Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket: FDA-2016-D-1099

RE: Inorganic Arsenic in Rice Cereals for Infants: Action Level; Draft Guidance for Industry; Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants; Arsenic in Rice and Rice Products Risk Assessment: Report; Availability

To whom it may concern:

The Organic Trade Association (OTA) and the Organic Rice Working Group (ORWG) are pleased to submit comments on the Food and Drug Administration (FDA) Action Level, Draft Guidance, Supporting Document, and Risk Assessment regarding Inorganic Arsenic in Rice and Rice Products.

OTA is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

First, OTA and the ORWG thank the FDA for the willingness to work collaboratively with us on this issue over the last number of years. This collaboration ensured proper consideration of the organic industry and consumers as the guidance was being developed. In particular, we appreciate being part of the conversation regarding the most effective way to communicate to consumers. The FDA's April release regarding Inorganic Arsenic in Rice and Rice Products thoughtfully incorporated much of the feedback we provided around how consumers – and particularly organic consumers – hear messages from the government regarding the food they purchase.

Second, we appreciate that the FDA simultaneously developed and released a Risk Assessment and Draft Guidance. This approach creates trust among consumers, industry, and regulatory agencies and ensures confidence in the safety of our food.

We have several key recommendations for consideration prior to the finalization of these documents.

Headquarters - The Hall of the States, 444 N. Capitol St. NW, Suite 445-A, Washington, D.C., 20001 • (202) 403-8513
Member Services - 28 Vernon St., Suite 413, Brattleboro VT 05301 • (802) 275-3800 • fax: (802) 275-3801
www.OTA.com

Recommend that the RACC for dry instant infant cereal be changed from 4T to 2T to reflect actual consumption behavior

With respect to the Action Level for Inorganic Arsenic in Rice Cereals for Infants, OTA and the ORWG support FDA's decision to set an action level at the finished product level, rather than the ingredient level. This is a sensible approach, as it provides clarity to industry and to consumers around the products they are buying – rather than requiring consumers to extrapolate from an ingredient level.

We recommend that the FDA reduce the Reference Amount Customarily Consumed (RACC) for dry instant infant cereal from 4 tablespoons to 2 tablespoons to reflect actual consumption behavior (21 CFR 101.12). The typical feeding behavior, as indicated on package, is to mix 1 T dry cereal of the 4 T recommended serving size with 3-4 T of breast milk or formula to reach a desired consistency. This can be adjusted with more cereal or less liquid over subsequent feedings. This feeding regime is short-lived, as by 6 to 8 months of age, infants move onto pureed fruits and vegetables, which may or may not be combined with baby cereal. This rapid change in consumption behavior is reflected in results from the Nestlé Feeding Infants and Toddlers Study (2004) which show that the percentage of daily energy from baby cereal peaks at 29% at 7-8 months of age, and by age 19-24 months, infants obtain 63% of energy intake from table food.

Because of this, a sensible approach would be to ensure that the RACC reflects actual consumption behavior, taking into account the short time that infants receive much of their daily energy from baby cereal. A RACC of 2 tablespoons would more accurately reflect actual consumption behavior, and give parents additional guidance as they make the best feeding choices for their infants.

Recommend that a discussion of alternative risk models be included in the Draft Guidance

We are concerned about the use of a linear risk model without discussion of other risk models. Several modes of action of arsenic's carcinogenicity have been investigated, and while some hypotheses suggest a linear model, there is also evidence for modes of action that clearly support a non-linear, threshold dose-response relationship for the deleterious effects of arsenic (Cohen *et al*. 2013)[1]. We are concerned that by adopting the linear risk model in the Draft Guidance without acknowledging the evidence supporting alternative modes of action and threshold risk models, the linear risk model could become the de facto standard. As there is no clear scientific consensus on the most appropriate risk model we recommend including a discussion of these alternatives in the Draft Guidance.

[1]Cohen, S.M., Arnold, L.L., Beck, B.D., Lewis, A.S., Eldan, M. (2013). Evaluation of the carcinogenicity of inorganic arsenic. Critical Reviews in Toxicology. 43(9): p. 711-752. DOI: 10.3109/10408444.2013.827152

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Recommend that FDA develop a methodology for testing inorganic arsenic

One key issue of concern is that analysis of inorganic arsenic in rice can be highly variable across laboratories, given the different methodologies used. When you consider this, in addition to the high cost of existing methodologies of testing, the level of confidence in that testing is not high. We of course support meeting the standards that CODEX and the FDA set – and recognize that this will be more feasible with a consistent, reliable, and cost-effective testing methodology in place. We encourage the FDA to develop a methodology for testing inorganic arsenic that will be used consistently across laboratories, and considers reliability, cost, duration, and availability to industry. We also support the development of criteria for appropriate methods of analysis, and the creation and maintenance of a list of labs that meet the required qualifications. This will ensure consistency among results across the rice industry and all products, and will encourage the development of more efficient technologies and allow for their adoption as they become available.

Encourage FDA to establish a level for inorganic arsenic in white and brown rice that reflects CODEX limits

Finally, we encourage FDA to move toward the development of a maximum limit for inorganic arsenic in white and brown rice that is in harmony with CODEX recommendations, which will support stable and predictable international trade.

OTA and the ORWG are pleased to see that the FDA has moved forward with a Risk Assessment and Draft Guidance, and we urge the agency to take our comments under advisement as you continue to move through the process.

On behalf of our members across the supply chain and the country, OTA thanks the Food and Drug Administration for the opportunity to comment.

Respectfully submitted,

Marni Karlin
Vice President of Government Affairs/General Counsel
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

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