Stakeholder Webinar on the Draft Guidance for Industry on Action Levels for Lead in Juice
6/14/2022

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[Captioner standing by]

>> Great. Thank you, Michael. Welcome, everyone and thank you for joining us today for the FDA stakeholder webinar on the draft guidance for industry on action levels for lead in juice.

We will provide an overview of the draft guidance on lead action levels as well as answer stakeholders questions. First I want to introduce our speakers for today. Dr. Susan Mayne will provide opening remarks. Dr. Paul South in the office of food will provide an overview of the guidance. Dr. Conrad Choiniere will speak on the Closer to Zero initiative. Following our speakers we will have a question-and-answer session. If you have a question or comment you would like to submit, e-mail us at the Closer to Zero at FDA email mailbox. Closer the number “2” Zero at FDA dot HHS dot gov. With that let's begin with remarks from Dr. Susan.

>> DR. SUSAN MAYNE: Welcome everyone. Thank you so much for joining us today. I am glad we have this opportunity to present and answer some of your questions about our draft action levels for lead in juice guidance for industry. This draft guidance supports our broader efforts to reduce exposures to lead, arsenic, mercury, and cadmium from foods and advances our goals in the Closer to Zero plan to reduce exposure to toxic elements while maintaining the availability of food that provides nutrients essential for growth and development. This is among the agency's top priority and has been an important issue for the FDA. Our approach follows the cycle of continuous improvement that starts by evaluating the current science, analyzing sampling data and advancing research to develop reference levels. The interim reference levels are among the key factors that the FDA uses to inform the development of action levels.

Our draft action levels represent this approach and are guided by the FDA's IRL for lead. In addition to IRLs we also considered exposure and risk assessments, detection and quantification capabilities and achievability. We are confident that the science driven transparent and inclusive process will help lead to further reduction in exposures to toxic elements. This approach has led us to those proposed action levels which if finalized would represent the most rigorous standard for lead and juice in the world.

Equally important to our process has been broad stakeholder engagement, including working with our stakeholders to assess achievability and feasibility of the proposed action levels. Our stakeholders including parents and consumer advocacy groups, public help professionals, the food industry, federal partners, academia and other stakeholders are vital to our successful efforts. We are committed to ongoing engagement with you throughout the process and this is the reason we are here today. Stakeholder engagement has been among one of our top activities this past year, and we are thankful for your ongoing support and input. We have met with industry stakeholders as well as numerous professional groups over the past year and we plan to hold more public meetings, webinars and

workshops to exchange information, disseminate knowledge and encourage implementation of practices to reduce the presence of these contaminants in foods.

These meetings help to further highlight areas where additional research and data sharing can help us build the scientific basis necessary to develop and revise action levels moving forward. In addition to stakeholder meetings, FDA has taken a whole government approach by collaborating closely with our federal partners, as well as our state and international partners to better understand associated health effects from exposure to these elements and the ways in which industry, including growers of the commodities used can achieve lower level of contaminants in the products.

We are working closely with the United States Department of Agriculture, including work to identify good agricultural practices and collaboration on nutrition related issues. In late April we held a public meeting with USDA to discuss agricultural issues, such as potential strategies to mitigate the uptake of toxic elements in crops.

We are also working in collaboration with the USDA Special Supplemental Nutrition Program for Women, Infants and Children or WIC on coordinating our messages for consumers to ensure that critical information such as the importance of eating a varied diet reaches this audience. In early April we participated at the USDA National Institute of Food and Agriculture workshop and discussed various research topics including soil chemistry and main sources of contamination, plant uptake and accumulation of toxic elements and practices to limit bioavailability of toxic elements in food products. We are also working with our other federal partners, including EPA and NIH. We are currently collaborating with EPA to evaluate the science for arsenic, to jointly address environmental mitigation efforts for lead and to provide joint advice to support families in eating seafood lower in mercury.

