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

Re: Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry (FDA-2022-D-0278)

Dear Sir or Madam,

The Food Industry Association (FMI) appreciates the opportunity to comment on the U.S. Food and Drug Administration's (FDA's) Draft Guidance, "Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry." As the food industry association, FMI works with, and on behalf of, the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as a wide variety of companies providing critical services — to amplify the collective work of the industry. Read more about us at www.FMI.org.

FMI appreciates the Draft Guidance and the transparency that comes with FDA providing stakeholders with insight into the agency's current thinking on important topics like its Closer to Zero initiative and associated efforts to reduce exposures to ubiquitous environmental contaminants, including lead, that affect our food supply. FMI supports the goals of the draft guidance and the fundamental components of the Closer to Zero framework.

In the comments that follow, we raise the following considerations:

- FDA is uniquely positioned to undertake the highly complex, multi-factorial analysis necessary to establish action levels that are not only scientifically sound and meaningful, but achievable in practice throughout the food supply chain starting with production.

- FMI appreciates FDA's recognition of lead's ubiquity in the broader environment and the challenges involved in controlling its presence in agricultural products and urges FDA to recognize explicitly that the factors that contribute to lead in food are present throughout the growing regions of the U.S. and the world, but that their impact varies by geographic region and commodity.
- Setting action levels for lead in foods requires FDA to consider the full range of potential consequences that may flow from adopting them, including consumption, supply chain, and market impacts.
- FMI urges FDA to modify the Introduction and Background sections of the draft guidance to focus more clearly and explicitly on the objective at hand, reducing the exposure of a specific subpopulation, namely babies and young children, to lead from foods and, in so doing, mitigate the risk that consumers mistakenly understand the guidance as extending to the general population, negatively affecting dietary choice/quality.
- FMI encourages FDA to include a more fulsome discussion of the rationale underlying the action levels in the final guidance and, before finalizing the action levels, urges FDA to consider the limitations of the data set underlying the proposed levels, particularly with respect to achievability.
- FMI strongly encourages FDA to provide substantially more guidance and best practice resources to assist the entire affected supply chain in mitigating and minimizing lead in the foods covered by the draft guidance and, by extension, the raw agricultural commodities (RACs) and ingredients used to make them. The draft guidance states that the action levels are intended to be achievable when control measures are used to minimize the presence of lead. This is not possible without research and widespread translation of science to educate producers and processors on effective practices. FDA, USDA, research scientists and the food and agriculture industries need to work together to share information, collaborate, educate, and communicate to reduce exposure.
- FDA should provide at least a two-year phase-in period to allow for necessary adaptation across affected supply chains once mitigation factors are identified and communicated.
- FDA should collect additional data on current levels of lead in foods intended for babies and young children to address the challenges with low sample sizes and high variability of levels in the samples, especially for root vegetables, vegetables, infant cereals and mixtures since the standard deviations of those categories are well above values typically accepted by the scientific community.

- FDA should, as part of its Closer to Zero framework, develop enhanced consumer messaging to provide greater context around action levels and how the levels relate to consumption of such products including risk communication messaging and overall information about dietary recommendations consistent with the *Dietary Guidelines for Americans*.

FMI Supports the Goals of the Draft Guidance and FDA's Overall Framework for Achieving Them

FMI shares FDA's goal of reducing the exposure of babies and young children less than two years old to lead from foods, where such reductions are achievable and commercially feasible. We also support the fundamental components of the Closer to Zero framework that FDA brings to this important work. Setting action levels for ubiquitous environmental contaminants that cannot be entirely avoided through the use of good manufacturing practices is a complex task. We applaud FDA's commitment to addressing this challenge with a risk-based approach that is grounded in science, accounts for achievability, and recognizes that reducing exposure is an iterative process focused on continual improvement over time.

We encourage FDA to continue to cultivate an open, transparent approach to its work in relation to Closer to Zero. It is imperative that FDA solicit data and information available and ongoing research from stakeholders across the value chain at every opportunity and that it carefully evaluates all the data it receives before drawing conclusions or finalizing levels. Where data does not exist or is limited, FDA should work with stakeholders (USDA, scientific researchers, production agriculture and the food industry) to obtain information through research that produces statistically significant results with reliable data that is representative and of the appropriate sample size prior to making any determination regarding action levels. We firmly believe this kind of "deep data" approach will sharpen all aspects of the agency's analysis, particularly with respect to achievability.

