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Memorandum

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cc: Michele Walsh, DVM, State Veterinarian, Maine Department of Agriculture, Conservation and Forestry

From: Andrew Smith, SM, ScD, State Toxicologist, Maine Center for Disease Control and Prevention
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Date: August 4, 2020

Re: Action levels for PFOS in beef for use in determining whether beef at a farm is adulterated

Summary

The Department of Agriculture, Conservation and Forestry (DACF) requested that the Maine Center for Disease Control and Prevention (Maine CDC) develop an action level of perfluorooctane sulfonate (PFOS) in beef. A PFOS action level would guide recommendations on whether to allow a farm's beef to be sold in the commercial market.

There are currently no action levels or tolerance limits for PFOS in beef or food available from the U.S. Food and Drug Administration (FDA). Maine CDC derived action levels for PFOS in beef following standard risk assessment methodology using the U.S. Environmental Protection Agency (EPA) Office of Water's published toxicity information for PFOS and daily beef consumption rates for high-end consumers on a body weight basis. Beef consumption rates on an as consumed, cooked basis were adjusted to raw, uncooked rates such that the action level is applicable to PFOS levels measured in muscle tissue collected prior to entering the commercial food market. After accounting for additional background PFOS exposure the beef action levels are:

PFOS Beef Action Level (nanograms/gram, ng/g)*	
Children (1 to <6 years old)	3.4
Adults (20+ years old)	7.3

*Applies to raw, uncooked beef

PFOS action level derivation

General method

Action levels for PFOS in beef were derived following general health risk assessment methods (FR, 1992 and USEPA 2016). Action levels were calculated using the following equation:

$$PFOS\ action\ level\ (ng/g) = \frac{Reference\ dose\ (ng/kg\ body\ weight/day)}{Daily\ beef\ consumption\ (g/kg\ body\ weight/day)} \times RSC \quad (Equation\ 1)$$

The reference dose (RfD), a term commonly used by the U.S. EPA, in Equation 1 is a toxicity value that represents an estimate of an oral daily dose of a chemical below which there is likely to be minimal risk of any deleterious health effects even among sensitive sub-populations. Other agencies, e.g., the FDA, the European Food Safety Authority, refer to this threshold toxicity value as a tolerable or allowable daily intake. The denominator in Equation 1 is an exposure related term. In this case, the exposure term is daily beef consumption on a body weight basis. Beef consumption rates calculated on an as consumed cooked basis are converted to raw, uncooked consumption rates. The purpose of this conversion is to make the action level directly comparable to PFOS levels measured in muscle tissue post-slaughter prior to beef entering the consumer market. This also allows for comparison of PFOS levels in muscle tissue estimated from measured levels in samples of blood taken at the farm.

The relative source contribution (RSC) factor is a term which is used to account for other sources of exposure that are unrelated to beef consumption. The RSC factor is used when other exposures to a contaminant are expected and there is a risk management goal to ensure that total estimated exposure does not exceed the reference dose. The RfD, daily beef consumption rate, and RSC values used to derive the PFOS beef action level and the basis for their selection are discussed below.

Action level equation inputs

A. Reference dose

Maine CDC selected a RfD for PFOS of 20 nanograms per kg body weight per day (ng/kg/day)[1]. This RfD was developed by the U.S. EPA Office of Water in 2016 (USEPA, 2016). The U.S. EPA RfD was selected in order to be consistent with current risk assessment practices at federal agencies, including the FDA - the federal agency responsible for establishing food tolerance levels. Use of the U.S. EPA PFOS RfD is consistent with the current derivation of risk assessment-based values in Maine, such as the cow's milk action level, the Maine Department of Environmental Protection's (Maine DEP) Remedial Action Guidelines (RAGs) for soil and water, and the Maine DEP's screening levels for the beneficial use of solid waste. Since 2016, several states have developed PFOS RfDs that are 4- to 10-fold lower than the U.S. EPA RfD (CA, 2019; MA, 2019; MI, 2019; MN, 2019; NH, 2019; NJ, 2019). Maine CDC typically relies on toxicity values developed by federal agencies, e.g., the U.S. EPA or the Agency for Toxic Substances

[1] U.S. EPA typically presents RfDs in units of milligrams/kg-body weight/day. 20 ng/kg/day = 0.00002 mg/kg/day.

and Disease Registry (ATSDR). ATSDR in 2018 published a draft minimum risk level (MRL), a toxicity value equivalent to an RfD, for PFOS that is 10-fold lower than the 2016 U.S. EPA value (ATSDR, 2018). However, the ATSDR draft profile for PFAS has not been finalized and the toxicity values remain draft. While Maine CDC is in the process of reviewing the states' varying PFOS RfD derivations, it has not yet developed a Maine-specific RfD for PFOS.

