FDA Webinar: Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance

March 2, 2023

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>> Good afternoon and welcome to Closer to Zero Stakeholder webinar on the Draft Guidance for action levels for led in food intended for babies and young children.

I will hand it over to Jess Rowden. Take it away.

>> JESSICA ROWDEN: Thank you, Michael and welcome to today's webinar. I will serve as the moderator. During our webinar, we will provide an overview of the Draft Guidance and answering Stakeholders questions. First, I want to introduce the speakers.

We will hear from Dr. Susan Mayne, Director of the Center for Food Safety and Applied Nutrition, she will provide opening remarks.

And Dr. Paul South, Director of the Division of Plant Products and Beverages, Office of Food Safety. He will provide overview of the guidance.

And we will hear from Dr. Conrad Choiniere, Director of the Office of Analytics and Outreach. And he will speak on the Closer To Zero initiative.

We will have a Q&A. If you have a question, e-mail us at Closer2Zero@fda.hhs.gov. That is closer2zero@fda.hhs.gov.

With that, let's begin with remarks from Dr. Susan Mayne.

>> DR. SUSAN MAYNE: Welcome everyone. Thank you so much for joining us today. I'm glad we have this opportunity to present the guidance on industry for action levels for lead --

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>> DR. SUSAN MAYNE: Welcome everyone. Thank you so much for joining us today. I'm glad we have this opportunity to present our guidance for Action Levels for Lead in Food Intended for Babies and Young Children and also to answer some of your questions.

The draft guidance supports the FDA's goal of reducing dietary exposure to lead, arsenic, cadmium and mercury and the associated health effects, while maintaining access to nutritious food.

Work in this area has been, and continues to be, a priority for us. We are committed to a science driven, transparent, inclusive, and iterative process. It is a comprehensive process that includes many steps including Stakeholder engagement. This can take time to reach milestones, but this process also helps to ensure that all relevant information and data are considered to find effective ways to address the complex issue.

FDA considers the action levels described in this guidance to be achievable by industry when control measures are taken to minimize the presence of lead. Although action levels are levels at which FDA may regard a food to be adulterated, out Closer To Zero action plan outlines other actions we will take to further reduce lead and other toxic elements in food and our expectation is that industry will strive for continual reductions over time.

Food covered by the Draft Guidance includes processed food, such as food packaged in jars, pouches, tubs, and boxes and intended for babies and young children less than 2 years old.

Lead may be present in these foods because agricultural commodities they are made from including fruits, vegetables, grains and animals take up contaminants in the environment in much the same way they take up nutrients. While it is not

possible to remove lead entirely from the environment or the food supply, it is possible to lower lead levels in food.

To identify the action levels, the Agency considered, among other factors, the level of lead that could be in food without dietary exposure exceeding FDA's Interim Reference Level of 2.2 micrograms per day.

The Draft Guidance is containing the following action levels: 10 parts per billion for fruits, vegetables except single ingredient root vegetables, mixtures including grain and meat based mixtures, yogurt, custards, puddings and single ingredient meats. And the other action level is 20 ppb for root vegetables single ingredient and for dry cereals. Those levels go further than the European Union's lead standard of 20 ppb in cereal-based baby foods.

For babies and young children who eat the foods covered in this draft guidance, the FDA estimates that these action levels could result in as much as a 24-27% reduction in exposure to lead from these foods. The FDA will monitor industry's progress in reducing the levels of lead in the foods identified in this draft guidance, while ensuring that manufacturers are putting in place any needed preventive controls to reduce or prevent the presence of lead in their products.

In addition, we will continue to evaluate scientific advances in levels of lead in foods and the role nutrition plays in reducing the health impact of lead exposure. Before finalizing the action levels, we will consider Stakeholder comments and data to determine if further adjustments are needed. We are still accepting comments on the docket on this draft guidance until March 27th. To make sure comments are considered please submit before this date.

As I have said before, reducing levels of toxic elements in foods is complicated and we cannot do this work alone. We are committed to ongoing work with federal partners, industry, and consumer and health advocates on our shared goal of reducing consumer exposure to toxic elements from food. We've seen in the more than 30 years since we have been working to reduce lead exposure, there has been a dramatic decline in exposure from foods since the mid-1980s.

The proposed action levels, along with our continued work with Stakeholders, will result in long-term, meaningful, and sustainable reductions in the exposure to this contaminant from foods. With that, I would like to thank you for your time today. I will turn it over to Dr. Paul South who will give us an overview of the Draft Guidance.