And we are working with the National Institutes of Health to address research gaps on the toxicological health effects of toxic elements and the role of nutrition for mitigating the impacts of exposure. Reducing levels of toxic elements in foods is complicated and multifaceted and we could not do this work alone. We are committed to ongoing work with our federal partners industry and consumer and health advocates on our shared goal of reducing consumer exposure to toxic elements from foods. Our combined efforts have already led to meaningful reductions and exposure to toxic elements from food and we are dedicated to advancing this even further. With that I would like to thank you for your time today. Now I would like to turn it over to Dr. Paul South who will give us an overview of the draft guidance on action levels for lead in juice. Thank you.

>> DR. PAUL SOUTH: Thank you Dr. Mayne. I am Paul South a Division Director in CFSAN’s Office of Food Safety. In the next few slides I would like to provide an overview of FDA's draft guidance issued on April 27th. Um... and provide an overview -- again, this includes action levels for lead in juice. Just some background information, toxic elements like lead exist naturally in the environment, but also, present due to human activity. Because they are found in the environment, um, toxic elements like lead can also be found in food. Juice can be contaminated with lead with sources such as produce juice to make the juice, old lead containing equipment but also, through other pathways such as filter aids. Lead is toxic to humans and can affect people of any age or health status. Lead is especially harmful to vulnerable populations including infants, young children, pregnant women and their fetuses and others with chronic health conditions. Also nutrition deficiencies can result in vulnerabilities. Even low lead exposure can harm children's health and development, specifically the brain and nervous system. Neurological effects of lead exposure during early childhood include learning disabilities, behavioral difficulties and lower IQ. Lead exposures have been associated with immunological, cardiovascular, reproductive and developmental effects. FDA is committed to reducing lead in food to the extent feasible. Closer to Zero action plan is a science-based iterative approach to decreasing toxic elements such as lead in foods over

time including by setting action levels as we are proposing.

The action levels for lead in juice in this document, would, if finalized, replace the current level of 15 ppb described in the guidance for industry juice hazard analysis critical control point hazard control guide. Um, FDA considers the action levels... in this guide to be achievable by industry when measures are taken to minimize the presence of lead.

[Pause].

>> DR. PAUL SOUTH: This table outlines the two action levels being proposed in our draft guidance. The first category is apple juice and the proposed action level is 10 parts per billion. The second juice type is fruit and vegetable juices other than apple, and the action level is 20. Um, here I just want to note that this -- the action levels are applicable to single strength or ready to drink juices. Um, also I note for the second category, this includes juice blends that contain apple juice. Just some background. In 2001 the Codex established a maximum level of 50ppb per lead in ready to drink juices.

In 2001, the Codex Alimentarius Commission established a maximum level of 50 ppb for lead in ready to drink fruit juices and nectars in international trade. This is a joint FAO/WHO program, established back in 1963 and they formulate voluntary international standards, guidelines, and codes of practice. FDA has participated in this for decades. We participate in the Codex committee on contaminants in food. In 2004 FDA adopted a 50 part per billion as the recommended level not to be exceeded for lead in juice in the FDA juice guidance. Then from 2015-2018, Codex lowered maximum levels for juices in general, this was from 50 to 30 parts per billion. And also lowered um, grape juices from 50 to 40 parts per billion. In 2018, FDA developed reference level, um, for dietary lead to replace FDA's provisional tolerable total daily intakes from early 1990s.

In 2021 FDA initiated the Closer to Zero action plan that identifies actions FDA will take to reduce exposures to toxic elements, including establishing action levels for food. In response to Codex actions as well as FDA development of IRLs and the Closer to Zero plan, FDA re-evaluated the 50 parts per billion lead level in the current juice guidance.

And this slide addresses our approach. I do note in addition to the draft guidance document that's posted online, there also is a supporting document that provides details on the approach. Um, what we reviewed was toxic element program, TEP and total diet study data sets. In review we look specifically at total of the toxic element program data for use for what we are calling exposure and achievability assessments. Another reason why we didn’t use the TDE data sets is because the samples are composite samples from 3 different samples that are collected and therefore that is um, almost like an average. So we decided not to use these TDS samples. We did review the data from the TDS. In regard to different assessments, for the exposure assessment, FDA compared the concentration of lead in juice, as well as dietary exposure. The dietary exposure we looked at NHANES survey data. To lead from juice for children with and without the action level. We also did an achievability assessment to assess achievability or manufacturers ability to achieve the action levels we are proposing. FDA determines the percentage of samples that fell below the action levels, 10 parts per billion for apple juice and 20 parts per billion for fruit and juices other than apple juice.

