

June 1, 2010

Reginald C. Jordan, Ph.D., CIH
NC Division of Air Quality
North Carolina Dept of Environment and Natural Resources
Raleigh, NC 27699-1641

Dear Dr. Jordan:

I am writing on behalf of Public Employees for Environmental Responsibility (PEER) to urge the North Carolina Science Advisory Board (SAB) to recommend a Maximum Allowable Concentration (MAC) for Perfluorooctanoic acid (PFOA) in groundwater that is protective of public health.

Regardless of the final MAC recommended, due to serious public health concerns and demonstrated technical feasibility and efficacy of activated carbon treatment, we urge the SAB to include a recommendation for treatment upon detection. This recommendation is supported by the experience cited in Arnsburg, Germany, where charcoal filtration was installed soon after detection (at levels of 0.5 to 0.64 ppb). Treatment successfully brought PFOA levels below detection and reduced residents' blood plasma levels by approximately 20% (draft, Table 1, @ page 4). We note that **the SAB's draft recommended health based MAC of 0.9 – 1.6 ppb is in excess of the levels that triggered treatment requirements in Germany**

Similar reductions in serum PFOA were achieved by treatment systems installed in several communities in West Virginia and in Ohio (draft, Table 2, @ page 5). In this vicinity, residents were eligible to be included in a health study and bottled water and/or treatment were begun if the PFOA concentration exceeded 0.05 ppb, almost 20 times lower than the lowest MAC recommended by the NC SAB.

Moreover, the U.S. Environmental Protection Agency has issued a Provisional Drinking Water Health Advisory for PFOA which is intended for short term (not chronic or lifetime) exposure of 0.4 ppb, which is less than the North Carolina proposed MAC which is intended for lifetime exposure (See http://www.epa.gov/waterscience/criteria/drinking/pha-PFOA_PFOS.pdf).

PEER does not believe that the SAB requires mechanistic data or proof of causality in humans to establish a precautionary MAC standard that is protective of the most sensitive effects associated with PFOA, which are serious adverse fetal growth and developmental effects (see sources cited in Cooper letter, below).

We suggest that the SAB draft recommended range of 0.9 – 1.6 ppb may not be adequately protective due to:

- 1) Over-reliance on the work of Dr. Tardiff of “The Sapphire Group” which is well known (see <http://www.thesapphiregroup.com/>) for its representation of industrial clients; and
- 2) Application of uncertainty factors.

I) Over-reliance on the work of Dr. Tardiff

We are concerned about the use of the paper authored by Dr. R.G. Tardiff and others from the Sapphire group as the primary basis for the SAB deliberations and recommendations.

Dr. Tardiff and his Sapphire group colleagues were funded to develop the risk assessment presented in the paper by DuPont and 3M, two companies who are responsible for contaminating the environment with PFOA (see <http://www.thesapphiregroup.com/pdf%20documents/PFOA%20Press%20Release.pdf>). In that capacity, Dr. Tardiff has incentives to select studies, interpret data, and resolve uncertainty to the benefit of his clients, DuPont and 3M.

The financial connections create an appearance that Dr. Tardiff’s work on PFOA may not be independent and objective. Dr. Tardiff’s apparent bias conflicts with the SAB’s mission to conduct independent objective science. The SAB mission is to promote protection of public health by exercising sound, unbiased scientific judgment in making conservative and protective assumptions, data interpretations, and resolving uncertainty. At a minimum, transparency and scientific integrity require that Dr. Tardiff’s financial conflicts be disclosed to the public.

Our concerns were heightened by a letter to the editor of the journal Food and Chemical Toxicology (April 19, 2010), in which Dr. Keith R. Cooper of Rutgers University raises serious concerns about Tardiff’s analysis:

“...The journal’s length limit for letters to the editor allows for discussion herein of only some of the most important of the **numerous errors, omissions, misrepresentations, and deviations from established risk assessment approaches in this [Tardiff et al] paper.**[...] It is my opinion that the authors (Tardiff et al) selectively chose the studies and endpoints considered in their analysis and used unconventional application of uncertainty factors in order to inflate their recommended health based drinking water levels. The concentrations given as safe for chronic exposure, 0.88 – 7.7 ug/L are not supported by either animal data or current epidemiological studies. Chronic exposure to these levels in drinking water would cause elevation of serum concentrations to levels associated with dose-related effects in humans and with permanent developmental effects in rodents. **Thus, chronic exposure to these levels cannot be considered to be protective of public health.**” (emphasis added)

We strongly urge the SAB to review Cooper's full analysis, consider the sources cited by Cooper on developmental effects, and re-assess and more closely scrutinize the work of Dr. Tardiff.

Dr. Tardiff's work was reviewed by the SAB on August 26, 2009: <http://daq.state.nc.us/toxics/risk/sab/proceed/143.pdf> The October 21 and November 18, 2009 SAB minutes indicate that the SAB reviewed the risk assessment work of New Jersey and Minnesota, and discussed seeking New Jersey and Minnesota scientific reviews of the draft Risk Assessment. That apparently was not done. However, review of the minutes suggests that Dr. Tardiff was relied on as the source to critique the use of some uncertainty factors in the NJ risk assessment. We are concerned with this apparent asymmetrical situation.

SAB meeting minutes also show discussion and concern by Dr. Kenneth Rudo, North Carolina State Toxicologist, about Dr. Tardiff's inappropriate use of uncertainty factors in his risk assessment. Dr. Rudo supported the use of uncertainty factors of 10 for each component in order to be more protective.

II) Use of uncertainty factors

According to NCSAB Policy and Practices guidelines:
<http://daq.state.nc.us/toxics/risk/sab/sabpolicy.shtml>

“Following deliberation, the NCSAB develops a recommendation including a ‘range of risks’ for the compound being reviewed. NCSAB recommendations are part of a narrative (see model outline below) prepared by the NCSAB Liaison and approved by NCSAB members. The narrative is not an in-depth examination of the toxicology of the compound. Rather, it is a document that is intended to discuss the NCSAB recommendation, **with adequate explanation of all safety factors used, points of uncertainty or disagreement, a discussion on alternate recommendations and the resulting risks to the public health**, and a mathematical representation of the final risk assessment methodology.”
(emphasis added)

While the draft MAC recommendation does provide a narrative overview of the scientific literature, we do not believe there is full transparency and adequate explanation of all safety factors used and full discussion of points of uncertainty or disagreement.

This discussion is particularly warranted, as we sense that there is a high degree of scientific controversy regarding health risk of PFOA; because the SAB recommended MAC range deviates significantly from other state health based levels; and because the recommended range appears to be sensitive to study selection, target health endpoints, assumptions, data interpretations, and uncertainly factors used.

A more thorough discussion of these issues is warranted in order to adequately inform and meaningfully involve the public in the SAB recommendation. Complete

transparency and robust discussion are especially warranted, given Cooper's critique, a reasonable perception of Tardiff's bias, and DuPont's potentially inappropriate influence.

We urge the SAB to reconsider the draft MAC in light of the studies on developmental effects cited by Cooper and Cooper's analysis of Dr. Tardiff's risk assessment

PEER appreciates the opportunity to submit these comments and urges your favorable consideration.

Sincerely,

Jeff Ruch
Executive Director