>> DR. PAUL SOUTH: Thank you. Good afternoon my name is Dr. Paul South. I'm a Director in the Office of Food safety. Today I like to provide an overview of the draft guidance for industry on action level of lead and food intended for babies and young children. This guidance document was issued by FDA on January 24, 2023 and informs industry on proposed actions levels of lead in a wide range of commercial foods for babies and young children. The proposed action levels will result of significant reduction in dietary exposure to lead while insuring the availability of nutritious food.

The Draft Guidance including the proposed action levels are part of FDA's Closer To Zero plan which sets forth the FDA's science-based approach to continually reduce exposure to lead, arsenic, cadmium, and mercury to the lowest level possible in foods intended for babies and young children. Next slide, please.

The FDA considers the proposed action levels described in the guidance to be achievable by industry when control measures are taken to minimize the presence of lead. The purpose of the presentation is to present these proposed action levels and the background and rationale for setting them.

Consistent with what is found in the Code of Federal Regulations Title 21 section 109.6(d) these action levels reflect levels of lead which FDA may regard foods as adulterated within the meaning of Section 402(a)(1) of the Federal Food and Cosmetic Act. We intend to consider these action levels and other factors when considering whether to bring enforcement action in a particular case. In general FDA guidance documents do not establish the legally enforceable responsibilities, instead guidance is described FDA's current thinking on the topic and should be viewed as recommendations unless specific regulatory or statutory requirements are cited. The use word of the should in FDA guidance means that something is suggested or recommended but not required. Next slide, please.

FDA has worked on issues related to toxic elements in the food supply for several decades. In 2017 FDA created a working group that identified priorities in the area. At that time four toxic elements, lead, arsenic, cadmium and mercury, were identified as priority contaminants due to the relative toxicity and prevalence in the food supply and the relative contribution to food at the source of exposure. At that time we prioritized young children because of the impact exposure to toxic elements can have on their development. As part of our approach as laid out in 2021 when FDA released the Closer To Zero plan the Agency confirmed its commitment to establishing action levels of toxic elements for food for babies and young children. Based on the science on health impacts

and mitigation techniques and impact from industry on achievability. We expect the draft action levels discussed today and the ones in juice announced in 2022 will result in lower levels of lead in the U.S. food supply. Next slide, please.

At the heart of the FDA's Closer To Zero plan is the cycle of continual improvement. This is a science-based iterative approach for gradually driving exposures from foods lower over time. We evaluate the current signs to develop a reference level. Although we may not be able to say the reference level is a safe level, it is a level we could rely on as a benchmark to measure exposure to foods. Reference levels guide the development of action levels for specific foods and categories of food. Actions levels are the levels of contamination in a food that could lead FDA to take action. For example, a recall of domestic food or detention of an imported food. We will propose action levels and get input from Stakeholders on current levels of achievability and feasibility to make reductions. We will adjust the levels based on the current science for managing the contaminants and finalize the action levels based on this information. Next slide, please.

Now, focusing on lead, this element is toxic to humans and affects people of any age or health status. Lead is especially harmful to vulnerable populations, infants, young children, women who are pregnant and their fetus as well as others with chronic conditions. Even low lead exposure do harm their development, specifically the brain and nervous system. Neurological effects of lead exposure during early childhood include learning disabilities, behavioral difficulties, and lowered IQ. Lead exposure may be associated with immunological, cardiovascular, renal, and reproductive and developmental effects. Because lead could accumulate in the body even low level chronic exposure is hazardous over time. Next slide.

Regarding occurrence lead is widely present in the environment due to natural occurrence and human activity. Because lead is present in the environment or crops or food intended for babies and young children are grown, various foods may contain low levels of lead. Potential sources of lead in food include contaminated soil where crops are grown, contaminated water, atmospheric deposition from industrial activities, and old lead containing equipment used to manufacture food. As a result of the first three sources, agricultural crops can take up lead from contaminated soil and water and that may be deposited to plant surfaces. Next slide.

Studies suggest that manufactures may be able to reduce lead levels in food by using practices such as peeling root vegetables as well as washing fruits and vegetables, particularly leafy vegetables. It is also possible in some cases where manufacturers who have found elevated levels in food or food ingredients intended for babies and young children to source food or food ingredients with low or no detectable lead levels. Manufacturers could consider increased testing of ingredients or finished products that are historically known to contain elevated lead levels. This is important for ingredients or finished products for food intended for babies and young children. Manufacturers could consider examining their facilities, processes, and equipment to ensure they are not contributing to lead in their products. Next slide.