Note FDA issued a lower action level for apple juice because it is the most commonly consumed juice that young children drink. This slide provides a summary of the data that we reviewed, the first data set, the toxic element program data, this is part of FDA's compliance program. We looked at fiscal years FY2005 to 2018.

And again, the TEP data was the data we used for the exposure and achievability assessments. The

number of samples we reviewed was 1640 samples. Again, we also looked at total diet study data. We didn't use it for achievability and exposure assessments but we did review results and looked at them in regard to our proposed action levels. There were 643 samples from the TDS.

This slide provides some of the information that we looked at and developed based on our achievability and exposure assessments. The first column is the different types of juice and we have the apple juice and then the fruit and vegetable juices other than apple. Second, um, the proposed action levels of 10 and 20. And then the third column is the achievability um, looking at the different percentages that we applied the 10 part per billon action level, we saw that for apple juice, 95% could achieve that 10 PPB action level. Um, then looking at the fruit and vegetable juices and other apple we found that 97% um, could achieve the 20 part per billion action level. Moving across scenario A is where we apply no action level. Here we are looking specifically at the data, no changes to the data, looking at apple we had an estimated mean lead concentration of 2.4 PPB for apple juice. Um and then for the fruit and vegetable juices other than apple we found 2.9 PPB for the lead concentration. The estimated lead exposure in juice, this is for 0 to 6-year-olds for 90 percentile. We used a 90 percentile because this is um, what we consider um, consumers -- high consumers of the different juices. We found um, children to consume um, a rather estimated lead exposure of 0.79 micrograms per day for apple juice and then for the category on fruit and vegetable juices, 0.70 micro grams of lead per day. On the scenario B where we apply the action level and what we did with the data set for example, for the apple juice at 10PPB, we excluded all those samples that were above the 10 PPB. We found that estimated mean lead concentration dropped to 1.3 parts per billion, for the apple juice. And for the fruit and vegetable juices other than apple, um, the level was 2.4 parts per billion. Um, we also estimated lead exposure from juice for the 90 percentile. Again, this is for 0 to 6-year-olds. We used NHANES survey data and then we used 90 percentile because of those consumed high intake or high users or high consumption for juices. We saw um, 0.43 for micro grams of lead per day for the apple juice and 0.64 micro grams per day for the fruit and vegetable juices, other than apple juice.

So looking at the last column, looking at reduction, um... exposure at the 90 percentile, we saw 46% reduction if we applied 10 PPB action level for apple juice and 19% reduction if we applied a 20 PPB lead action level for the fruit and vegetable juices other than apple.

Um, in summary, FDA is accepting comments on the draft guidance through June 28. This is a 60-day comment period. We do accept comments after that time, however, so that your comments are used in looking or reviewing our draft guidance and so that they will be included in developing the final guidance, we do um, recommend that you do submit comments by June 28.

We note that may choose to implement the recommendations before the guidance becomes final. We are planning to work with manufacturers of these products to encourage the best practices of lower levels of lead in juice. And we do monitor the levels of toxic elements in food and consider these on a case-by-case bases, to determine whether or not a food that contains a contaminant is adulterated under the Federal Food Drug and Cosmetic Act -- with that thank you for your attention. I know that we have questions at the end. But from here, I will hand it over to Conrad Choiniere to provide an update on Closer to Zero. Thank you.

>> DR. CONRAD CHOINIERE: Thank you, Paul, and thank you for being here today at our webinar. I'm Conrad Choiniere, I direct our office of analytics at the center for food safety and applied nutrition. Many juices are commonly consumed by young children, so the proposed action levels that were -- Paul went over, will help us advance the goals of Closer to Zero plan, which is to reduce early childhood exposure to lead, arsenic and mercury through foods, to the extent possible. These are elements that exist naturally in the environment, that are present from manmade causes. And exposure to these

contaminants on early ages has shown to have impact on development.

