New government-sponsored studies confirm low-dose PFOA effects with potentially significant implications for human risk assessment

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Two new studies sponsored by the National Institute of Environmental Health Sciences (NIEHS) and US EPA were released this month that confirm effects in the mammary tissue of mice at doses far lower than those used to date in risk assessments generated for use in setting federal and state standards and guidelines for human exposure to PFOA in drinking water. These studies could have significant impact on existing and future PFOA risk assessments and related drinking water guidelines or standards.

On April 11, 2011, a paper was released on-line by *Toxicological Sciences*, entitled "Prenatal perfluorooctanoic acid exposure in CD-1 mice: low dose developmental effects and internal dosimetry," in which the authors report mammary gland developmental abnormalities in mice at even the lowest dose of 0.01 mg PFOA/kg. According to the authors, this finding is important, because the low dose level where mammary effects were observed is significantly lower than the dose level typically found to result in adverse liver effects. Most federal and state regulatory guidelines or standards to date for human exposures to PFOA in drinking water have relied on risk assessments using the adverse liver effects dose level as the lowest adverse effect level. The authors could not determine a NOAEL (no observable adverse effect level) for mammary effects, as adverse effects were observed at even the lowest dose levels. The authors also note that the levels of PFOA in the blood of the mice at the low 0.01 mg/kg dose level are actually "lower than those measured in young children living in areas highly contaminated with PFOA." Many risk assessors want to see at least 100-fold difference/margin of exposure (MOE) between the level of a chemical in the blood of exposed humans and the level of the chemical found in the blood of the experimental animals at the point where adverse effects are first observed.

The next week, on April 18, 2011, a paper was released on-line by *Environmental Health Perspectives*, entitled "Gestational and Chronic Low-Dose PFOA Exposures and Mammary Gland Growth and Differentiation in Three Generations of CD-1 Mice," in which the authors report adverse effects on mammary gland development at low-doses in mice, even among those exposed to 5 parts per billion (5 ppb) PFOA in their daily drinking water. The authors noted that they selected this 5 ppb dose level as it is equivalent to levels actually found in the public drinking water of at least one US community with confirmed PFOA contamination - Little, Hocking, Ohio. The authors note that the level of PFOA in the blood of the mice at the time

they showed adverse developmental mammary effects after exposure to this dose level were "approximately an order of magnitude lower than that seen in some chronically exposed human populations." The authors also noted that "similar developmental changes are physiologically possible in girls, but would likely not be realized until they enter puberty or attempt lactation." The authors, therefore, noted that "if human exposures in distinct populations are approximating those provided in this study, concern over human breast health and lactational competency are justified."

Earlier, researchers with the University of Cincinnati released preliminary results indicating effects of PFOA exposure on breast development among young girls with elevated PFOA exposures in the Cincinnati, Ohio/Northern Kentucky area. The abstract was published in the Novermber 2009 edition of the journal *Epidemiology* (Volume 20, Issue 6, p. S80), although the final results have not yet been published. Other researchers also have recently reported effects of PFOA exposure on the timing of puberty among young girls. One report was publicly released in September 2010 by the C8 Science Panel charged under a 2005 court settlement with determining whether there is a probable link between human exposure to PFOA and disease. In that study, the researchers evaluated exposures among young girls exposed to elevated levels of PFOA in their residential drinking water supply, including Little Hocking, Ohio. The report can be found on the C8 Science Panel's website. A second study, looking at girls exposed to PFOA within the general population of the UK, also reported effects of PFOA on time to puberty, and was published in the September 2010 edition of the journal Environment International (Volume 37, pp. 129-35).

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