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November 21, 2016

State of New Jersey  
Department of Environmental Protection  
Division of Water Supply and Geoscience  
Drinking Water Quality Institute

Submitted by email to: [watersupply@dep.nj.gov](mailto:watersupply@dep.nj.gov)

**Re: Health-Based Maximum Contaminant Level Support Document: Perfluorooctanoic Acid (PFOA)**

To whom it may concern:

We are writing to commend you for proceeding with a drinking water standard for PFOA based on a careful analysis, and we recognize that your proposed drinking water standard for PFOA is lower than the drinking water health advisory recently issued by US EPA. However, we urge you to lower the standard further so that it is also protective for the effects of PFOA on mammary gland development. Your analysis indicates that a standard that is protective for effects on mammary gland development would be almost 20 times lower than your proposed standard. Changes in breast development could have significant public health impact because of the long-term implications for breastfeeding and breast cancer, making this an urgent priority. Furthermore, even though altered development of the mammary gland previously has not been used in the development of drinking water standards, we think it is important to consider all developmental toxicity endpoints.

Up to now, testing methods have overlooked effects of chemicals on breast development even though we are learning that the breast is very sensitive. Review of the literature has shown that for some chemicals, the breast is more sensitive than other tissues to low-dose exposures (Brody et al., 2011; Rudel et al., 2011), and this observation continues to be true in more recent studies, for example for genistein, ethinyl estradiol (Latendresse et al., 2009), and PFOA. These studies also show that the male mammary gland is especially sensitive during development.

In 2009, Silent Spring Institute organized an international workshop of 70 experts in mammary gland biology and risk assessors, and the participants agreed that rats and mice are useful surrogates for human breast development, because the stages of mammary gland development are similar. We acknowledged that animal studies are crucial for studying the effects of chemicals on breast development, given that development of breast tissue cannot be studied directly in girls (Rudel et al., 2011). Furthermore, a definitive study of breast cancer development from birth to late adulthood in humans would be not be feasible because of the length of follow-up time required and the inability to control exposures in an observational setting. Thus, it is important to act based on findings from animal studies in order to protect human health.

Research by many scientists has demonstrated that early life environmental exposures can alter mammary gland development, disrupt lactation, and increase susceptibility to breast cancer (Rudel et al., 2011; Macon and Fenton, 2013). These findings support the conclusion that assessment of mammary gland development should be incorporated in chemical test guidelines and risk assessment, including your drinking water standard for PFOA. The importance of this issue is reflected other scientific experts, including NIEHS Scientist Dr. Susan Fenton, who was recently quoted in *The Intelligencer*.

Thank you for your consideration of our comments and your attention to this important public health issue.

Sincerely,



Ruthann A. Rudel, M.S.  
Director of Research  
Silent Spring Institute



Laurel A. Schaider, Ph.D.  
Research Scientist  
Silent Spring Institute

#### ***Peer-reviewed journal articles***

Brody, J.G., R.A. Rudel, M. Kavanyaugh-Lynch. 2011. Testing chemicals for effects on breast development, lactation, and cancer. *Environmental Health Perspectives*. 119(8):A326-7.  
doi: [10.1289/ehp.1104077](https://doi.org/10.1289/ehp.1104077)

Latendresse, J.R., T.J. Bucci, G. Olson, P. Mellick, C.C. Weis, B. Thorn, R.R. Newbold, K.B. Delclos. 2009. Genistein and ethinyl estradiol dietary exposure in multigenerational and chronic studies induce similar proliferative lesions in mammary gland of male Sprague–Dawley rats. *Reproductive Toxicology*, 28(3):342-53. doi: [10.1016/j.reprotox.2009.04.006](https://doi.org/10.1016/j.reprotox.2009.04.006)

Macon, M.B., S.E. Fenton. 2013. Endocrine disruptors and the breast: Early life effects and later life disease. *Journal of Mammary Gland Biology and Neoplasia*. 18(1):43–61.  
doi: [10.1007/s10911-013-9275-7](https://doi.org/10.1007/s10911-013-9275-7)

Rudel, R.A., S.E. Fenton, J.M. Ackerman, S.Y. Euling, S.L. Makris. 2011. Environmental exposures and mammary gland development: State of the science, public health implications, and research recommendations. *Environmental Health Perspectives*, 119(8): 1053–1061.  
doi: [10.1289/ehp.1002864](https://doi.org/10.1289/ehp.1002864)

#### ***Media coverage***

Bagenstose, K., J. Wagner. “Determining safe PFOA level an uncertain science.” *The Intelligencer*. published 7 Nov 2016. ([http://www.theintell.com/news/horsham-pfoss/determining-safe-pfoa-level-an-uncertain-science/article\\_89589d4c-9f89-11e6-a125-bfc90f2b032a.html](http://www.theintell.com/news/horsham-pfoss/determining-safe-pfoa-level-an-uncertain-science/article_89589d4c-9f89-11e6-a125-bfc90f2b032a.html))