September 5, 2024

N.C. Environmental Management Commission Chair John Solomon
Water Quality Committee Chair and NPDES Chair Steve Keen
1617 Mail Service Center
512 North Salisbury St.
Raleigh, NC 27699

RE: Regulatory Impact Analysis on NC DEQ's Draft Proposed 02B Surface Water Standards and Draft Proposed 02L Groundwater Standards

Dear Chair Solomon and members of the Water Quality Committee,

On behalf of the national and statewide business and regulated communities, we urge the North Carolina Environmental Management Commission's Water Quality Committee to develop an accurate Regulatory Impact Analysis (RIA) of the N.C. Department of Environmental Quality's (NCDEQ) Draft Proposed 02B Surface Water Standards and Draft Proposed 02L Groundwater Standards prior to releasing the current RIA for public comment.

The public should have the opportunity to weigh in on the benefits and costs associated with these regulations and the current fiscal note does not provide a true analysis of the impact on the public and/or the regulated community.

The business and regulated communities continue to support accelerating cleanup of PFAS in the environment based on the best science and risk management. However, our communities have been maligned on this issue by the regulators, with suggestions that our request for a more science-based approach to this process will cause illness and even death. These suggestions are inappropriately inflammatory. We have concerns regarding the current RIA, the associated underlying science, and the workability of levels proposed. More information is needed on the impacts of this proposal, including potential economic and health challenges.

This is a broad family of chemistries with essential uses in North Carolina's economy, and not all PFAS are the same. On behalf of the business community, we urge the N.C. Environmental Management Commission to extend the public comment period until a revised corrected and factual fiscal note is complete, providing an accurate estimate of the cost to local government and the business community to comply with these proposed regulations.

Sincerely,

American Chemistry Council
Carolinas AGC
Carolinas Asphalt Pavement Association
City Attorney, City of Greensboro
National Waste and Recycling Association North Carolina Chapter
NC Chamber
North Carolina Home Builders Association
U.S. Chamber of Commerce

Enclosure: Commentary By Michael L. Dourson, PhD and Richard A. Williams, Ph.D.

Cc:

Christopher Duggan	Michael Ellison	Kevin Tweedy
Yvonne Bailey	Dr. H. Kim Lyerly	Elizabeth Weese
Timothy Baumgartner	Jacqueline MacDonald Gibson	Bill Yarborough
Charles Carter	Joe Reardon	Senator Phil Berger
Marion Deerhake	Robin Smith	Speaker Tim Moore

Fiscal Note for Adoption Amendment of 15A NCAC 02B .0200 and 15A NCAC 02B .0400

Commentary By:

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General Comments

This report relies on risk assessment values determined by the United States Environmental Protection Agency (US EPA, 2024, Table 1, page F-1) that are much lower than other international values determined by experts in different governments. If these differences were of the order of threefold or less the use of the EPA values would not be inappropriate, since the imprecision of these risk assessment determinations is often in the range of threefold. However, EPA's risk values are dramatically lower---hundreds or perhaps even thousands of folds lower---than other government agencies, which also include erudite risk assessment scientists. An attached figure shows the disparity. These differences should be considered by any risk manager in a decision to promulgate a standard, since they point to large uncertainties in the underlying science, and as a result large uncertainties in the resulting cost/benefit assessment.

North Carolina needs to develop standards based in part on ambient water quality criteria. Using an EPA criterion as one basis of any standard is a typical approach, but in the case of PFAS the development of underlying criteria with EPA's risk assessment values introduces an extraordinary level of uncertainty that is not easily mollified. At the very least North Carolina managers need to highlight this uncertainty and not sweep it under the rug, so to speak. Of course, EPA should work on the source of this uncertainty, perhaps by meeting with its international colleagues to harmonize everyone's risk assessment judgments.

