

Comments concerning: Public Review Draft: Health-Based Maximum Contaminant Level Support Document: Perfluorooctane Sulfonate (PFOS)

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The State of New Jersey and its scientists from the Drinking Water Quality Institute are to be congratulated for a thorough, factual, defensible document, entitled Health-Based Maximum Contaminant Level Support Document: Perfluorooctane Sulfonate (PFOS). I am a clinician researcher, and I have contributed to the literature regarding PFOS and related products.

There is little doubt of many documented health endpoints following exposure, including the immune system alterations following exposure in animals, which was used in the document as the most sensitive endpoint. In addition, there are important and parallel findings in human populations following exposure to the perfluoroalkyl substances such as PFOS. This means that we need to pay particular attention to the recommendation. The important scientific questions will be about whether the implicated Maximum Contaminant Level (MCL) is too high, and therefore permits ongoing risk to the human population. Based on the data presented, as well as on the need to set the standard at a level for which accredited laboratories can reproducibly and reliably report small differences in contamination levels, the proposed MCL has my full support.

As the document points out, PFOS is detected in the serum of virtually all Americans. The levels of contamination were higher in the past; active intervention by Federal Agencies and cooperation from industry have resulted in decreased consumer-product exposure and documented decreases in serum PFOS concentrations in our nation, over time. This beneficial decline in internal contamination can be seen in the National Report on Human Exposure to Environmental Chemicals (Updated Tables, Vol 1, beginning on P 354, and publicly available at

https://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Volume1_Jan2017.pdf).

Consumer-product exposure is the most common source, and the decrease in national consumer exposure is encouraging.

However, as scientists from New Jersey have pointed out in the past, the improvement in serum PFAS contamination either does not extend to or is less applicable to those who suffer from ongoing exposure to contaminated drinking water. Once drinking-water contamination has occurred, it is understood to be long-lasting, requiring permanent specialty treatment of water supplies, or acquisition of alternative water sources. Failure to replace or repair contaminated drinking water has important implications. When humans are continuously exposed to water contamination at some steady state level, the very long "half-life" in humans implies that internal bioconcentrations of the contaminant PFOS will not decrease in concert with the rest of the population, and can even continue to increase. The beneficial decrease seen in the rest of the population is less applicable or not applicable to those drinking contaminated water. Further, PFOS is passed transplacentally to developing humans, and in breast milk

to newborns, so that mothers exposed to contaminated drinking water will pass on that contamination to their children. PFOS is not a chemical that can be safely ingested in drinking water.

New Jersey has identified an immune system finding as its most sensitive endpoint. There are other systems affected, of course, the toxicity is not limited to the immune system. The most sensitive system does bear further discussion. The consequences of the immune system alterations following human exposure are not fully known, yet we know enough to be sure that there is unacceptable risk to exposed populations. For example, it has been shown that adolescents and adults exposed to PFOS mount a less robust immune response to vaccination when they have higher internal concentrations of PFOS.¹ Exposure to PFOS has been associated with higher risk of important infectious diseases in young children,² as well as with symptoms of infectious disease such as fever.³ Other findings of great concern in animal studies, such as the decreased ability to fight bacterial intestinal infections,⁴ have not been studied in living humans. If we continue to expose people, we will actually figure out how to do these studies, and we should not predict that we will like the results.

In this setting, where biological activity at very low doses are documented in animals and humans, and ongoing consequences to humans are also certain if exposures are permitted to persist, the New Jersey recommendation is reasonable based on current data. Because the scientific process for the PFAS has consistently shown that consequences of exposure are discovered over time, the uncertainty factor of 30 chosen by New Jersey scientists is a reasonable choice. (Environmentalists can reasonably argue for an uncertainty factor of 100 in this setting, and that would create an MCL of around 4 ng/L. Detection and accuracy are also very important goals of science and policy documents for hazardous environmental contaminants.) Everyone wants a standard that is achievable and provides safety for themselves and fellow members of affected populations. An MCL of 13 is a defensible standard from a policy perspective. It sets a threshold that is driven by scientific data concerning endpoints, and the proposed standard is reproducibly measurable, and achievable with current technology.

As with previous New Jersey efforts such as its parallel and preceding PFOA document, this is now the most thorough and up-to-date review available. As occurred following the publication and acceptance of the New Jersey PFOA document, other entities will adapt information from this document. Standard setting will trend towards the New Jersey level.

It is worth emphasizing that the New Jersey draft document makes important points that scientifically defensible and are so far not commonly found in parallel US Federal efforts. We can expect the New Jersey analysis to be emulated widely. One important point is the choice of the immune system changes as the current most sensitive endpoint. This will change only if still more sensitive endpoints are found (in which case, arguments for still lower thresholds will have additional merit). Another is the consideration of infants who have been breast fed. This consideration is important because breast feeding is consistently shown to convey many health advantages to infants. Any contaminant exposure, such as PFOS, which may dissuade breast-feeding due to parental fears of contaminating infants and children is undesirable, costly, and a significant problem for both health and economic development of an affected geography. Setting a standard that minimizes this concern is in the public interest and economically sound. I support this standard because it is science-based, feasible to implement, and protective of the development of affected communities and persons living in them.

Sincerely,

A handwritten signature in blue ink, appearing to read "Alan Ducatman".

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Professor of Public Health, Professor of Medicine

References:

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3. Dalsager L, Christensen N, Husby S, et al. Association between prenatal exposure to perfluorinated compounds and symptoms of infections at age 1-4years among 359 children in the Odense Child Cohort. *Environ Int.* 2016;96:58-64.
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