Baby Formula

GOALS

The goals of this project were to:

- Check for chemical contaminants that have previously been reported in baby formula, including lead, arsenic, aluminum, acrylamide, bisphenols, and PFAS.
- Compare the measured levels of contaminants and the nutrient potassium to available health-based guidelines or limits.

TEST APPROACH AND METHODS

Forty-one models of powdered baby formula were tested. Two or three samples, representing one to three lots, plus two duplicates were tested for potassium and all the contaminants, other than PFAS (per- and polyfluoroalkyl substances), at an accredited laboratory. PFAS analysis was performed on only one sample per model at another accredited laboratory.

The baby formulas were prepared and analyzed in accordance with the following methods:

- PFAS by LC-MS/MS. EPA 537 (Mod) - Per- and Polyfluoroalkyl Substances (PFAS) by LC/MS/MS.
- Acrylamide by LC-MS/MS. J. Agric. Food Chem. 54.19 (2006): 7001-7008. - Rapid Sample Preparation Method for LC–MS/MS or GC–MS Analysis of Acrylamide in Various Food Matrices.
- Bisphenol A, F, and S by LC-MS/MS. Adapted from J. Chromatogr. A 1306 (2013): 44-58 - Development of a liquid chromatography-tandem mass spectrometry procedure for determination of endocrine disrupting compounds in fish from Mediterranean rivers.
- AOAC 2015.01 Mod, Heavy Metals, Aluminum and Potassium in Food - Lab's Internal Methodology.
- Inorganic arsenic by IC-ICP-QQQ-MS - Lab's Internal Methodology.

We reviewed all the test results and quality control data provided by the contract labs for accuracy and clarity, and checked for errors.

DATA ANALYSIS

We defined total PFAS as the sum of the concentrations of 33 PFAS compounds detected in each of the powdered baby formulas tested. To estimate the average concentration of a contaminant (acrylamide, aluminum, bisphenols, or heavy metals) in a baby formula model, we applied a method used by many risk assessors,[1] including the Environmental Protection Agency. If a contaminant was detected or measurable in any of the samples of the product, the samples that had test results below the method reporting limit, or MRL, were assumed to have a concentration of half the MRL for that contaminant. If the contaminant was not detected in any of the samples tested of the product, we assumed a concentration of zero for all the samples of that product for the contaminant. This approach to risk assessment appropriately considered important uncertainties about potential levels of undetected risk in samples with test results below the MRL.

RISK ASSESSMENT

We estimated a U.S. infant's daily intake (12 scoops of dry powder for 24 fluid ounces), at 3 months old (with an average weight of 6.1 kg, or 13.4 pounds), of the tested aluminum, acrylamide, inorganic arsenic, bisphenol A, cadmium, lead, or PFOS for each model and, where appropriate and applicable, compared the intake estimates to the exposure limits in the table below.

Health-Based Exposure Limits Selected for Risk Assessments for Acrylamide, Aluminum, Bisphenol A, Heavy Metals, and PFAS

Chemical	EPA RfD ug/kg bw/d	EFSA TDI ug/kg bw/d*	OEHHA MADL (NSRL) ug/day	FAO and WHO MPL ug/kg
Acrylamide	2[4]	NA	140 (0.2)[5]	NA
Aluminum	NA	1,000[6]	NA	400[7]
Inorganic Arsenic	0.1[8]	NA	NA	NA
Cadmium	NA	NA	4.1[9]	NA
Lead	NA	NA	0.5[10]	NA
Bisphenol A	NA	0.0002[11]	3[12]	NA
PFOS	0.02[13]	NA	NA	NA

EFSA = European Food Safety Authority; EPA = U.S. Environmental Protection Agency; OEHHA = California's Office of Environmental Health Hazard Assessment; FAO = Food and Agriculture Organization; WHO = World Health Organization. MPL = maximal permissible limit. *EFSA TDI units for aluminum are ug/kg bw/w (w = week). ug/kg = microgram per kilogram.

[1] Xue, J.; Zartarian, V.; Wang, S.; et al., "Probabilistic Modeling of Dietary Arsenic Exposure and Dose and Evaluation with 2003-2004 NHANES Data," *Environmental Health Perspectives* 118, no. 3 (2010): 345-50. [2] "Regional Guidance on Handling Chemical Concentration Data Near the Detection Limit in Risk Assessments," *Environmental Protection Agency,* https://www.epa.gov/risk/regional-guidance-handling-chemical-concentration-data-near-detection-limit-risk-assessments. [3] https://www.medicalnewstoday.com/articles/325630#by-age. [4] https://iris.epa.gov/ChemicalLanding/&substance_nmbr=286. [5] MADL and NSRL for acrylamide at https://oehha.ca.gov/proposition-65/chemicals/acrylamide. [6] https://health.ec.europa.eu/document/download/4f895ebf-bad2-4950-a32b-4099a0dc970a_en#:~:text=The%20European%20Food%20Safety%20Authority%20(EFSA)%20established%20in%202008%20a,dietary%20administration%20of%20aluminium%20compounds. [7] https://pmc.ncbi.nlm.nih.gov/articles/PMC9407326/#:~:text=*%20Maximal%20acceptable%20limit%2C%20(MPL,by%20the%20FAO%20and%20WHO. [8] https://iris.epa.gov/static/pdfs/0278_summary.pdf. [9] https://oehha.ca.gov/media/downloads/crnr/cadmium20madl.pdf. [10] https://oehha.ca.gov/proposition-65/chemicals/lead. [11] https://www.efsa.europa.eu/en/topics/topic/bisphenol. [12] https://oehha.ca.gov/proposition-65/chemicals/bisphenol-bpa. [13] https://19january2021snapshot.epa.gov/sites/static/files/2017-12/documents/ffrrofactsheet_contaminants_pfos_pfoa_11-20-17_508_0.pdf.