Why is addressing this uncertainty important? Quite simply, the resulting cost benefit assessments will also be equally uncertain. For example, the cost/benefit analysis for hypertension is based on the Nordic Council of Ministers (2019) and increasing blood lipids is based on an EPA analysis. Both effects are based on human observational studies that show associations. Associations cannot be used to establish *causation*, much like an association between the increasing sale of chocolate ice cream and an increasing level of outdoor crime cannot be used to state that eating chocolate ice cream *causes* outdoor crime, or that an increase in outdoor crime causes folks to eat more chocolate ice cream. In fact, we could show this *chocolate ice cream-outdoor crime* association in every city in the US because we know that both outdoor crime and the sale of chocolate ice cream are due in part to an increase in outdoor temperature.

Human studies that show associations are useful because they can be used to form a hypothesis which can then be tested. In the case of PFOA, increases in blood lipids has been tested in a

human clinical study at much higher doses than the human observational studies---up to 1,200,000,000 ng/week over 6 weeks, which is over 21,000,000 times higher than daily dose of 8 ng based on EPA's MCL of 4 ng/L (ppt). This human clinical study showed that PFOA *decreases* blood lipids---just the opposite of what the human observational associations suggest (Convertino et al., 2018).

Thus, it is unlikely that PFOA causes an *increase* in blood lipids, and any benefit claimed for a reduction in blood lipids as a result of decreasing PFAS concentrations is likely wrong. Based on the human clinical study the most likely benefit from this reduction is zero. Unfortunately, we do not have a clinical study testing whether hypertension is caused by PFAS exposure, but the uncertainty demonstrated for increase/decrease in blood lipids is a cause for concern for any claimed benefits due to the reduction of PFAS concentration for this endpoint as well. The claimed benefit in this case may also be zero.

North Carolina may also want to investigate the scientific conclusions of other international authorities. This may allow North Carolina to place its rulemaking on firmer scientific ground and will result in decisions by North Carolina businesses and citizens that are still appropriately health protective but not business destructive. After all, the purpose of risk assessment is to:

- Protect sensitive subgroups in our population; if they are protected, everyone else will be protected.
- Not be overly protective; a zero dose is also safe, but many chemicals are useful. It is important to pick the highest safe dose with a reasonable margin of safety. Afterwards, a reasonable RIA can be developed.
- Consider the findings of similar expert bodies. Differences of three-fold are often found among expert groups and generally of no concern. Differences of 3 to 30-fold are cause for reconsideration and larger differences are cause for concern.

Nor is it appropriate nor consistent with good risk management to base rulemaking on uncertain science, to quote:

> "The skepticism that I advocate amounts only to this: (1) that when the experts are agreed, the opposite opinion cannot be held to be certain; (2) that when they [*experts*] are not agreed [*as in the case of PFAS*], no opinion can be regarded as certain by a non-expert; and (3) that when they [*experts*] all hold that no sufficient grounds for a positive opinion exist, the ordinary man would do well to suspend his judgment."
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> *– Bertrand Russell, Skeptical Essays*

Thus, since experts from various government agencies are not in agreement, then one way to see the current PFAS rulemaking is that "no opinion can be regarded as certain by a non-expert."

What follows are specific health and economic comments on where North Carolina can improve its rulemaking. Specifically, these comments will enable North Carolina to develop an accurate RIA (Fiscal Note) *prior to* the rule going out for public comment. Our view is that for the public to accurately consider the benefits and costs associated with this proposed surface water

regulation during the public comment period that an accurate RIA (Fiscal Note) must be presented to them rather than the current draft that is seriously flawed.

Specific Health Related Comments

1. Appendix A, page 6. Notwithstanding that few authorities believe that PFAS chemicals are carcinogenic, the fact remains that all authorities believe that they are not mutagenic and, if carcinogenic, have the type of chemical structure, akin to a fatty acid, that indicates a threshold mode of action. Thus, EPA's linear approach to various PFAS chemistries based only on its inability to determine a Mode of Action (MOA), *is not scientifically plausible* since mutation is ruled out and threshold is indicated. This latter determination is supported by EPA (2005) cancer guidelines, page 3-21, where it states:

   > When the weight of evidence evaluation of all available data are insufficient to establish the mode of action for a tumor site *and when scientifically plausible based on the available data* [emphasis added], linear extrapolation is used as a default approach, because linear extrapolation generally is considered to be a health-protective approach.

