



I. Introduction

The Wisconsin Paper Council appreciates the opportunity to testify on Assembly Bill 85, which directs the Department of Health Services (DHS) to establish a groundwater quality standard for perfluorooctanoic acid and perfluorooctane sulfonate (PFOS and PFOA). As you may know the papermaking industry is a key economic driver for Wisconsin - employing over 35,000 highly skilled men and women whose efforts continue to make us the number one papermaking state in the United States. The Wisconsin Paper Council is the premier trade association which advocates for our entire industry – an industry which is focused on sustainability and strong environmental stewardship. Our industry prides itself on its continual scientific advancement to produce products that are renewable, recyclable, and sustainable.

The Wisconsin Paper Council generally supports exploring science-based groundwater quality standards for PFOS and PFOA. However, the following suggestions would ensure reasonable and predictable regulation in an area of science that is still very much in the development phase.

II. The legislation should be in Chapter 160 (“Groundwater Protection Standards”) rather than Chapter 254 (“Environmental Health”).

As drafted, this legislation adds a section entitled “Groundwater contaminants” to Chapter 254, Subchapter II. It may seem like a Chapter titled “Environmental Health” is the perfect place to add a groundwater standard. After all, no one would argue that groundwater regulation is not environmental regulation.

However, the term “environmental” in this chapter means something very different than it does to DNR. There are two widely accepted definitions of “environment”: 1) the surroundings or conditions in which a person...lives or operates, and 2) the natural world, as a whole or in a particular geographical area, especially as affected by human activity. (See Oxforddictionaries.com). DNR is responsible for environmental regulations of the natural world, while Chapter 254 speaks to a person’s more immediate surroundings. The two categories of “environmental regulation” are very different.

In Chapter 254, Subchapter II, DHS is charged with regulating toxic substances. The section speaks mainly to indoor health threats. It addresses lead paint, asbestos in building materials, and indoor air quality. With the exception of lead, none of the over 250 regulated drinking water contaminants are listed as Toxic Substances in Chapter 254, nor are the countless other air and water emissions DNR regulates.

As is the case with lead, when a toxic substance is found in both products and in water, the water portion is regulated by DNR. Contamination levels in paint and other lead-containing products are determined and enforced through Chapter 254, but the water quality criteria for lead is not. That is regulated separately by DNR, with wholly different standards for water limits than exist for product limits. In fact, the toxic substances, including many heavy metals, found in water are all listed separately in NR 105 rather than being incorporated in Chapter 254.

More troubling is the uncertainty surrounding DHS’s enforcement authority with respect to toxic substances listed in Chapter 254. Though it appears this legislation would not immediately give DHS

enforcement authority over the PFOS and PFOA limits, adding those two compounds to Chapter 254 would open the door to DHS enforcing those standards, similar to the lead product standards, and could eventually subject the regulated community to duplicative regulation, duplicative enforcement actions, and even criminal penalties.

In addition, DNR is not required, and in fact does not seem to have the authority, to promulgate a rule based on a standard established in Chapter 254. DNR's rulemaking authority for groundwater standards is found in §160.07(5) and relates only to those standards developed through the process in §160.07. (§160.07(5) authorizes DNR to promulgate rules *only* for substances transmitted to DHS under §160.07(2)).

Finally, it is unclear the methodology DHS will use when setting a standard required in Chapter 254, and there is no clear method of revising standards in Chapter 254 as science changes. The methodology and revision authority for groundwater standards is found in Chapter 160 and could be interpreted as only applying to standards set through the process prescribed in that same Chapter.

That is not to say that DHS has no role in determining water quality standards for potentially toxic substances; the process for that is already well defined in § 254.02(3)(a), and can be accomplished without listing PFOA and PFOS in the Toxic Substance Subchapter of 254. In fact, § 254.02(3)(a) *requires* DHS to work with DNR to perform a health risk assessment on these compounds, and to help DNR set standards for them (DNR "shall" enter into an MOU with DHS). Section 254.02 links DHS's expertise to DNR's authority to regulation air and water quality, negating the need to list specific ground water contaminants in Chapter 254.

