

Baby Food Council

Charter

FINAL – NOT FOR DISTRIBUTION

May 21, 2019

The Baby Food Council is a group of infant and toddler food companies, supported by key stakeholders, seeking to reduce heavy metals in the companies' products to as low as reasonably achievable using best-in-class management practices.

Approved for public release by Baby Food Council on January 19, 2021.

Members and Advisors: The four baby food companies created the Baby Food Council in January 2019 with the assistance of Cornell University's College of Agriculture and Life Sciences (CALS) and the Environmental Defense Fund (EDF). The four companies are Happy Family Organics (a part of Danone), Beech-Nut Nutrition (a part of Hero) and Earth's Best (a part of The Hain Celestial Group), the Gerber Products Company. All are members of the Working Group.

In March 2019, Healthy Babies Bright Futures joined the Working Group and the Food and Drug Administration (FDA) and American Academy of Pediatrics (AAP) joined the Advisory Stakeholder Group.

See Appendix A for current list of members, advisors and project participants.

Organizational Structure

In its first year, the Baby Food Council will operate using an informal, unincorporated structure. After the first year, it will reassess this structure and anticipates adopting a more formal arrangement. Under this informal structure, the Council consists of three groups:

- Working Group;
- Advisory Stakeholder Group; and
- Project Participant Group.

All companies that source ingredients, manage the upstream supply chain, and nationally market foods for children six to 24 months of age in the United States are welcome to participate, as they determine appropriate, on either the Working Group or the Project Participant Group. To participate on the Working Group, they must contribute to the operating and project costs of the Council.

The Working Group invites key stakeholders representing the public health and agricultural communities to participate based on their scientific and health expertise. These stakeholders may be invited to serve on one of the three groups as appropriate. They and other experts may also be informally engaged.

Overall Approach:

After reviewing the data from various sources including FDA's Total Diet Study results for 2014 to 2016 for heavy metals and preliminary estimates of children's cumulative exposure to lead in food, the Working Group for the Baby Food Council decided to:

- Begin with lead as the priority heavy metal and consider potential impacts on arsenic, cadmium, mercury, and other contaminants as well as nutrients.
- Treat the heavy metals as an unavoidable contaminant that should be manageable by admitting their presence, acknowledging no known safe level in the food supply, and striving to drive the levels as low as reasonably achievable using best-in-class management practices.

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- Prioritize ingredients most commonly used in infant and toddler food and the lead concentration shown in the FDA data.
- Identify laboratories capable of accurately analyzing heavy metals in foods and ingredients.

Responsibilities and Membership of Each of Three Groups:

- **Working Group:** The Baby Food Council is led by a group of individuals representing organizations with a strong interest in the issue and willing to commit the resources needed to fully participate in the Council's deliberations, decisions and the project's efforts. The Working Group's responsibilities include:
 - Making consensus decisions regarding the project;
 - Securing necessary funding for the effort;
 - Developing sampling, evaluation, and communication plans;
 - Overseeing plan implementation, including sharing of test results;
 - Analyzing the data and drafting reports;
 - Engaging Advisory Stakeholder Group; and
 - Keeping other stakeholders, such as the broader public health community, consumer organizations, private brands, and crop producers informed of the project as appropriate.

All Working Group participants must sign a common non-disclosure agreement (NDA) and anti-trust guidelines. An attorney with experience in anti-trust law reviews agenda and notes and, as necessary, participates in all meetings to ensure compliance with relevant laws. CALS serves as facilitator and convener. EDF serves as project coordinator.

- **Advisory Stakeholder Group:** The Working Group has convened a group of advisory stakeholders to:
 - Review and provide feedback on proposals and reports as requested; and
 - Share perspectives with the Working Group as appropriate.
- **Project Participant Group:** The Working Group will convene a group of companies who only want to participate in the testing, pilot project, and data-sharing but do not wish to be members of the Working Group. The initial invitees will consist of infant and toddler food companies and selected sweet potato and carrot producers with a presence in the U.S. market.

Background on Baby Food Council:

In November 27, 2018, CALS convened a meeting of EDF and four baby food companies: Danone's Happy Baby, Hero's Beechnut, The Hain Celestial Group's Earth's Best, and the Gerber Products Company. At that meeting, participants agreed to:

- Pursue a joint effort
- Meet in January to decide how best to proceed.

At the January 2019 meeting, they agreed to:

- Establish an informal organizational structure
- Invite other companies and stakeholders to participate
- Undertake a first-year-effort to conduct ingredient and product testing and evaluate best practices to reduce lead in carrots and sweet potatoes.

In February 2019, they finalized the organizational structure and invited others, including three other national infant and toddler food companies, to participate. HBBF agreed to join the Working Group, and FDA and AAP agreed to join the Advisory Stakeholder Group.