Given their presence in the environment, zero exposure may be difficult if not impossible. Our aim is to reduce exposures over time. We are following the cycle of continual improvement, where we evaluate the current science, use that reference level to guide the development of action levels for specific foods and categories of foods, propose the action levels and get input from stakeholders on what is achievable and feasibility for making reductions. Then we will adjust and finalize based on the current science for managing contaminants. Such as practices, grower can implement to reduce contaminant up take, steps that manufacturers can take to reduce contaminants in foods, or nutritional aspects we might consider. We will be monitoring progress, watching changes in levels of contaminants in foods to see if they change over time, as well as exposures among children. We are routinely sampling and will take actions when warranted as we continue our collaboration with federal partners and other stakeholders. At some point, we will start the process again because science will continue to develop and we will learn more about whether and how we can reduce exposures or the impacts of those exposures through nutrition. We will be re-evaluating and adjust the reference and action level as appropriate. As mentioned, today's action levels were guided by the reference level for lead exposures from food that FDA developed in 2018. This is based on CDC's reference lead for lead in the blood of children. CDC updated their reference late in 2021 so we will publish an update to our IRL. We are evaluating the science in order to develop reference levels for arsenic and cadmium and we are currently sampling and analyzing foods marketed for babies and young children.

I want to give you an update of where we are with respect to what we committed to in April of 2021.

For the evaluation, we have been spending a lot of resources evaluating arsenic. We held a public meeting in November of 2021. As well as co-hosted a colloquium with the Society of Toxicology in December 2021 focused on arsenic. We heard a lot about arsenic in the public meeting where we got a better understanding of how prenatal exposure leads to reduced fetal growth and increased childhood infection, as well as better understanding of how nutrition can influence arsenic toxicity. We are coordinating with EPA who is now leading a development of a dose response analysis for a variety of health outcomes related to arsenic exposure, including pregnancy related outcomes and neural developmental toxicity. The review and analysis will help inform our interim reference level which we hope to establish in the next year or so. We have proposed action levels today for lead in juices. However, we have drafted guidance proposing action levels for lead in foods intended for babies and young children and undergoing interagency review and OMB for final clearance.

We have met with numerous stakeholders in industry, both manufacturing and agriculture, as we have met with advocacy, academia and state and Federal Government. Our plan is to continue to meet with all of these stakeholders and get input on various aspects, such as the feasibility of achieving the action levels, learn about mitigating the update of the commodities, minimizing and reducing contamination during processing and the manufacturing of these products. As well as the role that nutrition can play.

We have also worked in the international arena. We have representatives to CODEX and they have been working to update the code of practice for lead. These are best practices for reducing contamination in foods and we will share that when that work is complete and we will share that with all of our stakeholders. Next slide, please.

Entering our second phase, we are actively engaged in evaluation of Cadmium. We have taken an integrated approach to cadmium, we've completed a review for cadmium exposure and children's health effects, we've conducted a systematic review of human and animal evidence of adverse health effects associated with Cadmium exposure and developing mathematical models that can help us

understand. We hope to bring all of the scientific information to our FDA science board, ideally this fall, in 2022, for public discussion of the work and to get input from experts about impacts of Cadmium on childhood health outcomes. We have begun work in -- on mercury as you may know. Mercury, the primary source of exposure to mercury, particularly methyl mercury is through seafood. So we will be engaged in scientific evaluation of mercury and beginning -- and we will have announcements in the next few months about that work. And provide more details about what we are planning.

We are committed to proposing action levels for arsenic in foods, and Once we have established that reference level, given progress on Cadmium, we are hopeful we will also be able to establish interim reference level in the coming year so that we can propose some action levels for Cadmium, well in advance of what we had previously committed to. So we will continue to do our consultation with stakeholders on these issues, as well as finalizing our lead action level that is we are proposing today, as well as the ones we hope to release in the upcoming weeks, for food, as indicated in our timeline. We have work that we are doing in drafting guidance for industry, on hazard analysis on risk based preventive controls for human food, drafting a chapter on chemical hazards and we will soon be publishing data from our sampling, as well as our total diet study and exposure assessments later this year. Next slide, please. And then we have work on Phase 3, continuation of what I already stated. So, I don't think I need to spend a lot of time on this slide. Next slide, please.