FMI also shares FDA's sense that action levels are a useful regulatory tool that has been deployed successfully in the past to lower levels of unavoidable contaminants in the environment that affect the food supply. Leveraging the legal authority granted to it by Congress under the Act (Sections 402, 406, 701(a)), FMI believes FDA is uniquely positioned based on this experience, as well as its scientific expertise to undertake the highly complex, multi-factorial analysis necessary to establish action levels that are not

only scientifically sound and meaningful, but achievable in practice. Federal leadership on a multi-faceted challenge of this nature is also crucial to avoid a patchwork of state and local requirements that may be hastily conceived, lack scientific foundation, and typically encourage frivolous class action litigation. In short, food manufacturers need the clarity and certainty federal standards provide to deliver the stable and affordable food supply American consumers have come to expect.

FMI Appreciates FDA's Recognition of Lead's Ubiquity in the Broader Environment and the Challenges Involved in Controlling Its Presence in Agricultural Products

FMI appreciates FDA's recognition in the Background section of the draft guidance that lead is widely present in the environment, particularly in soil, water, and through atmospheric deposition, and, as a result, may occur in small amounts in food crops. We urge FDA to expand its discussion and consideration of this point in the final guidance and recognize explicitly that the factors that contribute to lead in food are present throughout the growing regions of the U.S. and the world, but that their impact varies by geographic region and commodity. These factors simply do not affect all growing regions and commodities to the same degree. As a result, baseline levels of lead in agricultural crops will vary depending on growing media, location, and supply chain infrastructure. Thus, what may be achievable in a finished product using available control measures in one region may not be achievable in another.

Setting Action Levels for Lead in Foods Requires FDA to Consider the Full Range of Potential Consequences That May Flow from Adopting Them

FMI appreciates FDA's recognition during its recent webinar that setting appropriate action levels for lead in foods specifically intended and represented for babies and young children is a complicated undertaking. The multifactorial nature of the work extends beyond determining the levels of lead currently present in those foods and the exposure of babies and young children to them. It must anticipate and account for the broader consequences of adopting the action levels, including unintended, but nonetheless foreseeable, consequences. The benefits of the expected reductions in exposure must be weighed carefully against the full range of implications and likely costs to the broader food system. As discussed more fully below, FMI believes those costs and implications include:

- Communication Concerns: FDA must carefully evaluate whether and how action levels may affect product availability and dietary choice. Careful framing of the risks posed by background levels of lead that affect the food supply will be critical in mitigating the potential of final action levels to discourage the consumption by both babies and young children and the general population of nutrient dense foods (e.g., fruits, vegetables) that are encouraged by the *Dietary Guidelines for Americans.*

- Supply Chain Resiliency: FDA must carefully evaluate the impact that action levels will have on the operation of global supply chains, including the potentially disruptive effect of different standards across geographies.

- Market Impacts for Commodities Used in Both Covered and Non-Covered Foods: FDA must carefully evaluate the potential disruptive impacts the action levels may have not only on the markets for commodities used in products covered by the action levels but on those that are not, as well as the potential for an increase in food waste.

FMI Urges FDA to Modify the Draft Guidance to Emphasize Its Focus on Babies and Young Children, Mitigating the Risk of Consumer Misunderstanding

FMI urges FDA to refine the final guidance to focus more closely and clearly on the specific issue at hand, i.e., reducing the exposure of babies and young children under two years old to lead. This will ensure consumers do not misunderstand the guidance as applying more broadly to the general population, an outcome which could affect dietary choice and quality in a negative way. We recommend the following specific steps:

- Modify the Introduction by:

    - Eliminating references to "toxic elements." The final guidance and action levels address lead, which should be described and referred to as such.
    - Clarifying that the action levels are the levels of lead at which FDA may regard foods specifically intended and represented for babies and children under two years old to be adulterated under 402(a)(1), taking into account the full range of relevant factors on a case-by-case basis.

- Modify the Background discussion by:

    - Revising the discussion to ensure all statements regarding the health impacts of lead focus directly on the subject and objectives of the final guidance, i.e., babies and children under two. Statements regarding the health impacts of lead on other populations and subpopulations are not relevant and potentially confusing to the broader population.
    - Eliminating references to "toxic elements" as per the discussion above regarding the Introduction. Descriptions of FDA's broader Closer to Zero initiative and its elements may be appropriate in other agency communications but not in the final guidance, which by its nature is a more narrowly focused undertaking with a very specific objective, i.e., reducing the exposure of babies and young children under two years to lead from a specific set of finished food products.
    - Modifying the discussion about potential control measures available to manufacturers to clarify that the action levels do not mandate or otherwise change expectations regarding finished product and/or ingredient testing for manufacturers. The role of testing is governed by the agency's Preventive Controls rule, which requires manufacturers to evaluate the potential for hazards in their processing operations and supply chains. To the extent a facility determines that lead presents a hazard requiring a preventive control, it may look to finished product and/or ingredient testing as an appropriate verification activity to ensure control measures are implemented and effective, but that determination necessarily will vary from facility to facility depending on the facility's overall food safety system and related factors. See, e.g., 21 CFR Section 117.165(a); 117.410(d).
    - Putting the proposed action levels in context for non-scientific readers by explaining that exposures to lead from food constitute a very small part of overall lead exposures across the population; units of measurement (parts per billion and parts per million) in addition to interpretation of levels related to consumption amounts of products subject to the action level are needed to help communicate this complex issue.