The U.S. EPA RfD is based on a developmental toxicity study in rats where there was an observed decrease in rat pup body weight in pups born to dams exposed to PFOS for six weeks prior to mating and throughout mating, gestation, and lactation (USEPA, 2016). In deriving the PFOS RfD, the U.S. EPA selected a 'no observable adverse effect level' (NOAEL), from this study. The NOAEL is the dose at which there is no corresponding health effect in the animal; in this case, the level at which there was no observed decrease in pup body weight.

The U.S. EPA utilized a species-specific pharmacokinetic model to calculate an average PFOS serum level in rat dams at the corresponding NOAEL. U.S. EPA then applied a simple pharmacokinetic model to extrapolate the calculated average serum level at the NOAEL in rats to an oral human equivalent dose. In humans, the oral dose required to achieve similar serum levels to those observed in rodent studies is substantially lower. This is largely due to the much longer half-life of PFOS in humans as compared to rats and mice. The simple pharmacokinetic model takes this into account by calculating human PFOS clearance using PFOS-specific values for half-life and volume of distribution in humans. The clearance value is then multiplied by the average serum level in rats to calculate the oral human equivalent dose at the NOAEL.

To the oral human equivalent dose at the NOAEL U.S. EPA applied a total uncertainty factor of 30 to arrive at the reference dose of 20 ng/kg/day. It is standard risk assessment practice to apply uncertainty factors in developing a reference dose. To extrapolate results from animal studies to humans the standard practice is to apply a 10-fold uncertainty factor for animal-to-human extrapolations. However, because of the large differences in the half-life of PFOS in rodents (weeks) relative to humans (years), U.S. EPA used a pharmacokinetic model to perform an extrapolation from serum PFOS levels in the experimental rodents to estimated levels in humans as described above. For this reason, U.S. EPA applied only an additional 3-fold factor in extrapolating from animals-to-humans to account for potential species differences in toxicodynamics, i.e., differences in how PFOS may disrupt biological processes in animals versus humans. U.S. EPA applied a standard 10-fold uncertainty factor for intraspecies variability to account for any human populations that may be more sensitive to PFOS exposure. Combining the 3-fold factor for toxicodynamic extrapolations between animals and humans and the 10-fold factor for more sensitive human populations results in a total uncertainty factor of 30.

B. Beef consumption

Maine CDC calculated values for daily beef consumption on a body weight basis using beef consumption and body weight data from U.S. Department of Agriculture (USDA) Food Patterns Equivalents Database (FPED) and U.S. Centers for Disease Control and Prevention's (U.S. CDC) National Health and Nutrition Examination Survey (NHANES) (USCDC, 2020 and USDA, 2019). NHANES is a nationally representative sampling of the population of the United States, and provides food

consumption data collected using 2 day, 24-hour recall surveys under the What We Eat in America (WWEIA) food survey. NHANES also provides demographic and body measures data including age, gender, and body weight for individuals participating in the dietary recall surveys. USDA FPED provides the daily amount of various foods, including beef consumed, for each individual participating in the NHANES dietary recall surveys.

USDA FPED individual food consumption datasets for 2009-2010, 2011-2012, 2013-2014, and 2015-2016 were combined with NHANES demographic and body weight datasets for the corresponding survey years[2]. Beef consumption in FPED individual food files was identified using food codes specific to beef and any food description that included the word 'beef' or 'hamburger' or 'cheeseburger'. Meat and cured meat variables for individuals reporting beef or foods with beef were summed for each survey day. Beef consumption rates were calculated for individuals that completed the 2-day dietary recall survey and reported consuming beef on day 1, day 2 or both days. Beef consumption, provided as ounces consumed, was averaged over the 2-day survey period. The 2-day average in ounces was converted to grams and divided by the respondent's body weight for a consumption rate on a gram per kg body weight basis (grams of beef/kg body weight/day).

Mean and 90th percentile beef consumption rates were calculated for age groups with similar intakes (Table 1)[3]. These rates represent consumer-only rates as only individuals reporting beef consumption were included in the derivation. Maine CDC used the 90th percentile beef consumption rate to represent daily consumption for high-end consumers of beef. Using a 90th or 95th percentile for an exposure scenario is common practice in human health risk assessment. For example, the U.S. EPA PFOS/PFOA drinking water health advisory is based on the 90th percentile consumer-only estimate for water ingestion on a body weight basis for lactating women (USEPA, 2016). The FDA typically uses the 90th percentile of a daily intake to represent a high-end consumer (FDA, 2006).