In the coming weeks, we will be releasing data from our total diet study. This is long-term study which collects and analyzes foods that come across the United States, a representative sample of foods from the U.S. diet, that helps us understand trend and exposure, as well as levels of contaminants in the foods. Also assesses levels of nutrients in foods. We recently completed multiyear update of the TDS including improvements to the sampling design and analytical methods and we will soon be posting the toxic elements data for the 2018 to 2020/21 sampling period. Next slide, please. We heard nutrition is a key factor in the Closer to Zero plan. Children without adequate body stores of nutrients can be at greater risk of the impacts of exposure. However, children whose diets align with the recommendation from the Dietary Guidelines are more likely to have adequate nutrient status and could be better prepared to ward off the effects. With these levels and others to follow, FDA will provide information for consumers to help support them in making nutritious choices while also eliminating exposure to toxic elements. Many children overconsume juices as compared to the recommendations of the dietary guidelines for American and under consume whole foods and vegetables. Following the recommendations on juice consumption can have additional reductions and exposures to lead. Next slide, please. FDA is not working alone on this issue. We will continue our robust collaboration with USDA focusing on the issues that we covered at the public meeting in April, such as Agricultural, nutrition and economic issues. We will expand collaboration with other federal partners, such as EPA, CDC, NIH as we work through the scientific issues, including related to the challenges and communicating about this issue with stakeholders and consumers. We look forward to your ongoing support and engagement on this plan. We look forward to the comments. We encourage submission of comments to the docket for the juice action levels proposed action levels. And we look forward to getting any data and scientific information you have to help inform our decision-making. Thank you. And with that I will pass this back to Jess.

>> Great. Thank you. We will now have our question-and-answer session. We have a panel of subject matter experts that will answer your questions. Joined today by Dr. Kellie Casavale, a senior nutrition advisor in the office of nutrition and food labeling. We received a range of questions on a number of topics in advance of this webinar. While at the time we may not be able to answer all of the questions that we received we do encourage everyone to submit comments to the public guidance documents. Please submit these questions and comments to the docket by June 28, 2022 to ensure that the

comments or questions and any other relevant data and information are considered before we begin developing the final guidance.

So let's go to our first question. Um, the question is although this is nonbinding, will this action level be considered by FDA when determining recall class?

Dr. South, I'll hand that one to you.

>> DR. PAUL SOUTH: Thanks and that's a good question. Again, this is draft guidance, so it hasn't been finalized yet. So we are requesting comments on that. But when we do, we review comments and look at the science and finalize the guidance and including the action levels. We would use the action levels as well as other factors on a food offer a level lead in juice. I do note um, in regard to recall class, there are specific guidelines on recalls. Um, and that is based on what is called a Health Hazard Evaluation. So we would use a Health Hazard Evaluation to determine that the recall class, but nonetheless, the safety information that's including in developing an action level would be part of the health hazard evaluation. Thanks.

>> Thank you. The next question: Can you provide an update on timing regarding Closer to Zero on finalizing heavy metal limits and dates to be implemented? Can additional clarity be given beyond the posted timeline?

>> DR. CONRAD CHOINIERE: As I just mentioned, our goal is to finalize guidance documents in a timely manner. The timeline for finalizing each of these guidance documents as they come out will be contingent on several factors, including the number of comments we received or the amount of data and information that might influence the decisions related to finalizing the action levels. Our draft guidance as I mentioned, the draft guidance on action levels for lead and foods intended for babies and children is undergoing agency review and it's our hope that we can issue this soon.

We are working to develop levels and hope to have those reference levels for arsenic and cadmium established some time in 2023 so we can have action levels for those of both contaminants proposed in late 2023 until sometime in 2024. We have received additional resources that we are using to hire new staff, purchase equipment and other resources needed that can help us facilitate this work.