This slide provides background information on actions taken by FDA and the international community involving lead in food. Briefly, in 2011 the WHO/FAO joint expert committee on food additives, or JEFCA, reassessed the safety of lead and concluded that it is not possible to establish a new provisional tolerable weekly intake or PTWI for lead that would be health protective. In 2018, FDA replaced the provisional tolerable daily intakes established in the early 1990s with its first interim reference level, or IRL. In 2022 FDA updated the lead IRL to reflect CDC's updated blood lead reference value and the recently published IRL is was used to inform the development of action levels found in this guidance. Next slide, please.

Developing the action levels FDA wants to ensure dietary exposure from the identified food does not cause babies and young children to exceed the interim reference level for lead, while still being achievable for manufacturers. Fruits, vegetables, excluding single ingredient root vegetables, mixtures, yogurts, custards and puddings, and single ingredients meats, all of which have low lead levels. Action levels are proposed at 10 parts per billion. For single-ingredient root vegetables and dry infant cereals, FDA expects that action levels of 20 parts per billion will minimize the likelihood of significant exposure to lead while also considering achievability. Next slide, please.

In developing the proposed action levels, FDA considered both the intake of the food and maximum level of lead that could be in the food without that is not causing the interim reference level to be exceeded. As part of the evaluation, FDA examined FDA toxic elements in food compliance program data, FDA survey data, and FDA TDS data collected between FY 2014-2020 to determine current lead levels in food for babies and young children.

TDS data was not used in exposure and achievability assessments because it is composite data. To examine the effect of the proposed action levels for food intended for babies and young children on lead exposure, FDA compared the estimated concentrations of lead in these foods and dietary exposure to lead in the foods with and without the action levels. To assess achievability or manufacturers' ability to achieve the action levels for lead FDA determine percentage of samples in each food category that fell at or below the proposed action levels. In the end we propose a higher draft action levels of 20 parts per billion for single ingredient root vegetables and dry infant cereals to minimize the likelihood of significant exposure to lead while also considering achievability. Next Slide.

On this slide is the summary of the data set used to develop the proposed action levels for lead in baby food. Data used from the toxic elements compliance level program included 356 baby food samples collected in FY 2008-2021. In addition, data used from FDA surveys included 147 baby food samples collected in FY 2013-2014 and 360 baby food samples collected in FY2021. Review of 688 samples of TDS data is in the draft guidance, however, because TDS samples are composite samples rather than individual samples they are not used in the exposure and achievability assessments. Next slide, please.

To examine the effect of the proposed action level for food intended for babies and young children on lead exposure FDA compared the estimated concentration of lead in these foods and dietary exposure to lead from these foods with and without the proposed action levels. On the table, removing all samples with lead concentrations greater than the proposed action level from the data sets resulted in a decrease in the estimated mean lead concentrations and the estimated dietary exposures from these foods. Upward bound percentile, or 90th percentile, was chosen as a health protective measure to account for babies and young children ages 0-23 months who consume larger amounts of food and would therefore have higher exposures. The proposed action levels for lead are estimated to result in reduction in lead exposure from consumption of these foods at the 90^{th} percentile consumption level for babies and young children as follows.

For fruits and vegetables, excluding single-ingredient root vegetables, mixtures, yogurts, custards, puddings and single-ingredient meats, there would be a 26% reduction in lead exposure. For single-ingredient root vegetables there would be a 27% reduction in lead exposure. And for dry infant cereals there would be

a 24% reduction in lead exposure. To determine achievability, or manufacturers' ability to achieve proposed action levels for lead, FDA determined the percentage of samples in each food category that fell at or below the proposed action levels. The achievability for each food category at the proposed action levels is in the 90th to 95th percentile range except single ingredient root vegetables that had a lower achievability of 88%. Next slide, please.

In conclusion, the proposed action levels are part of FDA efforts under the Closer To Zero to reduce exposure to toxic elements from foods eaten by babies and young children to the lowest possible levels. In our experience, action levels have been effective tools to encourage manufactures to lower the levels of contaminants in their products. We establish these action levels in consideration of our interim reference level for dietary lead and the action levels are achievable by industry when control measures are taken to minimize the presence of lead. We intend to consider the proposed action levels as an important source of information for determining whether food intended for babies and young children is adulterated within the meaning Section 402(a)1 of the Federal FD&C Act. We are accepting comments on the Draft Guidance until March 27, 2023. A manufacturer may choose to implement the recommendations in the draft guidance before the guidance becomes final. In addition to establishing action levels for lead in baby foods, FDA will work with manufacturers of the products to encourage the adoption of Best Practices to lower levels of lead in foods intended for babies and young children. Next slide, please.