Consumption rates were also calculated for women of child-bearing age (females, age 13 to 49) to determine if rates were higher in this population than adults (male and female combined) or young children[4]. However, the mean and 90th beef consumption rates for women of child-bearing age are lower than adults 20+ male female combined and rates for young children. Thus, action levels developed for young children or adults 20+ should also be protective of women of child-bearing age.

Beef consumption rates calculated on an as consumed, cooked basis were converted to rates on a raw, uncooked basis. PFOS action levels to determine when beef at a farm is adulterated applies to muscle tissue from cattle as measured on a raw muscle tissue basis or estimated from measured blood (plasma or serum) samples. A conversion factor of 1.35 was applied to the cooked, as consumed consumption rates to estimate raw, uncooked consumption rates. The 1.35 factor is based on the

[2] USDA FPED datasets - https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/fped-databases/
NHANES datasets - https://wwwn.cdc.gov/nchs/nhanes/Default.aspx

[3] Mean and percentile distribution estimates were calculated following NHANES analytic guidelines - https://wwwn.cdc.gov/nchs/nhanes/analyticguidelines.aspx#analytic-guidelines

[4] Selection of females 13 to 49 years of age representing women of child-bearing age is consistent with U.S. EPA practice within the Exposure Factors Handbook - https://www.epa.gov/sites/production/files/2018-06/documents/efh_-_chapter_11_update_2018.pdf

average percent cooking yield (74.5%) for beef cuts and ground beef derived from USDA estimates for calculating nutrients from raw and cooked beef cut preparations (USDA, 2014).

Table 1. Mean and 90th percentile consumer-only daily beef consumption rates.

		As consumed, cooked (g/kg bw/day)		Raw, uncooked (g/kg bw/day)*	
Age group (years)	**Sample size**	**Mean** (95% confidence interval)	**90th Percentile** (95% confidence interval)	**Mean**	**90th Percentile**
1 to <6	1426	1.7 (1.6-1.8)	3.5 (3.2-3.8)	2.3	4.7
6 to <12	1842	1.3 (1.2-1.4)	2.6 (2.3-2.9)	1.8	3.5
12 to <20	1335	1.1 (1.0-1.2)	2.4 (2.0-2.8)	1.5	3.2
20+	6876	0.8 (0.79-0.83)	1.6 (1.6-1.7)	1.1	2.2
Women 13 to 49	3045	0.7 (0.68-0.74)	1.5 (1.3-1.6)	0.9	2.0

* Raw, uncooked mean and 90th percentile estimates were calculated by multiplying the as consumed, cooked mean and 90th percentile estimates by 1.35 to account for average percent cooking yield.

C. Relative source contribution

The purpose of the RSC factor is to account for additional sources of PFOS to help ensure that the daily dose of PFOS from all sources combined does not exceed the RfD. It is clear from U.S. CDC biomonitoring programs that exposure to PFOS is ubiquitous, as it is present in the blood of most of the individuals tested in recent samplings of Americans 12 years and older (USCDC, 2020). The presence of PFOS in the general U.S. population is the result of exposures from multiple sources, including dietary sources, house dust, drinking water, and indoor and outdoor air (Egeghy and Lorber, 2011; Gebbnik et al., 2015; Tittlemier et al., 2007; Trudel et al., 2008; USEPA, 2016). Serum PFOS levels may also reflect the contribution of exposure to PFOS precursors that have undergone *in vivo* biotransformation (Gebbnik et al., 2015 and Vestergren et al., 2008). Studies have estimated daily PFOS intake based on the amount of PFOS found in various dietary items and environmental media, and individual diet- and media-specific consumption rates. From these studies, the largest contributor to overall PFOS exposure seems to be the diet for adults, and diet and house dust for young children (Egeghy and Lorber, 2011; Tittlemier et al., 2007; Trudel et al., 2008). However, the magnitude and relative contribution of these daily intake estimates from various sources, such as diet, indoor dust or drinking water, are uncertain, and may not be entirely representative of current exposures for the general U.S. population.

Maine CDC calculated an RSC for background exposure based on measured PFOS serum levels in NHANES biomonitoring studies. This method - using nationally representative serum PFOS data - has the advantage of estimating a daily PFOS intake by integrating all potential sources, which better

represents overall PFOS exposure for the general U.S. population. Considering this daily intake to represent general background PFOS exposure, the remaining dose which could be allocated to other sources is calculated by subtracting the background exposure from the 20 ng/kg/day PFOS RfD. The RSC is derived by dividing the remaining dose by the PFOS RfD.