   Although a mode of action is not determinable, according to EPA, a linear extrapolation *is not scientifically plausible* based on the available data. Thus, a linear extrapolation is not appropriate, and North Carolina dependence on EPA's linear approach for its cost/benefit assessment leads to highly inflated, and inappropriate values. It is difficult to know how much EPA overestimated the health benefits associated with a reduction in cancer from a reduction in PFAS concentration, but it might be that no health benefits are gained since a threshold in the presumed cancer response is very likely. Note that other authorities do not agree that PFAS causes cancer.

2. Appendix A, page 13. "Acronyms." The use of the older term, q1*, from the linearized multistage procedure of EPA (1980, 1986) is not correct. EPA's (2005) CSF is a straight line from the point of departure determined by one of several possible models from EPA's benchmark dose software (EPA, 2012).

3. Appendix A, page 14. "Exposure Factors used in…". If EPA's MCLs are based in part on 80 kg adults and 2.4 liters of water per day as 90^{th} percentiles of the population, then do not all estimates of health risk and benefit need to be adjusted to the average population? If this adjustment has not already been done, then North Carolina should focus on using average values for body weight and water consumption. This would lower the estimates of benefits, perhaps by at least as two-fold, since the amount of PFAS consumed would be lower.

4. Appendix A, page 14, "…Ambient Water Quality Criteria for the Protection of Human Health EPA published its national 304(a) water quality standard at a 10^{-6} risk level, which EPA considers appropriate for the general population (EPA, 2000)." While this is an accurate quote from EPA, it is also true that EPA (2000) guidance allows risk levels of

10^{4} to 10^{-6}. Clearly stating this fact to the public as a part of this RIA is an important point of transparency.

5. Appendix A, page 15 the sentence: "The defined standard for PFOS and PFOA are lower than both the analytical method LOQ set by the EPA (89 FR 32532, 2024; EPA, 2024d)." If certain water sources cannot be measured for PFOS and PFOA, how then can estimates of risks and benefits be determined with any certainty?

6. Appendix A, page 15, the sentence: "However, the limitation in laboratory capability to accurately report the health-based defined criteria value is used to regulate PFOS and PFOA at 4.0 ng/L during NPDES permit issuance and compliance." So, if the laboratory capability is limited to 4 ppt, does this mean that North Carolina will regulate all water systems to this level? What if the laboratory capability is 10 ppt? The usual approach is to estimate unmeasurable concentrations to ½ the laboratory limit. What is North Carolina suggesting? This area of the RIA needs clarification.

7. Appendix A, Table 3, page 16. The international community does not agree with these values and does not agree with them in a very big way, with safe doses thousands-of-fold higher. An international workshop held in Washington DC just last October readily demonstrates this for PFOA[1] as does the attached figure.

   However, one does not have to rely on the international community to see the show-stopping problems with these values. The difference between water supply values for PFOA at the unmeasurable level of 0.06 ppt and PFHxA at 3,000 ppt is 50,000-fold. The non-water supply difference is over 3,000,000! Although similar chemicals can have very different toxicities, these chemistries are only different by 2 carbon atoms, leading to the expectation of only a small difference, not thousands-of-fold. One of these values is likely to be very wrong.

8. Appendix A, Table 4, page 17. The safe doses based on human observational studies in this table have been nearly uniformly rejected by the international community, because these studies generally only report associations, have unstated confounders, and rely on biomonitoring effects of generally no clinical relevance. Often these positive associations are in contrast to negative or null findings. For example, hypertension is not supported by a large epidemiology study in the US (Winquist and Steeland, 2014). The safe doses for some of these other chemistries based on experimental animal data also need to be more carefully checked since they too are at odds with other expert groups. Relying on information from this table to establish a cost/benefit assessment, without first understanding why international groups vary so very much in their assessments, will result in a large degree of uncertainty, because of the possible enormous over-estimate of benefits. This uncertainty in the cost/benefit assessment may result in a constant reassessment by decision makers and possibly protracted litigation.

[1] See https://www.tera.org/Alliance%20for%20Risk/ARA_Dose-Response.htm, and specifically: Workshop XIV in Washington D.C., October 17-19 2023.