It appears that adding these compounds to Chapter 254 will result in debate over agency authority and that will further draw out the process and muddy the regulatory waters around PFOA and PFOS.

Chapter 160 (Groundwater Protection Standards) on the other hand, is the correct place for this legislation. The legislative intent of Chapter 160 could not be clearer: to "establish an administrative process which will produce numerical standards...for substances in groundwater." (Wis. Stat. §160.001(1)).

In fact, DNR has already begun the process laid out in §160.07 of establishing enforcement standards for PFOA and PFOS. DNR categorized the two compounds as Category 1, assigned them a high ranking within the category, and then requested DHS recommend a standard for them. (See letter 3/21/2018 from DNR to DHS).

The main concerns this legislation addresses is the length of time it is taking for DHS to make a recommendation to DNR. Section 160.07(5) requires DNR to propose rules implementing DHS's recommendations within 9 months of requesting the recommendation from DHS, but neither it nor Chapter 254 set a timeline for DHS to develop a recommendation. Thirteen months have passed since DNR's original request. DHS has yet to make a recommendation, and consequently DNR has yet to begin rulemaking. The legislature is correct to be frustrated with the agencies for not following the statutory timeline.

But this frustration can be remedied by simply adding the proposed language to §160.07. In addition, the rulemaking process for PFOS and PFOA limits would be the same as every other groundwater standard and could begin immediately upon transmission of the numbers to DNR.

Moreover, adding this requirement to Chapter 160 will ensure that the standards will change if EPA's recommendations change, or if science further develops. Chapter 160 has a built-in process for revision of standards based on changing science. (see § 160.07(5)(e) and (6)). That process is followed for all groundwater standards set through Chapter 160. Once again, the sections of §160.07 that allow for adjusting standards only refer to standards set using the process in the same chapter. Absent new legislation, it is unclear how standards set in Chapter 254 could be adjusted as science advances.

Finally, as explained above, the methodology by which DHS sets all other groundwater standards developed through Chapter 160 may not apply to a standard developed in Chapter 254. Adding this requirement to Chapter 160 rather than Chapter 254 will ensure the statutory methodology for setting standards is followed, allow the agencies to revise the standards as science changes, ensure that DNR maintains enforcement authority of the standards, and allow rulemaking to begin immediately following DHS's recommendations.

- III. The legislation should prescribe specific risk assessment methodology for setting PFOA and PFOS standards.

If the standards are established under Chapter 160, DHS has two options for developing recommendations for PFOS and PFOA: they can adopt the 'federal number' or they can recommend a different, justifiable number based on significant technical information which is scientifically valid and which was not considered when the federal number was established. (§160.07(4)(a),(e)). 'Federal number' means either an enforceable regulation set by EPA *or* a suggested advisory number from EPA. In this case, there is not yet an enforceable limit from EPA, but DHS *could* rely on EPA's non-enforceable, non-regulatory advisory level of 70 parts per trillion as the federal number, which "offers a margin of protection for all Americans throughout their life from adverse health effects." See <https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos>. That number is an overly conservative limit at which no harm can be linked to the compounds, and is meant to be a placeholder while EPA researches and develops a more reasonable limit. DHS should not simply adopt that advisory limit.

Given that 13 months have passed, it is likely that DHS is following the latter option of developing a number different from the federal number. WPC agrees with this approach, but it is imperative for this legislation to prescribe a methodology for assessing risk in setting those standards.

General methodology for establishing standards is found in §160.13, and gives DHS similar options for setting daily intake for substances: either accept EPA's recommendation or develop a different number based on the most recent science. Since EPA has not set a daily intake for these compounds, DHS can calculate one based on the considerations in §160.13. However, through this process, DHS has significant discretion in calculating a standard because the agency, on its own, determines the acceptable risk level for the substance. (See §160.13(2)(b)3 explaining the uncertainty factor).