I will end there. I like to introduce Dr. Conrad Choiniere who will provide additional information and comments on the draft guidance document. Thank you.

>> DR. CONRAD CHOINIERE: Thank you, Paul. And thank you all for being here today to allow us to provide information about our guidance.

Before we start to take questions, I'd like to take a few moments to talk more about Closer To Zero taking the guidance in the context of our initiative and give you an update where we are with the other aspects of the plan.

First, I want to remind you that we are actively seeking information and data on levels of exposure that have health effects and the contaminates in the food and growers could reduce -- could take to reduce the presence of the commodities and the food. We are interested in the role of nutrition it could play to mitigate the impact on exposure particularly on the young. I want to encourage the

submission of any information, comments, and particularly data that you may have related to the action levels we proposed and presented today so it could help us inform the decision-making as we move forward to finalize the action levels for lead in baby foods.

This guidance is one of many of our steps in the plan. We continue to work on other aspects of the plan. Including work on the other elemental contaminants we identified. We prioritize arsenic, cadmium and mercury among the very young. For arsenic we have been in discussion with the EPA for the work they've done to assess the impact not on organic exposure it could have on human health. We will look at their information and other information to work to establish a level for dietary exposure. We continue to be committed to establish that interim reference level. Along with the proposed draft action levels for foods consumed by babies and young children sometime in 2024.

For cadmium, our scientists have published several papers. We reviewed the literature to understand the health impacts from dietary exposure assessing the level on the child development and developing models related to dietary intake to the markers of exposure. We held a public meeting of December of last year to present our work together FDA science board and discuss scientific questions.

Our staff, currently are taking all their work along with the input from the meeting and other information. And working to develop an interim reference level to do the proposed action level.

We continue to be committed to meet the timeframe we laid out in the Closer To Zero plan to propose the levels. In fact, we are doing better. As we are on track to propose the levels sooner than anticipated. Potentially as soon as 2024. For mercury we did a study on science and engineering medicine to access the role in consumption in child growth and development. Unlike the other plans that is across other varieties and food, Mercury is primarily prevalent in seafood. The study was kicked off and conclude in early 2024.

The work in the study will inform our efforts regulatory and communications, to reduce dietary exposure to methyl-mercury. We work with our federal partners on other issues related to agriculture, nutrition, and communication. We held a joint workshop with NIH called Bridging the Biological and Communication Science on Nutrients and Environmental Contaminants in Foods to Support Child Development. The workshop explored the exposure and challenges to communicate with consumers and others about the issues. We expect other

workshops on wide range of issues that are important not only to FDA but the partners at USDA, EPA and NIH. We meet with Stakeholders and see the concerns they have. We appreciate the feedback we received from you all. We've taken your feedback and look at our approach to move forward Closer To Zero -- a more transparent in the approach, updating the Closer To Zero web page and pages on leads, arsenic and mercury. A link is below the video you are viewing now in the description on the webinar. We will continue to update and add new pages. In particular research and Stakeholders meetings are key to develop the action levels and inform the guidance. One update I want to draw your attention to, we posted data on arsenic, cadmium and mercury in the foods that we use to inform the development of today's guidance. In the foods that are commonly consumed by babies and young children. This data posted in addition to the table we posted on January, for lead.

Those tables are in a single file and available on the testing results web page as well as on the lead, arsenic, and mercury pages. We look forward to work with you on the Closer To Zero initiative and our intention is to finalize the Draft Guidance in a year's time. So at this point I like to now turn our attention to answering some questions you have submit today us ahead of today's webinar.

I like to ask our other panelists to come back. Including Dr. Paul South and introduce our other panelist, Dr. Kellie Casavale, who is a Senior Science Adviser for Nutrition in the Office of Analytics and Outreach and on the Closer To Zero initiative. So, Jess I will pass it to you to ask the question. I want to remind folks below our images, you could see the e-mail address. Closer2zero@fda.hhs.gov. You can send any -- join the webinar and send questions to that e-mail address. It is monitored we will try to answer those questions.

>> JESSICA ROWDEN: Thank you, Conrad. We received a number of questions on a range of topics in advance to the webinar. We will not be able to answer them all during the Q&A. As Conrad mentioned additional questions could be sent to the e-mail address. We encourage you to submit the comments to the dockets that closes on March 27. We will go to the first question.