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In March 2019, the Working Group met, with FDA as advisor, and agreed to:

- Establish a Charter
- Undertake an effort to identify and evaluate laboratories to test materials for heavy metals
- Share results of unpublished studies they have conducted regarding heavy metals in sweet potatoes and carrots
- Refine pilot projects.

Background on the Issue of Heavy Metals in Food:

In May 2017, the Food and Drug Administration (FDA) announced it had “established a [Toxic Elements Working Group](#) whose mission in part is to develop a strategy to prioritize and modernize its activities with respect to food/toxic element combinations using a risk-based approach” and set a goal of limiting lead contamination “to the greatest extent feasible.”

In April 2018, FDA provided an update on the Working Group’s activities. The Working Group would focus on children’s exposure to “metals like [lead, arsenic, cadmium, and mercury in foods, cosmetics, and dietary supplements](#).” The agency explained that “Even though the level of a metal in any particular food is low, our overall exposure adds up because many of the foods we eat contain them in small amounts.” Therefore, rather than looking at one food at a time, the Working Group would look at all the metals across all foods. Two short-term actions were “finalizing the draft guidance that sets an action-level for the presence of inorganic arsenic in infant rice cereals and apple juice” and “begin reevaluating the specific lead levels that FDA has set for a variety of foods.”

In September 2018, without fanfare, FDA [reduced the maximum allowed daily intake of lead](#) for children from 6 to 3 micrograms per day ($\mu\text{g}/\text{day}$). The agency now refers to this limit as the “Interim Reference Level” to match the Centers for Disease Control and Prevention’s (CDC) terminology for [elevated blood lead levels](#) that warrant action. If CDC lowers its definition of an elevated blood lead level from the current 5 to 3.5 $\mu\text{g}/\text{dL}$ as expected, FDA is anticipated to lower its reference level proportionally to 2 $\mu\text{g}/\text{day}$.

Environmental Defense Fund (EDF), using FDA’s Total Diet Study results for samples collected in 2014 to 2016, estimated that just under 5% of children ages 0 to 6 years of age—[about 1.3 million children](#)—currently consume more than 3 $\mu\text{g}/\text{day}$ of lead in their food. EDF’s analysis indicate that 5.6 million children aged 0 to 6 – or just over 20% of young children – would exceed 2 $\mu\text{g}/\text{day}$. Children younger than six are most vulnerable to harm from lead.

Reports from [EDF](#), [Consumer Reports](#) and [Healthy Babies Bright Futures](#) (HBBF) have highlighted potential concerns with heavy metals in infant and toddler foods. More broadly, the [American Academy of Pediatrics’ \(AAP\) Council on Environmental Health \(COEH\)](#) has highlighted the negative impact of heavy metals intake on children’s growth and development.

As part of its ongoing commitment to reducing contaminants in baby food, leading infant and toddler food companies have chosen to work collaboratively to accelerate their ongoing efforts to reduce heavy metals in their products to as low as reasonably achievable using best-in-class management practices.

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Appendix A Members, Advisors, and Participants in Baby Food Council

As of April 15, 2019, the following are the members, advisors and project participants in the Baby Food Council:

A. Members:

1. Beech-Nut Nutrition Company*
 - Represented by Jason Jacobs Vice President, Quality and Technical Services, with support from Tara Nielsen, Food Safety Manager
2. Campbell Soup Company
 - Represented by Tracy Hicks, Program Manager – Global Analytical Chemistry, with support from Jeffrey Ragasa, Quality Program Manager
3. Cornell University*
 - Represented by Randy Worobo, Professors in College of Agriculture and Life Sciences, with support from Matthieu Stratton and Motoko Mukai, Assistant Professor
4. Environmental Defense Fund*
 - Represented by Tom Neltner, Chemicals Policy Director, with support from Boma Brown-West, Senior Manager of Consumer Health
5. Gerber Products Company
 - Represented by Cheryl Callen, Senior Director of Regulatory Affairs, with support from Joel Lim, Medical Director Nestle Infant Nutrition
6. Earth's Best (The Hain Celestial Group)*
 - Represented by Allison Milewski, Senior Director of Quality Systems, with support from Gary Korb, Director of Technical Services
7. Happy Family Organics*
 - Represented by Jason Rosecast, Vice-President for Quality
8. Healthy Babies Bright Futures
 - Represented by Charlotte Brody, National Director, with support from Jane Houlihan, Research Director
9. Sprout Nutrition
 - Represented by Rick Klauser, Chief Executive Officer, and Sunita Adams, Vice-President of Marketing

B. Advisors

1. Food and Drug Administration
 - Represented by Conrad Choiniere, Director of the Office of Analytics and Outreach at FDA's Center for Food Safety and Applied Nutrition
2. American Academy of Pediatrics
 - Represented by Aparna Bole, Chair of AAP's Council on Environmental Health, with support from Zach Laris and Lucas Allen

C. Project Participants

1. *None other than member at this time*

* Founding members of Baby Food Council.