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Rationale for Concurrence by Maine Center for Disease Control and Prevention on the Designation of Perfluorooctane Sulfonic Acid (PFOS) and its Salts as a Priority Chemical

February 23, 2018

Summary

38 MRSA §1694 requires that the designation of a "priority chemical" under Maine's Toxic Chemicals in Children's Products law be made in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention (Maine CDC). Once a chemical is designated as a priority chemical, the Maine Department of Environmental Protection (DEP) has the authority to establish reporting requirements on the use of the chemical in children's products, request an alternative chemical assessment, and propose a prohibition on the manufacture, sale or distribution in the State of a children's product containing a priority chemical. In a November 7, 2017 letter, the DEP requested Maine CDC's concurrence on the designation of perfluorooctane sulfonic acid (PFOS) and its salts as a priority chemical. Maine CDC is informing the DEP of its concurrence with the proposed designation of perfluorooctane sulfonic acid (PFOS) and its salts as a priority chemical.

Under 38 MRSA §1694, designation of a priority chemical first requires the chemical be identified as a chemical of high concern. To be identified as a chemical of high concern, there must be strong credible scientific evidence that 1) the chemical is a reproductive or developmental toxicant, endocrine disruptor or human carcinogen; and, 2) the chemical is found to be present in human tissues, the home environment or in a consumer product present in the home. Maine CDC has previously interpreted strong credible scientific evidence to mean a top-tiered weight-of-evidence determination by an authoritative federal or international government agency, or the presence of multiple studies published in peer-reviewed scientific literature with consistent findings.

When the chemical of high concern list was developed in 2012 and reviewed in 2015, PFOS did not have a relevant top-tiered weight-of-evidence determination by authoritative federal or international agencies. Thus, at the time the existence of strong credible scientific evidence was based on a review of studies published in the peer-reviewed scientific literature. Since 2015, the Japanese government updated its reproductive toxicity classification for PFOS to a top-tier, category 1A listing in its chemical

classification database. Based on the 2017 Japanese authoritative governmental agency listing and the previous review of peer-reviewed scientific literature, PFOS and its salts continue to meet the chemical of high concern toxicity criteria.

Maine CDC in 2012, 2015 and now in 2018 confirmed the presence of multiple biomonitoring studies, including nationally representative studies conducted by the U.S. CDC and studies in peer-reviewed scientific journals, with findings of PFOS in human blood and breastmilk. While national biomonitoring data suggest a decreasing trend in PFOS serum levels, it continues to be detected in adults and children in the U.S. Additionally, multiple studies in the peer-reviewed scientific literature were identified that found PFOS through sampling and analysis to be present in household indoor dust. These findings continue to provide strong credible scientific evidence that PFOS is present in the human body and household environment.

Collectively, PFOS and its salts continue to meet the chemical of high concern listing criteria with strong credible scientific evidence and may appropriately be listed as a priority chemical.

Background

Under 38 MRSA §1694, a chemical must first be identified as a chemical of high concern in order to be designated a priority chemical. The statutory criteria for being designated a priority chemical is identical to that for being designated a chemical of high concern (38 MRSA §1693-A and §1694). To be designated a chemical of high concern, there must be strong credible scientific evidence that 1) the chemical is a reproductive or developmental toxicant, endocrine disruptor or human carcinogen; and, 2) the chemical is found to be present in human tissues, the home environment or in a consumer product present in the home. Credible scientific evidence is defined by statute as results of a study, the experimental design and conduct of which have undergone independent scientific peer review, that are published in a peer-reviewed journal or publication of an authoritative federal or international governmental agency (38 MRSA §16918-A). Strong credible scientific evidence is undefined by statute or rule. Maine CDC has interpreted strong credible scientific evidence to mean a top-tiered weight-of-evidence determination by an authoritative federal or international government agency, otherwise, the presence of multiple scientific studies published in peer-reviewed scientific literature with consistent findings. As there are no authoritative governmental databases that provide weight-of-evidence classifications for chemical presence in human tissues, in the home environment or in a consumer product present in the home, Maine CDC has evaluated the presence of strong credible scientific evidence for these exposure criteria based on human biomonitoring data from a federal or international governmental agency and/or multiple biomonitoring and exposure studies published in scientific peer-reviewed journals.