What products are subject to FDA Draft Guidance for industry: action levels for lead for food for babies and young children? Does it include infant formula, snacks, meal type products or beverages? Paul, I will hand it over to you.

>> DR. PAUL SOUTH: Thank you, Jess. The draft guidance describes the products covered by this guidance as “processed food intended for babies and young children refers to food packaged in jars, pouches, tubs and boxes represented or purported to be specifically for babies and young children less than 2 years old. It may include ready to eat foods … semi-prepared foods, dry infant cereals. It does not include raw agricultural commodities or homemade food such as, fruit purees made at home. This guidance does not apply to infant formula, snacks, meat type products -- sorry meal type products or beverages.” Lead in juices is addressed in a separate guidance available on the website.

>> JESSICA ROWDEN: Thanks, Paul. We received a number of questions related to foods that are not covered by the guidance infant formula and foods consumed by children that are 2-6 years old. We received questions on our decision not to propose an action level for grain-based snacks. Conrad, would you like to address this?

>> DR. CONRAD CHOINIERE: Sure. Thanks. I want to remind folks Closer To Zero is an iterative approach. I want to acknowledge that establishing these action levels today for foods intended for young children, babies and young children, is the first step to the approach.

We know as children age, their diets could be more closely resembles the diets of adults. Establishing action levels for broader categories of foods that are commonly consumed by young children but also adults, produce and dry cereals is a complex venture. As we progress through the cycle of continual improvement we will assess whether to propose action levels for additional foods, including foods that are "Not intended for babies and young children" but yet commonly consumed by young children. We evaluate what extent if any, infant formula contributes to dietary lead exposure among the very young. In the Draft Guidance the infant formula is collected through the Total Diet Study program, but not included in the Draft Guidance’s analysis- these are composite samples. In the case of TDS study data on infant formula the majority samples collected contain no lead. Meaning they have levels below the limit of detection of 4 parts per billion. FDA is currently looking actively seeking data on infant formula levels. Levels of lead in infant formula in various types we will work to propose action levels for the products in the progression of Closer To Zero.

The levels FDA proposed in the products today, are the levels that FDA believes may render the product adulterated based on the exposure of the lead in the food and food categories. Exposure from grain snacks for children under 2 years

of age are low. We are requesting data on the consumption of the snacks that will help inform our decision on the action level for this category.

>> JESSICA ROWDEN: Thanks, Conrad. We have questions about why we didn't consider lower action levels for certain foods where higher levels of achievability are possible. Such considering lower levels than 10 parts per billion for vegetables, or lower than 20 parts per billion for cereals. Conrad , do you want to take this one?

>> DR. CONRAD CHOINIERE: Sure. Our levels are preventing exposure to lead from the food categories from exceeding the Interim reference level of exposure we establish. However, we took into account, achievability. The levels that we have proposed are levels that FDA believes may render the product adulterated based on the food categories. Consistent with our regulations, the draft action levels reflect a level that is sufficient for the protection of public health taking into account the extent the presence of the substance could not be avoided.

>> JESSICA ROWDEN: Great. Thank you. Next question. From our experience, baby food that are mixtures and include root vegetables may not be able to achieve the proposed draft action level of 10 parts per billion for baby food mixtures. Are baby food mixtures made with root vegetables intended to comply with the 10 parts per billion? Will you raise the level for the cereal grains, for example, mixtures with more than 50% root vegetable or cereal grains?

>> KELLIE CASAVALE: So these are two points that we believe are appropriate to raise in a submission to the docket for FDA to consider as we finalize the guidance. We encourage you all to submit the comments to the docket the date for that is March 27. That really would help to ensure your comments on the Draft Guidance before we begin work on the final version of the guidance.

>> JESSICA ROWDEN: Thank you. For each category of food it is helpful if the clarification could be made to the portion or state of commodity to which the action level applies- for example whole commodity as sold or on a dry matter basis. When evaluating dehydrated products against the established action levels, will it be evaluated as is or be evaluated within the context of their intended serving suggestions, such as hydrated with water or milk. Conrad, I will give that one to you.

>> DR. CONRAD CHOINIERE: Sure. These action levels apply to the food product as it is -- as is, and as sold, for all of the processed food categories

covered by the U.S. guidance. The dry products are evaluated as is and compared to the established action levels.

>> JESSICA ROWDEN: Thank you. The next question: how soon after the draft form is issued are the established lead limits set in stone? How and when does the FDA plan to begin enforcing its lead action levels. Paul, you like to take that one.

