immune organs. Dong et al. did not measure any immune cell numbers nor did they look at / report blood lymphocyte counts, which is part of the standard CBC panel parameters. Furthermore, Dong et al. did not provide any histological evidence for thymus, spleen, or bone marrow. These are important technical omissions if immunosuppression is assumed by the authors.
- The standard clinical marker for antibody titers to vaccination is secondary IgG antibody isotype, not primary IgM. Dong et al. reported the PFOS dose-dependent reductions in serum IgM with statistical significance at higher dose groups; however, there were no statistically significantly decreases in serum IgG or IgE. In addition, the use of the SRBC-induced antibody response to measure antigen-induced antibody response is very crude and non-specific to T cell activation. Furthermore, the memory response was not properly evaluated in this study; they only challenged the animals with SRBC (antigen) once, which was insufficient to determine a memory response.
- While Dong et al. reported alterations in cytokine releases upon PFOS treatment, however, the data were solely based on splenocyte and they did not evaluate other key immune organs (such as thymus and serum) to illustrate that the responses are consistent in other primary immune organs. By way of similar scientific rationale, Dong et al. should have looked at immunoglobulin profiles in thymus and spleen as well.

For a known immunosuppressing agent, one would expect several hallmark events to occur across major key organs. Responses such as decreased IgM and IgG in spleen, thymus, and serum; and decreased cytokine levels and altered histology in these organs are often indicative of the suppressive immune responses. As discussed above, the study by Dong et al. did not provide any robust or compelling scientific evidence to support the claim that PFOS is associated with immune suppression in mice.

II. THE OCCURRENCE DATA DO NOT SUPPORT DEP'S CONCLUSIONS

DEP's reliance on targeted sampling intended to identify sources of water mostly likely to contain PFAS is unscientific and biased. In developing the Proposed Rule, DEP collected sampling data from 372 "targeted" sites and 40 "baseline" sites. The targeted sites were selected based on their proximity to potential sources of PFAS contamination. In other words, approximately 90 percent of the data DEP used was cherry-picked because of the increased likelihood that PFAS would be detected in the samples. This skewed data set nonetheless does

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not support DEP's Proposed Rule. The occurrence data detected PFOA and PFOS in less than 30% of all samples, with even fewer detections above the proposed MCLs. For PFOA, only 5.7% of the samples were over the proposed MCL. Only 5.1% of the samples were over the proposed MCL for PFOS.

DEP's study does not provide an unbiased look at statewide occurrence data. The data are not representative of statewide occurrence of the sampled PFAS, because the sampling locations were biased in favor of detecting PFAS in the samples. Even so, the data shows infrequent, and low detections of the sampled PFOA and PFOS.[2]

III. THE ECONOMIC IMPACT ANALYSIS INFLATES HEALTH BENEFITS AND IMPOSES UNNECESSARY COSTS

A. Low occurrence data shows the MCLs will not benefit all public water users

In spite of the low occurrence of PFAS in select water supplies, DEP states that the Proposed Rule will "benefit" 11.9 million Pennsylvanians because it will be applicable to all 3,117 public water supply systems in the state. This ignores the data discussed above, however. PFOA and PFOS were detected in less than 30% of the sites sampled in the skewed sample set, and less than 6% of samples were over the proposed MCLs. DEP's conclusion that every public water user will benefit from statewide MCLs vastly overstates the purported benefits of the Proposed Rule. In fact, the majority of water users experience no benefit at all.

Even assuming the standards do provide health benefits, the lack of these purported benefits to a large percentage of public water users means that DEP is imposing unnecessary costs of compliance on public water users. Of the 3,117 public water systems, "at least 2,898 would be required to monitor … for four consecutive quarters."[3]

B. DEP's "90% improvement in health protection" goal is modeled on irrelevant standards

DEP states that its goal "was to provide at least a 90% reduction in adverse health effects (a 90% improvement in health protection) when compared to the HAL of 70 ng/L." The Proposed Rule goes on to note that the "90%" goal is consistent with various "existing drinking water standards" that are entirely irrelevant. DEP's examples relate to various treatment

[2] DEP uses the low occurrence data to say that it may be overestimating costs because they are based on the MCL exceedance rate, which "may overestimate the exceedance rate for the other PWSs in Pennslyvania that were not sampled, because the occurrence data sampling predominantly targeted sites near potential sources of PFAS contamination[.]" Executive Summary, Safe Drinking Water PFAS Rule, available at: https://files.dep.state.pa.us/PublicParticipation/Public%20Participation%20Center/PubPartCenterPortalFiles/Environmental%20Quality%20Board/2021/November%2016/03_7-569_PFAS%20MCL_Proposed%20RM/01_7-569_PFAS%20MCL_Proposed_Exec%20Summary.pdf

[3] Analysis Form at p.9.

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techniques or a percentage of water samples that must meet standards. An MCL is very different. It applies to all regulated drinking water, and the standard must be met 100 percent of the time. Establishing a goal to improve "health protection" by a certain percentage bears no relationship to inactivating a certain percent of *Giardia* or meeting turbidity standards a certain percentage of the time. DEP provides no other basis for its selection of 90% as its target level.

C. DEP's economic benefits are erroneously calculated and not based on sound science

DEP asserts that Pennsylvanians will experience significant economic benefit as a result of reducing health problems associated with PFOS and PFOA. To make this assertion, DEP calculated a 90% "improvement in health protection for PFOA," and a 93% improvement for PFOS.[4] The percentages are based on a formula that assumes a "linear improvement in health protection between the EPA HAL and the DPAG MCLG."[5] DEP provides no citation for this formula or any basis for such an assumption. 3M has not identified any information in the Proposed Rule or supporting materials that supports DEP's conclusions regarding linear improvement in health protection. This information is critical because DEP's conclusion that a 90 percent improvement in public health can be achieved for a 253 percent increase in costs is based on the assumption of linearity, as demonstrated in Figure 1 of the Proposed Rule. The same linearity assumption underlies DEP's PFOS cost-benefit analysis as well. If there is a sound scientific basis for an assumption of linear impacts from increasing or decreasing an MCL, DEP should disclose that information to the public.

In evaluating the purported benefits of the rule, DEP overestimates the number of Pennsylvanians who would be impacted by the MCL, as explained above, assumes a linear improvement in public health as a result of decreasing an MCL without explanation or citation, and offers no sound basis for its arbitrary "90% improvement" target. To explain "how the benefits of the regulation outweigh the costs," DEP simply states "[i]mproved health benefits expected to result from implementation of the proposed rule include a reduction in instances of developmental effects … and decreased immune response associated with exposure to PFOA and PFOS[.]" But DEP has not quantified or estimated these purported health benefits.

DEP should clearly define the purported benefits of its rule, based on relevant and scientifically sound information and standards. Without doing so, it cannot claim to have engaged in a meaningful cost-benefit analysis.

3M appreciates the opportunity to provide comments on the Proposed Rule and respectfully encourages DEP to revisit the issues identified above.

[4] Analysis Form at p. 10.
[5] Analysis Form at p. 33.