PFOS and it salts was previously designated by Maine CDC as a chemical of high concern based on the identification of multiple peer-reviewed scientific publications detailed in the initial identification of chemicals of high concern in 2012 and a subsequent triennial review of the chemicals of high concern list in 2015 (MECDC, 2012 and MECDC, 2015). Because PFOS is considered an emerging chemical with ongoing toxicity evaluations and measurement in humans and the environment, Maine CDC reviewed the most current federal and international authoritative chemical classification database listings for

designating PFOS and its salts as a chemical of high concern, and consequently, as an appropriate candidate for designation as a priority chemical.

This document provides an overview of the evidence for listing PFOS and its salts as a chemical of high concern and proposed listing as a priority chemical. The evidence is organized by the statutorily designated toxicity criteria and exposure criteria. A summary of the individual peer-reviewed studies identified in the 2015 chemical of high concern list review are provided in Appendix 1.

Chemical of High Concern Listing Review

Toxicity criteria

Developmental or reproductive toxicant

In 2015, the Maine CDC reviewed the available scientific peer-reviewed literature for PFOS and determined there were multiple studies with consistent findings of reproductive and developmental toxicity and endocrine disruption in animals (MECDC, 2015, Appendix 1). There were also multiple epidemiological studies identified finding associations between PFOS and reproductive or developmental toxicity as well as endocrine system function (MECDC, 2015, Appendix 1). In addition to these studies identified by the Maine CDC in 2015, the USEPA in 2016 developed a lifetime drinking water health advisory for PFOS based on an adverse developmental outcome in an animal toxicity study (USEPA, 2016). Several other studies demonstrating developmental effects in response to PFOS in animals were identified by the USEPA as candidate studies to derive a drinking water health advisory. While the USEPA Office of Water does not classify chemical toxicity according to a weight-of-evidence approach into a tiered classification system, the USEPA finding of multiple studies showing developmental toxicity is in line with the Maine CDC literature review findings and lends credence to PFOS being a developmental toxicant.

PFOS is now listed by an authoritative international governmental agency under a top-tier classification for reproductive toxicity. The Japanese government maintains a Globally Harmonized System of Classification and Labelling of Chemicals (GHS) database which contains toxicity classifications for hundreds of chemicals. The Japanese GHS database is currently used as a database to identify chemicals that meet the reproductive[1] or human carcinogenesis toxicity criteria for chemical of high concern listing (MECDC, 2012, and MECDC, 2015). In 2017, the Japanese GHS updated the reproductive toxicity listing for PFOS from a Category 1B to a top-tier Category 1A: known human reproductive toxicant listing (Japanese GHS, 2017). Based on this updated classification, there is now strong credible

[1] Japanese GHS (http://www.meti.go.jp/policy/chemical_management/int/files/ghs/h25jgov_en.pdf) reproductive toxicity Category 1: Known or presumed human reproductive toxicant classification -

This category includes substances which are known to have produced an adverse effect on sexual function and fertility or on development in humans or for which there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans. For regulatory purposes, a substance can be further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).

Category 1A: Known human reproductive toxicant
The placing of the substance in this category is largely based on evidence from humans.

scientific evidence coming from a top-tiered weight-of-evidence determination by an authoritative international government agency that PFOS is a reproductive toxicant.

Human carcinogen

No federal or international governmental agencies have classified PFOS or its salts as a human carcinogen.

Toxicity criteria conclusion

From the previous scientific peer-reviewed literature review in 2015 and the 2017 top-tier reproductive toxicity listing from the Japanese government, Maine CDC considered there to be strong credible scientific evidence that PFOS is a reproductive toxicant and continues to meet the toxicity criteria for listing as a chemical of high concern and therefore criteria for designation as a priority chemical.

Exposure criteria

Present in bodily tissues or fluids

U.S. CDC National Biomonitoring Program, which is designed to be representative of the general U.S. population, continues to detect PFOS in human blood (USCDC, 2017a). In the most recent U.S. biomonitoring results published in 2017 based on specimens collected during 2013-2014, PFOS was measured and detected in blood with a mean serum concentration of 4.99 µg/L (USCDC, 2017b). Since the U.S. CDC began measuring PFOS in its national biomonitoring surveys in 1999, PFOS serum levels have been steadily decreasing (Table 1). This decreasing trend likely reflects the phase-out of PFOS manufacturing, and import and use reductions in the U.S. over this period (USEPA, 2016 and USEPA, 2017). PFOS exposure remains an ongoing concern due to the long half-life in humans and the long-term stability and persistence of PFOS in the environment.