>> DR. PAUL SOUTH: Yes. There is an open comment period for the Draft Guidance for lead and food. This March 27, 2023 is the deadline for submitting comments on the Draft Guidance to ensure we consider the comments before we begin work on the final version of the guidance. The FDA will consider data and other information provided by Stakeholders to evaluate if there is a scientific basis to revise the action levels. The timeline to finalize the guidance is dependent upon the volume and complexity of comments received, however, advancing the guidance is a priority. We consider the action levels achievable by industry when control measures are taken to minimize the presence of lead.

As this is a Draft Guidance for public comment we encourage you to submit data and information to the public docket regarding how long it may take for manufacturers to make steps to reduce the levels of lead in the products as appropriate. If finalized, the action levels in the draft guidance will reflect the levels of lead at which FDA may regard the food as adulterated within the meaning of Section 402(a)1 in the Federal Food and Drug Act. After the FDA issues final guidance on action levels, we will review existing documents to determine whether they need to be changed or withdrawn.

But please note, there is never a point in time that the action level or rather action level limits are set in stone. These are not regulations or tolerances. Although action levels are not binding on the public or FDA, they encourage manufacturers to maintain levels below the action levels. The FDA considers action levels an important source of information for determining whether to take enforcement action. The agency, however, does not need an identified action level to determine whether enforcement action is warranted. Irrespective of whether the agency has guidance on an action level on a particular contaminant, the agency considers on a case-by-case basis whether the food that contains a chemical contaminant is adulterated.

>> JESSICA ROWDEN: Thank you, Paul. In the draft guidance, FDA did not describe any sampling plan to be used for compliance testing. It is known that

within lot variability and the test method-related variability lead to a margin of uncertainty for test results. Will FDA provide guidance to industry on sampling plans and acceptance criteria. Conrad, I will pass that to you.

>> DR. CONRAD CHOINIERE: Sure; thanks, Jess. So, I will provide controls framework. Each firm is responsible to develop their own food safety plan and determine what controls are needed. This could include whether or not they want to do sampling of the final product and thresholds they want to set and where and when to test the product. This is likely to differ depending on the type of product and what might work for one firm, might not work for another. So currently, FDA does not intend to lay out the specific sampling plans.

>> JESSICA ROWDEN: Thank you. Here's another question on compliance as well. I will give this to you, Conrad. How does the FDA plan to monitor compliance and assess the impact of the guidance? How does the FDA plan to monitor compliance to make sure lead levels are reduced?

>> DR. CONRAD CHOINIERE: We outlined in the Closer To Zero plan we intend do routine monitoring on levels of lead in food as part of our total diet study that will help us assess the progress we're making, but also as part of the compliance program. We anticipate, we currently are, and we anticipate we will routinely do surveillance of the industry by way of testing and sampling a product, as well as doing inspections. Including the specific evaluation of the supply chain controls.

The draft levels are not considered tolerances or limits that are set in stone. They are one of several factors we will consider on a case-by-case basis whether a food that contains the contaminant is adulterated.

>> JESSICA ROWDEN: Thank you. Next question, what can be done to mitigate the toxic element levels in the food supply, particularly dietary pattern decisions and agriculture practices and process approaches? How does the FDA plan to liaison with other agencies to ensure that Closer To Zero toxic element concerns are reflected in federal nutrition programs, WIC and SNAP, and with the dietary guidance. Kellie, this is for you.

>> KELLIE CASAVALE: We are collaborating broadly with industry Stakeholders and professional groups, and, of course, our federal partners as well as our State and international partners among others to better understand the health effects from exposure to heavy metals and metalloids and the ways that industry,

including growers of the commodities used in baby food can achieve lowered levels of contaminants in their food products.

Specifically, with USDA, we work on agricultural issues, such as potential strategies to mitigate the uptake of toxic elements in crops and we are working with USDA' s Special Supplemental Nutrition Program for Women, Infants and Children, known as WIC on coordinating the messages for the consumers in the populations they serve to make sure the information is reaching this crucial audience.

We are working with the EPA, currently focused on evaluating the science for arsenic, jointly address environmental mitigation efforts for lead, on then on mercury, we're also working with EPA to provide our advice to support families in eating seafood lower in mercury.

We also are working with NIH to address research gaps on the toxicological health effects of arsenic, lead, cadmium and mercury and role of nutrition for mitigating the impacts of exposure. In February we just hosted a two-day virtual workshop with the NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development that was focused on research in risk communication, environmental contaminants in food, and the role of nutrition in relation to child development.