>> Great. Thank you. And before we go to the next question, I do want to remind everyone, all of our participants if they do have any questions or comments they can submit them to the Closer to Zero address that is on the screen.

So we have another question. Does the modeling used to establish the level in juice correspond to the latest blood lead reference value of 3.5 micro grams per deciliter?

>> DR. CONRAD CHOINIERE: This is in reference to the CDC blood level reference value. They recently reduced it from 5 to 3.5 micro grams per deciliter. When we um -- the approach we use to establish or propose these action levels was guided by the older CDC reference value of 5 micro grams per deciliter, because our interim reference level established in 2018 was based on that old reference level. But since the update and our proposed -- what we anticipate to be our updated interim reference level, we did go back and check that our approach is consistent with the new reference level.

>> Great. Thank you. Next question: What is the collection protocol used to obtain the juice sample? Dr. South?

>> DR. PAUL SOUTH: Sure. As I mentioned in my slides, um, there are two sets of um, of um -- juice samples. One to the total diet study and one through the toxic element program. So in regard to the

achievability and the exposure assessments, we use the toxic element program samples for those reasons, I think I outlined during the presentation. Um, for the collection protocol for toxic element program because that's a compliance program, it is described on the FDA website under compliance program guidance manuals. So there's I think a link there for that information.

Um, but generally we do have what we call sample food collections, um, that are basically super juice samples, distributed throughout the country to different districts and we have FDA district staff collect samples and they send those back to district laboratories for analysis. And then the information would be um, inputting to our computer system for um, for us to take out and analyze.

So um, but nonetheless there is a specific protocol for collecting juice samples or food samples, um, and for analysis as well. Thanks.

>> Great. Thank you. Next question. Has the widely accepted findings of the protection against neurotoxic activity of background levels of naturally occurring heavy metals that is provided by other elements for example, Selenium or evolutionary protection, been incorporated into the guidance? Dr. Casavale, I'm going to hand that one to you.

>> DR. KELLIE CASAVALE: Thanks. The answer is no. Research shows that some nutrients do interact with heavy metals. However more science is needed to better understand these interactions and in this case, the degree in variation of protection that they provide. So at this time we don't um, have enough information and we are not able to quantify the counteracting effects that nutrient may have on heavy metals although we know that those situations exist. Right now we are working to evaluate the toxicological and nutritional science together to help us begin to better understand, um, what is going on there.

>> DR. CONRAD CHOINIERE: If I can build on that, that is a reason why we have this cycle of continual improvement because our intention is to revisit the science on a periodic basis. One aspect is nutrition science and how does nutrition play a role. And as we get more information on this -- in this space and if we are able to quantify, then we can take that into account when we update reference levels and more action levels.

>> Great. Thank you. Next question, has the FDA or any other agency found methods for at home testing of foods and juices? Do parents have the ability to submit samples for lab testing of similar ingredients found to contain heavy metals? Dr. South?

>> DR. PAUL SOUTH: FDA hasn't -- we haven't evaluated any home methods for testing. Lead levels are generally quite low, but nonetheless, I don't believe we ever look at those specifically. Also, um, we don't look at labs. We are um -- so unfortunately we don't have that information. Thanks.

>> Has the FDA considered development of action levels for other heavy metals in juices? Has the FDA considered other populations vulnerable to heavy metals exposure, such as older adults?

>> DR. CONRAD CHOINIERE: Sure. Juices are consumed by younger children. As part of the plan we are considering the presence of other heavy metals in juice and are considering development of action levels for those other contaminants such as arsenic, Cadmium and mercury in juices in the future. As well as other foods consumed by young children. We do consider other vulnerable populations. We have an interim reference level, for example, for women of childbearing age. And when we um, when we identified very young children as a vulnerable population, we presumed that actions that were protective of that population would likely be protective or beneficial to all segments of the population, including older adults. So we do believe that these action levels will have a benefit to all um,

populations.

>> Great. Thank you. Another question we received is: Does FDA have additional information on the samples such as country of origin or brand name? Dr. South?

