February 26, 2025

Quynh-Anh Nguyen
On behalf of Lauren Posnick Robin, U.S. Delegate to CCCF
U.S. Food and Drug Administration
Human Foods Program
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Re: Comments on February 20 Draft from EWG for CCCF18

Dear Quynh-Anh Nguyen:

Unleaded Kids appreciates the opportunity to respond to your February 20 request for comments on the "Proposed Draft Maximum Levels for Lead in Culinary Herbs and Dried Bark" that was prepared by the Electronic Working Group (EWG) for the 18th meeting of the Codex Committee on Contaminants in Foods (CCCF18). As I understand it, CCCF18 will be held in Bangkok, Thailand from June 23-26, 2025.

Unleaded Kids is the only national organization focusing on reducing the cumulative impact of all sources of children's exposure to lead. For more information see www.unleadedkids.org.

While at the Environmental Defense Fund, I submitted comments to the U.S. Delegation on January 20, 2022 regarding the maximum levels (MLs) for lead in various food categories (attached). Those comments urged the U.S. Delegation to "ensure that MLs as low as possible are proposed and finalized as rapidly as possible," explaining that:

> The US and CCCF have shown a willingness to allow a rejection rate of almost 10% for other contaminants. For total aflatoxins in peanuts, CCCF is considering MLs with rejection rates higher than the 0-5% range customarily followed by CCCF, and that the U.S. draft position states that the U.S. does not object to these (e.g., to a 9.7% rejection rate (15 ug/kg)). We can think of no more compelling case where rejection rates above 5% are needed for consumer health protection than lead, especially for foods that are important sources of exposure to infants, children, and women of childbearing age, given the significant detrimental health effects of lead exposure for those groups.

We again ask that the U.S. Delegation push harder for tighter standards at CCCF. The Codex standards are promoted by industry to consumers as evidence that the lead residues are safe, when the reality is that they are set simply to remove outliers, those with extraordinarily high levels. And those limits implicitly give permission for industry to accept ingredients that could be produced with much lower levels of lead contamination.

The EWG's approach is contrary to FDA's Closer to Zero program since it effectively removes the incentive for industry to do any better than the worst 5% of the international marketplace.

Put simply, it is difficult to Make America Healthy Again, if we are adding lead to kids' brains and to people's hearts.

Modeling Dietary Exposure Using EPA's AALM Shows Disturbingly High Blood Levels Possible

Rather than apply a formulaic approach, we ask the U.S. Delegation to consider the public health implications of these dietary exposures to lead using tools that the Environmental Protection Agency (EPA) has developed.

We used EPA's All Ages Lead Model (AALM)[1] to calculate the blood lead levels for a women exposed only to lead from cinnamon (including canella and cassia bark) and dried culinary herbs at the ML for every day starting at age 20. Figure 1 shows the results for the "worst case consumption scenario" of cinnamon at 0.4 grams per day and herbs at 8.89 grams per day. By age 30, the person would have a blood lead level of 28 µg/dL.

This is an extraordinarily high level! The Occupational Safety and Health Administration (OSHA) considers a blood lead level of 25 µg/dL as serious and warrants an inspection.[2] It is just below the level at which the American College of Occupational and Environmental Medicine (ACOEM) and Association of Occupational and Environmental Clinics (AOEC) recommends medical removal from work.[3] And this scenario considers no other source of lead exposure even though we know lead is commonly found in other foods, our homes, and our workplaces.

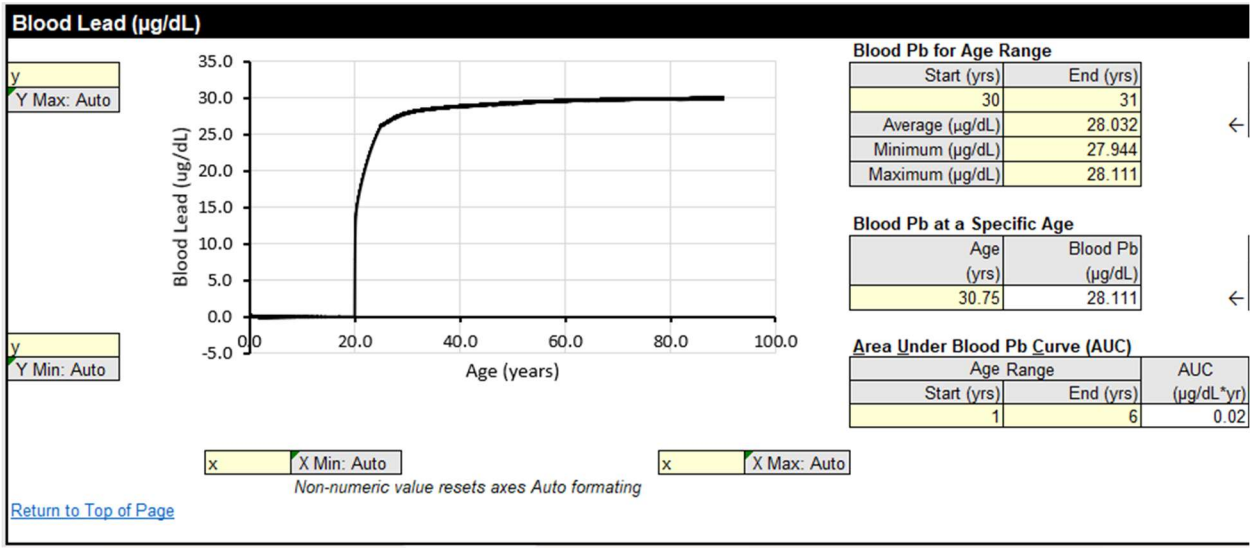

Figure 1: Daily consumption of 0.4 grams per day of cinnamon at ML and 8.89 grams per day of herbs at ML