Links to these activities can be found on the Closer To Zero web page, where we iteratively update a new table of Closer To Zero related events, including these public meetings, workshops, and webinars. So definitely go check it out. Together these activities help to support the scientific underpinnings to our advice to families on the role of nutrition to modulate the effects of contaminants and the science on exposures to both toxicants and nutrients and other bioactive components in food in the whole-diet context to help us understand the effects on the health outcome. Thank you.

>> JESSICA ROWDEN: Thank you, Kellie. Another question: are producers/ packers committed to lowering the level of lead in fruits, juices, and other food items, or will the FDA have to sample regularly? Conrad, I will pass that to you.

>> DR. CONRAD CHOINIERE: Yes. We have been in active discussion with Stakeholders about what we're trying to do here in Closer To Zero. When I say Stakeholders, I use this term broadly. It includes the internal Stakeholders,

federal and state and local Stakeholders, Industry Stakeholders, and our consumer public health advocacy Stakeholders about Closer To Zero. Across the board we have seen commitment to the goals we laid out in the Closer To Zero plan. We do expect we will do routine sampling to monitor and assess. That level of commitment particularly among our industry Stakeholders. We will do surveillance not only through sampling and inspections we will be looking at the preventive control plans to insure they are committed to reduce the levels of the contaminants in their foods.

>> JESSICA ROWDEN: Great. Thank you. Next question. Does FDA expect food manufactures to conduct testing for lead in baby food. Paul, would you like to answer this one?

>> DR. PAUL SOUTH: Thank you, Jess. You may be familiar with FSMA under the *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food* rulemanufactures and processors are responsible to consider risk in chemical hazard that is environment contaminants such as toxic elements when conducting a hazard analysis in products for babies and young children. We have a letter from March 5, 2021, that provides information on that topic.

The preventive control provision is to significantly minimize or prevent any identified chemical hazards requiring a control. Some manufactures may conduct a verification of activities, like testing the final product. Thanks.

>> JESSICA ROWDEN: Thank you. Next question, are there any actions import manufactures could take to expedite the custom process at the ports in regard to the new limits of lead, such as third-party lab test results or higher formulations in the entry packet. Paul, you like to answer that as well?

>> DR. PAUL SOUTH: Sure. Thanks, Jess. As stated in the guidance and I mentioned it earlier, for the draft action levels, FDA considers on a case-by-case basis whether a food that contains a contaminant is adulterated. When considering to bring enforcement action in a particular case, we consider whether lead caused a particular food for adulterated under Section 402(a)1 under the FD&C Act. We would expect baby food manufacturers and importers may find information in the guidance useful to develop and modify the food safety plans and practices as appropriate manage the supply chain and approval. The availability of food safety information and testing results during the import process is of assistance. Thanks.

>> JESSICA ROWDEN: Thank you. How many servings of grain-based snacks are safe to serve given they have high lead levels will not likely decline in the continued absence of an action level. For babies and toddlers, especially older toddlers, how many servings of grain base snacks could be given taking into account the other dietary lead exposure daily accumulative exposure level under the interim reference level?

>> KELLIE CASAVALE: Lead exposure from grain based snacks intended for children under 2 years at the 90th percentile intake is below the lead Interim reference level and unlikely to add significantly to exposure from the other food sources at current levels estimated. Action levels are an important source of information that FDA considers in determining whether it renders the food adulterated. Action levels have been effective tools that encourage manufactures to lower chemical contaminants in food when a certain level is unavoidable. We need to keep in mind action levels are not interpreted as dietary advice to consumers. The Draft Guidance is not to intended to direct consumers to make food choices. We recommend the children eat a varied and well-balanced diet.

>> JESSICA ROWDEN: The next question is related to that. What do the action levels mean to parents for what parents should feed their children?

>> KELLIE CASAVALE: As I mentioned, this Draft Guidance is not intended to direct consumers to make food choices. Separate from our regulatory related guidance, FDA provides advice to parents and caregivers to support families in moving the intake of the children to better align with the Dietary Guidelines for Americans recommendations which aims to achieve nutrient adequacy and help children to have healthy eating patterns related to life-long health. FDA develops information for consumers and we have a new web page available at Closer To Zero link.

It is called “Help protect children from environmental contaminants: Healthy food choices for your baby”. It describes what parents of older infants from 6-12 months of age could do to help protect their children. For example, the web page provides actionable steps for parents and describes key messages. One of those is to focus on variety. Feeding a variety of age-appropriate healthy foods helps them get the essential nutrients for their development and make it less likely to be exposed to the same contaminant from the same food many times.