9. Appendix F, Table 2, page F-1. This table needs to specify that the stated values are per 100,000 people.

10. Appendix F, Table 3, page F-2. Please specify what PFAS levels are being used in these calculations. Are these average level across the state? If not, are they average EPA values across the USA? If so, why not make this specific to North Carolina?

11. Appendix F, Table 4, page F-2. What is the source of data for this table? EPA 2024, ES page 1-5? If so, please cite. If not, please specify the data source.

Specific Economic Comments

12. Please give a succinct statement of the problem. This is a necessary, indeed obvious, first step to any RIA and it is missing. Although not in the text, the problem appears to be the reduction in the number of illnesses associated with certain PFAS materials in the state of North Carolina. All costs and benefits will be derived from solving some portion of that problem. Because the RIA fails to state the problem that is intended to be solved, it leads to discussion and estimation of benefits that do not exist (detailed below).

13. Benefits are overstated as some categories of benefits do not exist. In Table 20, the Summary of Costs, Benefits and Cost Offsets, three categories should be eliminated, specifically, "Downstream Drinking Water Utility Savings ($436.84 million), Private Well Avoided Treatment ($382.50 million) and Retaining Property Value ($1,527 billion).

    Why? The first two categories are regulatory options, things that are not expected to occur if the current proposal is enacted. Therefore, there are neither costs nor benefits associated with them. Benefits and costs arise because of an action taken in response to the decision option chosen. Another way of saying this is that there must be a change from the baseline of no regulation for there to be benefits and costs. For example, if the decision is that primary producers of PFAS must install equipment to reduce the levels of PFAS into the environment, then their actions will entail both costs and benefits. What others will not do, or have to do, has no costs or benefits. Because there are no requirements for downstream producers, there are no benefits or costs because they do not have to do anything.

    The third category is double counting. The decreased value of land is averted by the proposal and retaining the property value will occur because of the decrease in risks, already accounted for in human health improvements. However, this calculation could serve other purposes. If this is the value people are willing to pay for the reduced risk, it is a lower bound estimate of the health risks.

    Thus, the total claimed benefits that should be eliminated is $2.346 billion. In addition, the willingness-to-pay to prevent loss of land value because of potential illnesses should be viewed as a lower bound on the health benefits.

14. The analysis notes on page 8 that over 40% of surface-water based public water systems exceed the MCLs. It also notes on page 45 that "PFAS exposure via food ingestion containing these compounds compared to drinking water was only three times higher from food" and that they calculated the percentage of exposure from ingestion of food containing PFAS as 21-23%. The totality of the RIA leads to a conclusion that food from North Carolina is dangerous and should be avoided, particularly by those who have other options in other states or countries.

    North Carolina currently exports $780 million of pork, $584 million of broiler meat, $533 million of tobacco, $497 million of other plant products and $489 million of soybeans. As North Carolina "continues to lead the way on addressing PFAS," it seems logical that importers might look at these North Carolina products as tainted and seek other sources. This would set up a strong incentive for these farmers and ranchers to quickly address incoming water to offset that perception. Given that some incentives currently exist for privately affected facilities to take action, the zero cost/no action baseline reported on page 32 should be adjusted to account for private actions based on private benefits and costs. Note that p. 37 suggests other reasons for compliance with the rules although no evidence is offered of their likelihood.

    The RIA should analyze the option for current producers who have affected products to take action independently of the proposed action. These actions should affect both the benefits and costs of the proposed action.

15. The average concentrations of PFAS detections in Table 7 (page 29) average between 8.3 and 48 nanograms per liter (ng/L) or an average of 24 ng/L. Given that Australia's PFOA limit is 560 ng/L and Canada is 200 ng/L (as on the attached Figure), the average concentration in these facilities might reasonably be concluded to be within an international uncertainty bound for safety. Nevertheless, they identify 612 facilities in need of treatment in Table 8 (p. 30). If these international values are considered reliable, and they certainly are in their respective countries, then no health risk exists for these average concentration of PFAS. And as a result, no health benefits accrue from reduction of PFAS concentrations in these areas, only costs associated with the reduction.

    This suggests that RIA should consider, and North Carolina should consider, adjusting the allowable limits to be more in line with the international community.