- Sharpen Communication Concerning Scope by:

    - Including more substantive direction in the final guidance as to what constitutes a food intended for babies and young children. Specifically, we urge FDA to recognize explicitly that foods not labeled with an infant or child nutrition label (21 CFR § 101.9(j)(5)) are not intended for babies and young children and, thus, are outside the scope of the final guidance.
    - Incorporating all discussions about scope into the body of the document, not in footnotes, as is the case in the draft.
    - Stating clearly in the final guidance that the action levels are used to evaluate covered finished products and do not apply to raw agricultural commodities or other ingredients that may be used in manufacturing the covered finished products.
    - Stating explicitly in the final guidance and in the materials that accompany its release that the action levels are not dietary advice and should not be treated as such by parents of babies and young children or consumers more generally.
    - Resolve in future Closer to Zero-related documents to incorporate references to updated Food Chemicals Codex specifications and standards, where relevant and applicable, to promote common understanding across industry and facilitate rapid adoption.

FMI Encourages FDA to Include a More Fulsome Discussion of the Rationale Underlying Establishment of The Action Levels in the Final Guidance

FMI understands that a special focus on the levels of lead in foods specifically intended and represented for babies and children under two is warranted because this population's low body weight and stage of developmental progression make them more vulnerable to potential adverse neurodevelopmental impacts from lead. It is for this reason that FDA has established an IRL that includes babies and children under two, as well as women of childbearing age (to protect against fetal exposure), but not for the general population which does not share this susceptibility nor have such a highly concentrated diet.

As FDA recognizes, consumption patterns and reliable data about those patterns play a foundational role in the complex process of setting action levels. For babies and young children under two, these patterns are fundamentally different than those of the general

population, whose diets are far more varied. We encourage FDA to address these points in its final guidance to ensure the rationale underlying its decision to establish action levels for the covered foods is clear.

Likewise, we encourage FDA to acknowledge in the final guidance, that because of their varied diets, establishing action levels for foods consumed by older children and the general population would not only present a far more complex undertaking from an analytical perspective, but that the public health value of such an action is unclear given the lack of evidence that current exposure levels to lead are harmful and the lack of physiological outcomes due to lead exposure in the general public.

In addition to explaining in more detail why these action levels are focused on babies and children under two, we also encourage FDA to provide a fuller explanation of how FDA will apply them in practice, if finalized. FDA states in the Background section of the draft guidance that "no safe level of lead exposure has been identified for protecting children's health." FMI urges FDA to provide context for this statement by explaining in close proximity that, although there may be no "safe" threshold level of lead for babies and children under 2, the action levels are not a recognition that any particular level of lead is "unsafe" in any particular product. As FDA has noted in other forums, including during its recent webinar held to explain the draft guidance, the question of any particular product's safety and legal status under the Act is a multifactorial one, and action levels, to the extent they apply to a product, are only one factor the agency considers in evaluating that question.

Finally, before finalizing the action levels, we urge FDA to consider the limitations of the data set underlying the proposed levels, particularly with respect to achievability. By way of example, for root vegetables, FDA based its achievability determination (Table 2) on only 51 data points with a mean and standard deviation of 8.5 ± 8.4 ppb; and the broad category of dry infant cereals had just over 300 samples with a mean and standard deviation of 8.3 ± 8.8 ppb. In fact, five out of the seven categories in both Table 2 and Table 3 had standard deviations greater than the mean which indicates the data has a high level of variability and is simply not acceptable for drawing conclusions. Larger sample sizes are needed to provide more accurate results and to more effectively assess achievability. Although FDA did not propose an action level for grain-based snacks, we question how a total of 166 data points for such a diverse category would be adequate to support an achievability determination in the 90% plus range.

