

January 22, 2013

Michael Baes
Pesticide and Environmental Toxicology Branch
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
1515 Clay St., 16th floor
Oakland, California 94612

Re: Draft Technical Support Document
On Proposed Public Health Goal For
Perchlorate In Drinking Water

Dear Mr. Baes,

The International Formula Council (IFC) is responding to the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) December 2012 request for comments on the revised draft technical support document "Public Health Goal for Perchlorate In Drinking Water." The IFC is an association of manufacturers and marketers of formulated nutrition products, e.g., infant formulas and adult nutritionals, whose members are based predominantly in North America.*

As a general comment, it is relevant to note that perchlorate is not an ingredient in infant formula. Perchlorate, which is naturally occurring, can be present in the environment, drinking water, and the food supply chain, and thus trace levels may be found in infant formula and breast milk. The body of scientific evidence indicates that these trace levels do not pose a health risk. Additionally, all infant formulas manufactured in the U.S. are required by law to contain iodine to aid in the development of the baby's brain and thyroid. That iodine would also counteract any potential effects associated with perchlorate.

The IFC does not support the proposed public health goal (PHG) of 1 part per billion (ppb) for perchlorate in drinking water. The proposed PHG has not been shown to increase safety and is inconsistent with other well-established safe levels. The IFC recommends that OEHHA instead adopt the U.S. Environmental Protection Agency's (EPA) reference dose (RfD) for perchlorate in drinking water of 0.7 ug/mg/day. The EPA and the U.S. Food and Drug Administration have studied perchlorate extensively and the EPA RfD is considered appropriate for all consumers, including sensitive sub-populations like infants. OEHHA adoption of the EPA RfD will provide sufficient safety to consumers, ensure consistency across jurisdictions and minimize the potential for confusion.

We do not agree with the calculation OEHHA used in deriving its proposed PHG. In fact, several of the factors used in calculating the PHG and the RfD are the same. For instance, the definition of Acceptable Daily Dose (ADD) in the draft document is similar to the definition for the EPA RfD. In addition, the human study data on iodide uptake which OEHHA used to calculate the ADD (i.e., Greer et al.), is the same data the EPA used in developing the RfD. Furthermore, both EPA and OEHHA used an uncertainty factor of 10 to account for inter-individual variability. The primary difference between the two levels is that OEHHA used the Benchmark Dose approach rather than the more common No Observed Effect Level (NOEL), which was used by EPA and generated the higher RfD.

* IFC members are Abbott Nutrition, Mead Johnson Nutrition, Nestlé Infant Nutrition and Perrigo Nutritionals.

The primary focus of the IFC and its member companies is and will always remain the health and welfare of infants and children around the world. As an industry, members of the IFC take all potential safety issues very seriously. Our research and development programs are designed to produce the highest quality of infant formula products available. When new information becomes available on substances like perchlorate, we support bringing the information forward through the accepted process of scientific peer review and evaluation. This helps ensure that it is evaluated with consideration to existing science and that policies are driven by sound science.

In closing, the IFC does not support OEHHA's proposed PHG of 1 ppb for perchlorate in drinking water, and believes OEHHA should adopt the U.S. EPA's reference dose of 0.7 ug/kg/day. The RfD is well-established, applies to all populations including infants, and its adoption by OEHHA will ensure consistency across jurisdictions and minimize confusion. We appreciate the opportunity to comment on this matter. Please contact me with any questions.

Sincerely,

A handwritten signature in black ink, reading "Mardi K. Mountford". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mardi K. Mountford, MPH
Executive Vice President