16. Page 31. The analysis notes that "PFAS can be used directly in the manufacturing process. Although this rule does not ban PFAS, there seems to be no mention of substitutes, i.e., replacing the compound, for PFAS and their relative risk profile. This is called risk/risk analysis and should be performed prior to any decision. It should be noted that, where there are risk/risk trade-offs, it makes the policy of protecting the most sensitive individuals difficult to justify as risks are often raised to others.

17. North Carolina repeats the maximum contaminant level of zero from the EPA's analysis. This hypothesis follows from the 100-year-old theory that some chemical substances can be dangerous down to one molecule, simply because they have been found to be

dangerous at much higher levels of exposure. It ignores the possibility that there is a level, i.e., a threshold, below which there is no harm despite many thousands of papers showing that thresholds exist for most chemicals and all radiation, and the fact that the Mode of Action (MOA) appears to have a threshold for these PFAS, even for the hypothesized cancer endpoint.

The fact that DEQ estimates that 3.5 million residents have drinking water supplied by public water systems and 25% of the wells exceed one or more MCLs, is cloaked by uncertainty with respect to actual risk. After all, EPA guidelines state that risks given by its no-threshold linear extrapolation are unlikely to be exceeded---meaning that these risks are likely to be less. In fact, EPA states that these risks might actually be zero (EPA, 1986, page 13). Exceeding a level set in nanograms on the basis of a possible theoretical risk, is different than exceeding a level based on an actual risk.

To understand a level of exposure in terms of a few nanograms, a single grain of sugar weighs between 0.05 and 0.2 milligrams or 50,000 to 200,000 nanograms. A level of five or ten nanograms requires an electron microscope to be able to see. The standard discussed on page 48 of surface water being within 1.0 ng/L of the MCL for PFOA or PFOS (4.0-5.0 ng/L) being in an acceptable range seems tight, given the uncertainty of the original MCL. The acceptable range of exposure should allow for at least 70 to perhaps as high as 490 ng/L, based on an unfunded, and most recent, international collaboration regarding the safe dose range for perfluorooctanoate (PFOA), particularly given the large uncertainty associated with EPA's 4 ng/L MCL.[2]

18. Pages 46 and 47, the analysis should explain why "lost economic productivity, and willingness to pay to value lost opportunity costs due to non-fatal illnesses are different.

19. In the analysis on page 56 concerning shifting burden to "polluters pay," it should be noted that, for private firms, many of the costs will be shifted to taxpayers, utility ratepayers, consumers of the affected products and workers. Who ends up actually paying for these activities is complicated as costs to firms are often passed on to buyers (including firms and consumers) or workers. This is a distribution issue; it is not a matter of benefits and costs. Distributional issues are often included in Regulatory Impact Analysis (RIAs), but they are a separate consideration from benefits and costs.

20. In the cost and benefit summary on page 57, quantified benefits should be reduced from $9.96 billion to $7.62 via comment #13 above. As noted in the analysis, there are qualitative benefits and uncertainties in both costs and benefits.

21. There are multiple regulatory options and there appears to be some confusion about what those are. For example,

[2] See: Burgoon et al., 2023. This paper was awarded "Regulatory and safety paper of the year," by the Society of Toxicology's Regulatory and Safety Evaluation Specialty Section. The safe dose range in this paper was 10 to 70 ng/kg body weight per day, which when multiplied by 70 kg body weight, divided by 2 liters of water per day, and multiplied by a relative source contribution of 20% equals 70 to 490 ng/L.

a) One option could be for the state to do nothing, at least at present until there is better data. There is considerable uncertainty about the various health hazards associated with PFAS materials at the current exposure limits. As a result, there is considerable uncertainty in this cost/benefit assessment. In this case, some primary and some secondary sources of contamination, such as food manufacturers and some well owners, might choose to install equipment based on their perceived sales or individual perceived risks. If for example, the government did nothing, it is not true that all owners of wells would install filters, some may reject the government's assessment of risk.
b) A second option would be to mandate that downstream manufacturers and consumers install equipment to remove PFAS. Sellers of products that could be negatively impacted by PFAS contaminated materials and consumers relying on personal wells, could be responsible for using water from uncontaminated sources or applying their own filters to water.
c) A third option concerns the time allowed for state solutions. More or less time should be analyzed allowing for development of better information about technologies, health effects based on current exposures to PFAS chemicals, the distribution of PFAS in the population and better technologies for control of PFAS and other contaminants. More time might also allow for a better understanding of the results of the current proposal to refine the options.
d) The current analysis also provides three more options for different levels associated with permitting.