The U.S. CDC National Biomonitoring Program results are representative of levels in children 12 years and older and adults. Several published studies have reported results for PFOS in blood from children less than 12 years old (Olsen et al., 2004; Schecter et al., 2012; Wu et al., 2015). Olsen and colleagues measured PFOS serum levels in 598 children ages 2-12 and found levels ranging from 6.7 to 515 µg/L with a geometric mean of 37.5 µg/L (Olsen et al., 2004). Researchers measured PFOS serum levels in 68 children under the age of 8 from homes in California and found that all children had detectable levels of PFOS in their serum with a geometric mean of 6.28 µg/L (Wu et al., 2015). In Texas, 300 children less than 13 years old had a median serum PFOS level of 4.10 µg/L (Schecter et al., 2012).

In addition to the presence of PFOS in human blood, studies conducted in the United States, Canada, Sweden, Norway, Germany and Japan as well as others have measured and detected PFOS in human breast milk (Kubwabo et al., 2013 and USEPA, 2016).

Table 1. U.S. CDC biomonitoring PFOS serum levels (µg/L) for total population sampled (age 12 years and older) from 1999 to 2014.

Survey Years *	Geometric Mean (95% confidence interval)	50th Percentile (95% confidence interval)	95th Percentile (95% confidence interval)
99-00	30.4 (27.1 - 33.9)	30.2 (27.8 - 33.9)	75.7 (58.1 - 97.5)
03-04	20.7 (19.2 -22.3)	21.2 (19.8 - 22.4)	54.6 (44.0 - 66.5)
05-06	17.1 (16.0 - 18.2)	17.5 (16.8 - 18.6)	47.5 (42.7 - 56.8)
07-08	13.2 (12.2 - 14.2)	13.6 (12.8 - 14.7)	40.5 (35.4 - 47.4)
09-10	9.32 (8.13 - 10.7)	9.70 (8.50 - 10.8)	32.0 (22.6 - 48.5)
11-12	6.31 (5.84 6.82)	6.53 (5.99 - 7.13)	21.7 (19.3 - 23.9)
13-14	4.99 (4.50 - 5.52)	5.20 (4.80 - 5.70)	18.5 (15.4 - 22.0)

* Table adapted from the Fourth National Report on Human Exposure to Environmental Chemicals, USCDC, 2017b.

Present in the home environment

PFOS is found in the home environment in indoor dust with several studies finding higher exposure levels for children from indoor dust in the home (Egeghy and Lorber, 2011; Schecter et al., 2012; USEPA, 2016). The literature review conducted by the USEPA in developing a PFOS drinking water health advisory found several studies that measured and detected PFOS in indoor dust from homes in the United States (USEPA, 2016). Maine CDC also identified several studies that detected PFOS in indoor house dust. (MECDC, 2015, Appendix 1).

Exposure criteria conclusion

In addition to the U.S. CDC biomonitoring studies, there are multiple studies published in peer-reviewed scientific journals demonstrating that PFOS is found in humans, particularly blood and human breast milk. There are also multiple studies that found PFOS in the home environment in indoor dust. Taken together, there is strong credible scientific evidence that PFOS is present in humans and the home environment.

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USCDC 2017a. National Biomonitoring Program, Biomonitoring Summary, Perfluorochemicals. https://www.cdc.gov/biomonitoring/PFAS_BiomonitoringSummary.html

USCDC 2017b. Fourth National Report on Human Exposure to Environmental Chemicals, Updated Tables, January 2017, Volume One. https://www.cdc.gov/exposurereport/index.html

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Appendix 1

2015 Maine CDC Chemical of High Concern listing review - inclusion criteria for Perfluorooctane sulfonic acid (PFOS) and its salts (CAS 1763-23-1)

Toxicity criteria for reproductive and developmental toxicity

Animal studies:

1. Butenhoff, J.L., Ehresman, D.J., Chang, S.C., Parker, G.A., Stump, D.G. (2009). Gestational and lactational exposure to potassium perfluorooctanesulfonate (K+PFOS) in rats: developmental neurotoxicity. Reproductive Toxicology 27 (3-4):319-30.
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Human studies:

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Exposure criteria, biomonitoring

1. CDC. (2015). Fourth National Report on Human Exposure to Environmental Chemicals. Serum Perfluorooctane sulfonic acid (PFOS) (1999 – 2010 and 2011– 2012). Centers for Disease Control and Prevention, Atlanta, Ga.
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Exposure criteria, presence in indoor air and/or dust:

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