To derive an RSC using a background exposure estimate from serum PFOS levels, Maine CDC utilized a one-compartment pharmacokinetic model (Equation 2). This is the same pharmacokinetic model U.S. EPA utilized in their PFOS lifetime drinking water health advisory to convert a dose on a serum level basis to an oral intake dose (USEPA, 2016). A background exposure estimate was calculated with NHANES PFOS serum level data for adults age 20+ years (2015-2016 survey years). The geometric mean was selected to represent the central tendency PFOS serum level, as it is U.S. EPA guidance to use central tendencies for RSC intake estimates (USEPA, 2000). Values for volume of distribution and elimination rate as described in the U.S. EPA's drinking water health advisory for PFOS were selected (USEPA, 2016). The elimination rate parameter was adjusted with a more recent serum PFOS half-life estimate of 3.4 years (Li et al., 2017).

$$Background\ exposure\ (ng/kg/day) = CP \times kP \times Vd \qquad (Equation\ 2)$$

where:
CP = PFOS serum concentration (5.02 ng/mL adults 20+, 3.38 ng/mL children 3-5 years old)
kP = first-order elimination rate (0.00056 day^{-1})
Vd = volume of distribution (230 mL/kg-body weight adults, 253 mL/kg children[5])

The calculated background PFOS exposure for adults based on a recent, 2015-2016, nationally representative PFOS serum level is 0.65 ng/kg/day. For children, it is uncertain how well a background PFOS exposure estimate for adults represents an exposure for a child, especially younger children. In 2013 and 2014 U.S. CDC performed PFAS biomonitoring in samplings of children age 3 to 11. The calculated background exposure for a young child based on the geometric mean PFOS serum level for a child age 3-5 years old is 0.48 ng/kg/day. These estimated background exposures of 0.65 ng/kg/day for adults and 0.48 ng/kg/day for young children were used to calculate an RSC (Equation 3).

$$RSC = \frac{PFOS\ RfD\ (ng/kg/day) - Background\ exposure\ (ng/kg/day)}{PFOS\ RfD\ (ng/kg/day)} \times 100 \qquad (Equation\ 3)$$

Using the background exposure estimate for an adult or a young child in comparison to the PFOS RfD produces an RSC of 97% for adults and 98% for young children. According to U.S. EPA guidelines for drinking water, RSC values should not exceed an 80% ceiling, nor fall below a 20% floor (USEPA, 2000). As the calculated RSC using the background exposure estimate for either adults or young children is

[5] The PFOS volume of distribution for young children was adjusted from the adult value of 230 mL/kg by a factor of 1.1 to account for age-specific differences during young childhood (Goeden et al., 2019).

above the 80% ceiling, the RSC was limited to 80%. The RSC of 80% is the result of a relatively small background exposure as compared to the RfD.

It may also be appropriate to consider exposure to additional PFAS such as PFHxS, PFOA, and PFNA. These PFAS may have toxicities similar to PFOS and potentially have an additive effect. Daily background exposures for PFHxS, PFOA, and PFNA were calculated using the one-compartment pharmacokinetic model with NHANES serum data and volume of distribution and clearance rates specific to each PFAS. Adult background exposures from geometric mean serum levels for PFHxS, PFOA and PFNA are 0.078, 0.22 and 0.091, respectively. For children, background exposure estimates are 0.05 ng/kg/day for PFHxS, 0.31 ng/kg/day for PFOA and 0.13 ng/kg/day for PFNA. Using the sum of PFOS, PFOA, PFHxS and PFNA background exposures, 1.04 ng/kg/day for adults or 0.97 ng/kg/day for 3 to 5-year-old children, the calculated RSC is 95%.

Action level calculations

$$PFOS\ beef\ action\ level, Child_{\ 1-<6\ years\ old} = \frac{20\ (ng/kg\ body\ weight/day)}{4.7\ (g/kg\ body\ weight/day)} \times 0.8 = 3.4\ ng/g$$

$$PFOS\ beef\ action\ level, Adult_{\ 20+\ years\ old} = \frac{20\ (ng/kg\ body\ weight/day)}{2.2\ (g/kg\ body\ weight/day)} \times 0.8 = 7.3\ ng/g$$

Discussion

Maine CDC developed age-specific action levels for PFOS in beef of 3.4 ng/g for young children and 7.3 ng/g for adults, assuming a 90th percentile beef consumption rate on a raw, uncooked basis, and allowing 80% of the reference dose to come from beef consumption. These action levels apply to PFOS levels measured directly in uncooked muscle tissue or to muscle tissue concentrations estimated from measured blood levels in beef cattle. These action levels are established as guidance for determining whether a farm's beef from cattle should be considered adulterated, and therefore should neither be sold or delivered for sale in accordance with Title 22 MRS §2155-A.

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