Closing Thought

The current RIA is seriously flawed, in part because it relies on health information that is at great odds with health authorities in our US trading partners. The use of these international safety data would reduce the estimated benefits with this rulemaking considerably, perhaps even reducing such benefits to zero. This RIA also lacks important details for an accurate contemplation of costs by the public by inappropriately including items that are not normal parts of any RIA, i.e, distributional issues, and including items that should not be included. To summarize, the North Carolina staff would do well to consider the safety evaluations of our international trading partners and redo its RIA based on additional consideration of actual benefits, if any, and more realistic costs.

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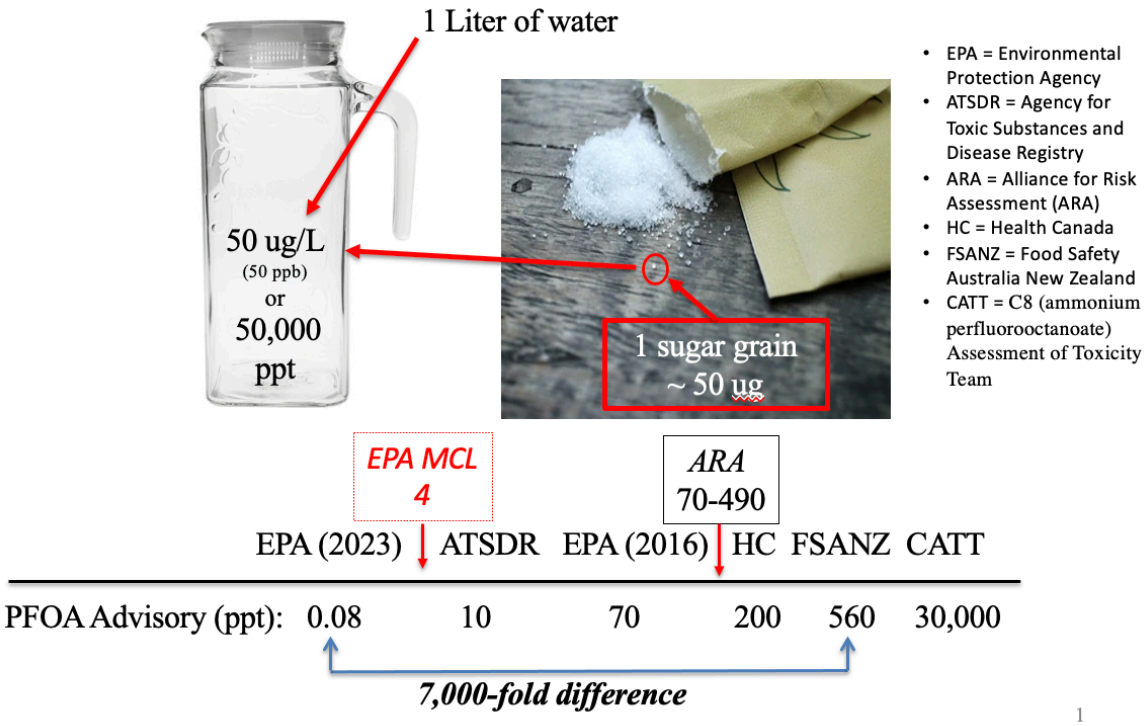
EPA vs. Other PFOA Health Advisories



- EPA = Environmental Protection Agency
- ATSDR = Agency for Toxic Substances and Disease Registry
- ARA = Alliance for Risk Assessment (ARA)
- HC = Health Canada
- FSANZ = Food Safety Australia New Zealand
- CATT = C8 (ammonium perfluorooctanoate) Assessment of Toxicity Team

1