Another key message is to include foods rich in iron and zinc. And so, it is essential that intake of iron and zinc are adequate in early childhood nutrition. Iron and Zinc can also help prevent harmful effects of lead and other heavy metals by decreasing absorption. In fact, there are many nutrients that can help to protect from the effects of contaminants, the ones we are talking about today and including lead, but others that can absorb from the environment into food. We advise parents to include iron and zinc-fortified infant cereals, to choose whole grain varieties that provide B vitamins to protect against arsenic and that rice cereal should not be the only source of iron and zinc-fortified infant cereal. We recommend as well, sources of iron and zinc that you could include in the infant's diet- meat, poultry, seafood, and beans, as sources of iron and zinc and other nutrients.

>> JESSICA ROWDEN: How will this guidance affect the ingredients suppliers whose products may be included in food for babies and young children?

>> DR. CONRAD CHOINIERE: These action levels we propose are applicable to the final product. Not to the ingredients used to make the products. So therefore, it is the manufacturers' responsibility to assess whether the ingredients they use in the product have a significant contribution of lead in the final product. As appropriate manufacturers could adjust their ingredients or the source to make sure they are not adulterated. We anticipate they will incorporate the information from the guidance into the food safety plans or specifically, their supplier control provisions as we discuss in preventive controls regulation.

>> JESSICA ROWDEN: Thank you. Next question, when suppliers provide nutrition, ingredient, and allergen information for the raw materials or finish products, are they required to declare the amount of lead in the ingredient specifications? Conrad, would you like to take that?

>> DR. CONRAD CHOINIERE: Sure. What we're proposing is not a labeling requirement. These action levels are provided to industry to understand the agency thinking about what a product may be deemed adulterated. They are also not intended as recommendations for label declarations on the amounts of lead in the product.

The guidance applies to the final product like I said, before. But it does not apply to the ingredients used in the final products. It is the manufacturers' responsibility to arrange agreements with suppliers to make sure the ingredients they use do not contribute amounts of lead that renders the product adulterated

>> JESSICA ROWDEN: We have a couple more questions, let's see if we can get to them. Paul, how did you conduct an achievability assessment? Is it based on lead levels currently found in food in addition to technologies and methods to reduce lead, or just the former?

>> DR. PAUL SOUTH: That is a great question. For achievability we used the data that we currently have on our surveys looking at lead in different types of food. We simply compare that to the proposed action level to see how and whether they meet the action level. That is exact exactly how we calculated achievability. Thanks.

>> JESSICA ROWDEN: Thank you. We have time for one more question. Are accurate lead quantification methodology available for all food categories covered by the Draft Guidance. Paul, would you like to take that as well?

>> DR. PAUL SOUTH: Sure. There are methods to analyze all these different food categories, these baby food categories for lead. FDA has methods available that could be used. Again, it is one example of a method that is available. We do have it posted online. And perhaps we could include that in the chat so folks could access that. There are other methods available; this is what FDA uses. But, definitely there are methods available to look at lead in the different food categories.

>> JESSICA ROWDEN: That is all we have time for today for questions. Conrad, would you like to provide closing remarks before we close the webinar?

>> DR. CONRAD CHOINIERE: Sure. Thanks. I want to thank you all again for being here today participating in the webinar. Very much appreciate the interests you have shown. Not only in the guidance we proposed with action levels for draft action levels for lead in food intended for babies and young children19ut in the overall Closer To Zero initiative. I apologize we could not get through every question we received. We tried our best to hit all the major themes.

And I also want to apologize if we misinterpreted any questions and provided an answer that did not' satisfy you. So, I want to encourage you all, if you have questions, related to this specific guidance, as well as any comments or information and particularly data that could support your position on the guidance, that you submit it to the docket in response to the guidance. Any other questions you may have, you are always welcome to continue to submit to the mailbox. We have all the questions that have been submitted there and we

will look for opportunities to answer or provide answers to those additional questions.

Whether it is individually in response to you or through future Stakeholder engagement we continue to meet with Stakeholders on routine basis and welcome any opportunities to provide information to you. So, if you have any information -- any further questions please submit them to the mailbox or reach out to -- I hope I could say this Jess, they could reach out to you. With that --

(laughing).

>> JESSICA ROWDEN: Thank you, Conrad. Yes, we appreciate that. The easiest way is through the e-mail address, Closer2zero@fda.hhs.gov.

The recording of the webinar will be available in the next few days. So, with that, I want to thank everyone for attending today's event. This concludes the webinar I hope you have a great rest of your day. Thank you.

(end of webinar 11:00 a.m. PST)