>> DR. PAUL SOUTH: Yeah, um, we currently posted the results for the different juice samples, and the different types of juices um, including the lead levels. But um, we did include the information in regard to the country of origin and brand name. FDA does have that information, we do collect that when we um, collect samples for the program. Thanks.

>> Thank you. Another question that we received, What factors prevent the FDA from setting limits by children's serving size for all commodities akin to the Recommended Daily Allowances approach as opposed to by individual commodity like juices?

>> DR. KELLIE CASAVALE: So FDA is not undertaking labeling regulations as part of Closer to Zero. Um, but I do want to mention that, similar to the recommended daily allowances mentioned in that question, and those are amounts of nutrients per -- in per-day amounts, FDA does look at total exposure, um, and so it's actually one of the first steps. So for example, we establish what we call interim reference levels or IRLs and they are a benchmark for total daily exposure in micrograms per day. And then we can use that to help estimate um, and help us understand potential contribution of individual foods or categories of foods to a total exposure from foods. Along with other information, this informs the action levels like the draft levels for juice that we are discussing today. So our guidance to industry provides limits for concentration of lead in juices in the units of parts per billion or micrograms per kilogram. Also considers the interim reference level, which is in the units of micrograms per day similar to how recommended daily allowances are for a total amount of the nutrient per day.

>> Thank you. Another question: Will FDA establish a specific method for analysis or will we keep the same method used? Dr. South?

>> DR. PAUL SOUTH: Yeah, um, well currently we do have methods that we use in our laboratories. Um, and I think currently we use um, the um, MS analysis -- I believe it's EAM47. Um, I don't believe you know, we are going to require specific um... methods for this guidance document. You know, when we have requirements for um, analysis, I think we consider you know, what are methods that will comparable. But all I can say is that we do have methods ourselves and I think we would look at comparable methods, as well.

>> DR. CONRAD CHOINIERE: Yes we have information on our web page for the analysis we use.

>> Thank you. What other products with the FDA provide lead guidance on and what other heavy metals will be a concern for the food industry?

>> DR. CONRAD CHOINIERE: So Closer to Zero is committed to setting action levels for lead, arsenic, Cadmium and mercury. And these are on foods that are commonly consumed by babies and young children. So, we have -- today we have juices, with the guidance that we hope to have come out soon, will be for those foods that are intended for the use in young children.

>> Great. Thank you. Um... our next question, are other toxic element data available for juices and for other foods? Dr. South, would you like to take that one?

>> DR. PAUL SOUTH: Yeah, so in regard to juices we do have data for other juices, from toxic element program and TDS. TDS is planning to post some additional data soon. We are putting data together for arsenic, Cadmium, we also are pulling information in regard to Cadmium as well. Um, for mercury, some

of it we don't have as much data specifically for juices, um, in part because mercury is -- isn't generally an issue for juices. Um, but nonetheless, you know, our toxic element program as well as TDS do look at other foods other than juices, so there is data available for those.

>> Great. Thank you and there's another question that came in that I'll hand to you Dr. South. Are the action levels for lead also applicable for juice containing beverages such as lemonade.

>> DR. PAUL SOUTH: Actually, that's a really good question. These action levels are specifically for juice and so um, they wouldn't necessarily apply to say, lemonade where a lot of the um, the beverage is made up of water. Nonetheless, um, whether or not we have an action level or not, we do look at contaminants including toxic elements, we would use some of the same information with regard to the level found, um, of the toxic element and then consumption for the different population, vulnerable populations, as well as consumption data to determine whether or not there's an issue there.

[Dog Barking].

>> Thank you, Dr. South, for that clarification. Um, okay then the next question we have, um,: Did you consider how other public studies, for example, consumer report study might have influenced industry behavior and thus lead in juice concentrations?

>> DR. CONRAD CHOINIERE: Thanks. No, we did not consider those other published studies. This is based solely on the FDA toxic elements program data and from the compliance program, collected data between fiscal year 2005 and 2018. So only that data were used to development the exposure assessment to inform the action levels. However we do encourage all stakeholders to submit data and information through the docket by June 28, 2022 so we can consider that information before we begin work on the final guidance. We may also consider additional FDA data when developing that final guidance. Thanks.