In addition, FDA's achievability analysis rests exclusively on this small set of quantitative values and ignores the potential impact of differences in lead's incidence in the environment by growing region and the variability of growing conditions across growing seasons, as well as the susceptibility of individual commodities to that lead, which necessarily affect the feasibility of achieving lower levels in finished products on a consistent basis. We strongly encourage FDA not only to obtain more data points to confirm its conclusions regarding achievability but to ensure the data come from a representative cross-section of growing regions and seasons, taking into account regional differences in local conditions. Absent this approach, we question how FDA can have confidence the levels are truly achievable and on a consistent basis.

More Guidance and Input from FDA is Needed to Support Efforts Across the Supply Chain to Mitigate Lead and Protect Already Fragile Global Supply Chains

FMI strongly encourages FDA to provide substantially more guidance and best practice resources to assist the entire affected supply chain in mitigating and controlling lead in the foods covered by the draft guidance and, by extension, the RACs and ingredients used to make them. Specifically, we urge FDA to convene an expert panel with membership representing the full range of relevant disciplines (e.g., academia, agronomists, geologists, toxicologists, supply chain professionals) to identify commercially feasible short and longer-term actions that can be implemented to (1) reduce and manage lead content; (2) estimate the reductions in lead content these actions can reasonably be expected to achieve.

As part of its work, the expert panel should consider global and US regional differences in soil, environmental conditions, and supply chain infrastructure that may affect lead levels in crops grown or processed in those countries and regions, using United States Geological Survey maps and comparable international resources, where relevant, as references in structuring the inquiry. In identifying and recommending short and longer-term reduction measures, the panel should specifically consider the fact that contaminants like lead are unevenly distributed in RACs, adding to the challenge of implementing mitigation and control strategies that can achieve target levels on a consistent basis. The importance of the agriculture industry cannot be overstated in this conversation as many of the mitigation strategies are at the production level. Awareness, education, and translation of the science regarding effective strategies will be necessary to reduce exposure.

To further support the supply chain's ability to implement final action levels as rapidly as possible, we urge FDA to be transparent and direct about analytical methodology used to analyze lead in foods intended for babies and young children. FDA should identify and publish sample collection methods as well as analytical methodologies to help standardize and advance detection. Since methods are always improving in sensitivity and accuracy, FDA should allow for advances in analytical chemistry to be used as additional methods are validated. Recognized methods should include information on appropriate sampling protocols, measuring lead levels in the covered finished products, analysis of results and interpretation of data for finished product as well as in typical/common inputs in those products.

Finally, we urge FDA to consider how the action levels it adopts for lead as well as other contaminants in the future may impact supply chains that are truly global in nature. Differences in standards across geographies have the potential to add stress to already fragile, easily disrupted supply chains.

FDA's Analysis Fails to Account Fully for Potentially Disruptive Market Impacts Across the Broader Food Supply Chain

As discussed above and throughout this comment, achievability is a critical component of arriving at an appropriate action level for lead or any other contaminant that is widely present and cannot be entirely avoided. For the reasons discussed earlier, FDA's evidence that 90%+ of the covered foods already meet the proposed action levels seems thin, at best, to us. We urge FDA to collect and/or develop significantly more data to ensure its achievability conclusions are accurate and reliable.

In addition to this important step, we encourage FDA to consider more deeply and in greater detail the potentially disruptive impact the action levels may have on the broader market for commodities. As a threshold matter, action levels that are not commercially achievable may limit product choice for parents of babies and young children under two. Given regional differences in growing conditions, manufacturers may have to prune product portfolios or ration or discontinue products in specific areas where lead contamination rates in soil and water are higher. USDA is a key stakeholder in this conversation as action levels for lead in foods for babies and young children might impact the supply and demand for food crops and influence regional production patterns.

We stress as well that potential disruptions are likely to extend beyond the portion of the market that serves babies and young children. Tighter procurement specifications for materials intended for use in foods covered by the final guidance may result in higher average levels of lead in materials used outside that sector. Certainly, tighter specifications for covered products and, in turn, the broad array of raw materials used in their production will increase rejections for nonconformance, increasing food waste and stressing supply chains across the general food supply. Again, we urge FDA to consider these points and carefully reconsider the proposed action levels in light of the full range of follow-on implications before progressing to a final set of values.

FDA Should Provide at Least a Two-Year Phase-In Period to Allow for Necessary Adaptation Across Affected Supply Chains

The draft guidance does not raise the possibility of a phase-in period to give all nodes in the affected supply chain time to identify and fully implement control measures to meet the action levels once finalized. FMI members estimate it will take at least two years for all affected entities to make the necessary adjustments to controls as well as to move current materials through to finished product production.

We appreciate your consideration in these comments and welcome any questions you may have.

Sincerely,

Hilary S. Thesmar

Hilary S. Thesmar, PhD, RD, CFS
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