The good news is that risk is determined mathematically. Generally, regulators rely on either a deterministic risk assessment (DRA) or a probabilistic risk assessment (PRA) when determining the acceptable risk level for a contaminant. The difference is that PRA considers the probability of individual risk components while DRA considers the worst-case assumption for each risk component and multiplies the risks together which result in incredibly low limits based on 'not-in-the-real-world' sets of conditions. A PRA analysis might result in a 0.00001 risk rate while, for the same set of conditions, a DRA analysis might result in a 0.0000001 risk rate. One example of this is EPA's risk analysis for Human Health

Water Quality Criteria. The DRA results in 1: 10 million risk factor, which translates to reducing the number of cancer cases nationwide by 0.5 cases. The PRA, on the other hand, will range from a 1:1 million to a 1:100,000 risk factor, which is estimated to reduce cancer by between 5 and 48 cases per year nationwide. (<https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2019.html>). As this example illustrates, the PRA is still very conservative, and represents a low risk tolerance, but it is a more reasonable approach to setting regulatory standards.

Consequently, if groundwater standards are set for PFOS and PFAS at 70 parts per trillion using DRA approach versus 400 parts per trillion using a PRA approach, there can be orders of magnitude greater compliance costs under the DRA-derived limit yet there is no measurable health benefit in real world terms.

In this instance, PRA is the more appropriate approach and should be prescribed in the legislation. Given the uncertainty surrounding the variables that impact the health risks of PFOA and PFOS, it is imprudent to rely on one single, conservative (worst-case) limit. Though PFOA and PFOS are the most widely studied PFAS, the science is still very much developing and a specific level of acceptable risk has not been developed with any certainty for these compounds. Therefore, the best approach is to consider a range of probable exposures and risks when setting the limit.

Moreover, the process at DHS thus far has not been transparent, and stakeholders have had little or no ability to provide input on how these standards are derived. By prescribing a method, the legislature will assist stakeholders in understanding the resulting standard.

IV. The standard should not be more restrictive than EPA's enforceable limit.

As noted above, the science surrounding PFOA and PFOS is still developing. Given the uncertainty surrounding these compounds, DHS should follow EPA's lead on setting enforceable standards. EPA has significant resources dedicated to research and development of groundwater and drinking water limits for PFOA and PFOS. They have laid out a plan for studying these compounds and their impact on human health and setting enforceable standards accordingly. However, reliable scientific research takes time and Wisconsin should be patient as that research develops. Rushing to set a standard based on developing science can result in overregulation, and significant economic impact for no measurable health benefit.

That is not to say DHS should not work on determining a standard now. But ultimately, the limits set by DHS should be based on the science that has been fully developed, and not on speculation of where the science might lead. One way to ensure this is to require that DHS's standard be no more restrictive than EPA's enforceable regulatory limits, and to require DHS to revise standards if EPA sets limits that are less restrictive than DHS's prior recommendation.

In addition, DHS must consider the testing and treatment methods available when setting a standard. There are currently very few labs that can use the EPA validated method to test for these compounds, and the testing is onerous and expensive. There is also a lack of well-developed treatment methods available for the regulated community. Moreover, many of our members rely on pulp and other recycled input material that already contains PFAS or PFOA. All of these things should be considered by DHS and DNR as the regulatory process continues.

V. Conclusion

As we've seen in many other areas of air and water regulation, the quality of the input determines the quality of the regulation. Responsible regulation requires methods that are transparent and data-driven so the regulated community can meaningfully participate. Though WPC thinks 90 days is a reasonable amount of time for DHS to develop at least preliminary standards based on existing scientific studies, we believe this legislation should provide a more detailed framework for DHS to do so, including mandating the risk assessment methodology and providing the opportunity to adjust the standard if science proves it to be too more restrictive than necessary to protect human health. We also believe the rulemaking process should be followed to allow ample time for input on the methods of developing *and* enforcing standards for PFOS and PFOA.

Thank you for the opportunity to testify on this important piece of legislation.