EMAIL TO OFS

At the request of DCC, Division of Risk Assessment and Prioritization (DRAP) performed a human health assessment (HHA) for PFAS in 10 samples of clams. The estimated PFOA exposures (all samples) for children (MF 0-6 y), females of childbearing age (F 16-49 y), and the general population (MF 2+ y) from consumption of the clams are above the toxicological reference value (TRV) and are therefore a health concern. Although all samples had multiple PFAS present above their respective MDLs, DRAP only conducted the HHA for PFOA detected in the samples. The estimated exposures to any of the samples from PFOA alone are a potential health concern and the inclusion of additional PFAS, or consideration of additive effects, would not further affect the outcome of the analysis.

Clams Sample Number	PFOA Concentration (ng/g)	Health Concern[a]
1272259	3.173	Yes
1272403	4.051	Yes
1272434	2.585	Yes
1272560	7.654	Yes
1272792	17.724	Yes
1272802	3.834	Yes
1273414	15.171	Yes
1273466	10.871	Yes
1273659	3.108	Yes
1273663	4.320	Yes

[a] PFOA exposure in the sample exceeds the PFOA TRV (0.03 ng/kg bw/day)

For DRDA files:

Exposure Estimates

DRDA uses data from What We Eat in America (WWEIA), the food consumption portion of the National Health and Nutrition Examination Survey (NHANES), to estimate intakes of foods. To calculate dietary intake of canned clams, FDA used data on combined consumption of all mollusks, per kilogram of body weight, by individual participants in WWEIA/NHANES. FDA estimated intakes, based on individual participant data, per kilogram of body weight for the general population (MF 2+ y) and the subpopulations of children (MF 0-6 y) and females of childbearing age (F 16-49 y). Mollusk intakes were estimated using WWEIA/NHANES 2003-2018 data. To calculate the intake of mollusk for each population, FDA used the 90th percentile of the estimated intake of mollusk for each group.

To assess the exposure to PFAS resulting from consumption of each of the clam samples by the general population (MF 2+ y), and the special subpopulations of children (MF 0-6 y) and females of childbearing age (F 16-49 y), DRAP compared the estimated level of PFAS exposure from the clams samples to the TRV for PFOA (0.03 ng/kg bw/day; EPA, 2024). If the estimated exposure to PFOA for the population assessed was above the PFOA TRV, it was determined likely to be a health concern. Exposure estimates are provided in Table 1. Because all samples assessed contained PFOA at a level that would result in estimated exposure above the TRV, and thus would be a health concern, additional PFAS beyond PFOA were not assessed because inclusion would not further affect the outcome of the analysis.

Table 1. PFOA exposure estimates for all populations assessed from PFOA in samples of clams

Sample Number	PFOA Concentration (ng/g, as reported)	Children (MF 0-6 y) PFOA 90%ile Estimated Exposure (ng/kg bw/day)[a]	Females of childbearing age (F 16-49 y) PFOA 90%ile Estimated Exposure (ng/kg bw/day)[a]	General population (MF 2+ y) PFOA 90%ile Estimated Exposure (ng/kg bw/day)[a]
1272259	3.173	4.60	3.55	3.17
1272403	4.051	5.87	4.54	4.05
1272434	2.585	3.75	2.90	2.59
1272560	7.654	11.10	8.57	7.65
1272792	17.724	25.70	19.85	17.72
1272802	3.834	5.56	4.29	3.83
1273414	15.171	22.00	16.99	15.17
1273466	10.871	15.76	12.18	10.87
1273659	3.108	4.51	3.48	3.11
1273663	4.320	6.26	4.84	4.32

[a] Contaminant concentration ng/g (as reported) * intake (1.00 g/kg bw/day for general population; 1.45 g/kg bw/day for children; 1.12 g/kg bw/day for females of childbearing age) = Contaminant exposure (ng/kg bw/day) for samples of canned clams.

All estimated exposures to PFOA were above the TRV of 0.03 ng/kg bw/day (EPA, 2024a) for children, females of childbearing age, and the general population and are therefore considered a health concern for all populations assessed.

All samples had other PFAS present above their respective MDLs in addition to the detected PFOA. HHA for individual PFAS other than PFOA was not performed, nor was assessment of the potential additive effects of the other PFAS present because the estimated exposures to any of the samples are a potential health concern upon consideration of PFOA alone.

Reference

Environmental Protection Agency (EPA). (2024a). Human Health Toxicity Assessment for Perfluorooctanoic Acid (PFOA) and Related Salts. Available at https://www.epa.gov/system/files/documents/2024-05/final-human-health-toxicity-assessment-pfoa.pdf, Accessed 10/8/2024.