>> Great. Thank you. Um, here is another question we got. I think this is a good question that probably a lot of consumers have. Dr. Casavale, I will hand this one to you.

We serve a variety of 100% juice 3 times a week. I'm concerned. Should I stop serving the juice?

>> DR. KELLIE CASAVALE: Yes, that is a good question. And I imagine on the minds of a lot of individuals, and parents, families, or those in education settings, and that sort of thing. You know, I think for this kind of question you have to consider the age of the children and also the amount of juice that you're serving 3 times a week. So fortunately the dietary guidelines Americans provide recommendations for juice, for infants, who are children under age 1 year, actually are recommended to not consume any juice. And for older children, most of the time, they should have whole fruits instead of juice and the reason for that is that whole fruits have fiber that children need to stay healthy. But juice is a relevant source of nutrients, for example, of vitamin C which is an antioxidant that we are all familiar with. It also helps children absorb iron and that's an essential nutrient in child development. When children older than one year have juice, it should be 100% juice with no added sugar and also a small serving, 4 ounces or less per day, and you could also serve juice mixed with water. As you've seen in the presentation, we have an FDA web page, it's titled "what you can do the limit exposure" and it has more tips that you can go check out there. Um, and for planning meals for children, either for families or in school settings, I want to recommend that early care and education centers and parents can use MYPLATE.gov. There you can get a plan which describes the amount of foods from the food groups that fit into a healthy diet. No more than half of the fruit recommendation in the plan should come from fruit juice, per day. Thanks for that question.

>> Great and thank you for that information. Um, okay, next question: Will the FDA check just ready to drink juice? Or will they also check concentrates? For example, FDA found 11 parts per billion of lead concentrate, how would the FDA proceed considering it's not ready to drink?

>> DR. PAUL SOUTH: When we collect samples of juice a lot of times they aren't ready to drink because a lot of juice is concentrate that is um, transported around the country or import. So we do juice, based on -- we look at what is called the BRICS, is sugar concentration and we have a way to convert it to a level to drink bases and I believe our CFR does have a table on juices and there's actually a link, in the CFR that talks about what juices you should be at in regard to BRICS. So we do that conversion and we determine exactly how um, how much lead would be in that product. Thanks.

>> Great. Thank you. The next question is about data, so I'll pass this one to you Dr. South. Why include data from 2005-2007 when this is encompasses only 9 samples?

>> DR. PAUL SOUTH: What we did, we used all the data that was available after publishing in 2004, the guidance for industry, the hazard control guide for juice hazard. So again, you know, we didn't want to um, bias any of the information. We just collected the data that was available and so that's why we included those. Again, I guess at the time we weren't sampling juice as much as we are now. Thanks.

>> Thank you. Okay. I have another question. Why did the FDA reported limits of quantitation (LOQs) vary so much? What was the influence of these LOQs on the action levels? Again, for you Dr. South.

>> DR. PAUL SOUTH: Yeah, and that's a good question. Again, we have different labs throughout the country. And depending upon what instrumentation they have, it could be plain atomic absorption, spectroscopy, ICPMS methods and each of them have different LOQs and even the same instrument you could have different LOQs. We collected information over a number of years and we get instruments to be more sensitive because levels -- we are more interested now in lower levels. So that's probably the reason why levels have gone down in regard to the LOQ. Even in the same year you have different instruments at different district laboratories. But we have conducted an assessment, we saw the same thing in regard to LOQs. We did um, conduct an assessment to understand the influence of high LOQs on achievability estimates and we did determine that samples with high LOQs and 0 values had little influence on the achievability instruments. Nonetheless, that was a good question.

>> Thank you. Well I'm looking at the time. I think that's all we have time for today. I want to thank our speakers and panelists for their participation and all of our participants for the great questions they provide and for attending today's meeting. We do encourage everyone to submit comments to the public guidance docket by June 28, 2022. Thank you for attending. This concludes our event for today. I hope you have a great rest of your day. Thank you.