Figure 2 shows the results if we cut the consumption rates in half to 0.2 grams of bark per day and 4.45 grams per day of herbs. At this modest rate, a woman's blood lead levels at age 30 would be about 7 µg/dL. This is more than twice the level at which the ACOEM would advise women who are or may become pregnant to avoid occupational lead exposure that would elevate the BLL greater than or equal to 3.5 µg/dL.[4]

[1] See Version 3.0 released in February 2024 at https://www.epa.gov/land-research/all-ages-lead-model-aalm.
[2] See CDC, Blood Lead Level Guidance, accessed on February 26, 2025 at https://www.cdc.gov/niosh/lead/bll-reference/index.html.
[3] *Id.*
[4] *Id.*

Yet these blood lead levels would be the result not of an occupational lead exposure but of the person enjoying cinnamon and herbs in their diet completely unaware of the presence of lead.

If the person was pregnant, the fetus would be exposed to those levels. As a result, the typical child would be more likely to be born with low birthweight, with an increased risk of having Attention Deficit Hyperactive Disorder (ADHD), and a lower IQ that will limit their lifetime earnings. In addition, the pregnant person will have a greater risk of premature death from cardiovascular disease. Lat year, EPA quantified the dose-response relationship for each of these health impacts and calculated the societal costs of preventing these risks. The quantification cleared Interagency Review by the Office of Management and Budget (OMB).[5]

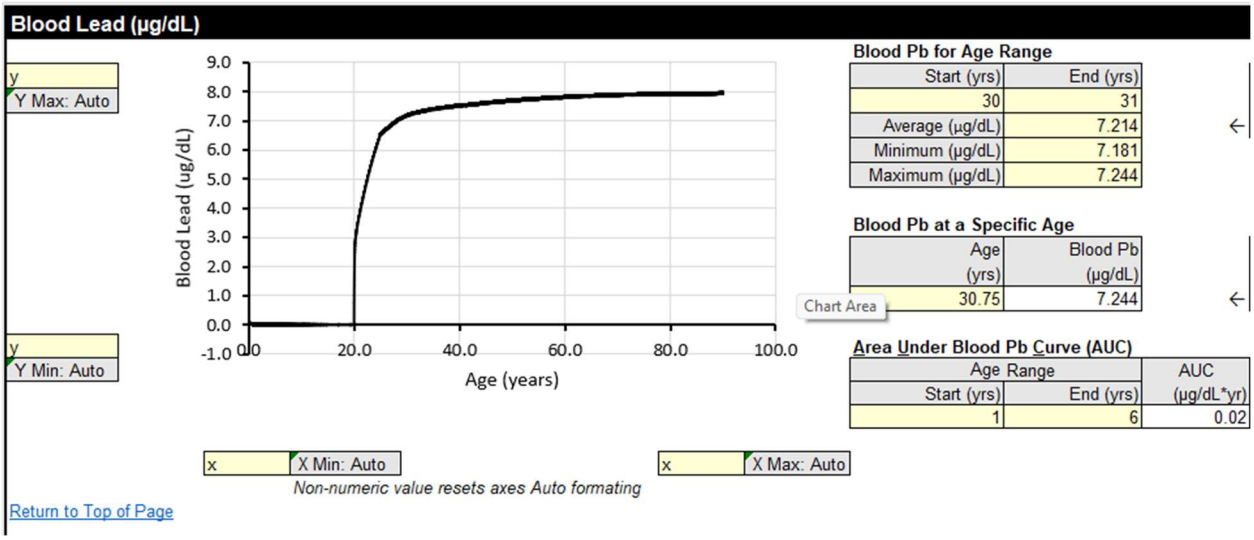

Figure 2: Daily consumption of 0.2 grams per day of cinnamon at ML and 4.45 grams per day of herbs at ML

One mg/kg in bark and culinary herbs is reasonably achievable

The charts below from EWG's draft report show that 1 mg/kg should be an ML that is reasonably achievable and will advance goal of Closer to Zero.

For dried culinary herbs, the proposed ML of 2 mg/kg would result in a paltry 1.9% of the products being rejected. If the ML were 1 mg/kg instead, the rejection rate would be 8.9% and double the dietary lead intake reduction.

[5] EPA, Economic Analysis of the Lead and Copper Rule Improvements EPA 810-R-24-005, October 2024, https://www.epa.gov/system/files/documents/2024-10/508_lcri_final_ea_10-21-2024.pdf. See Section 5.5.

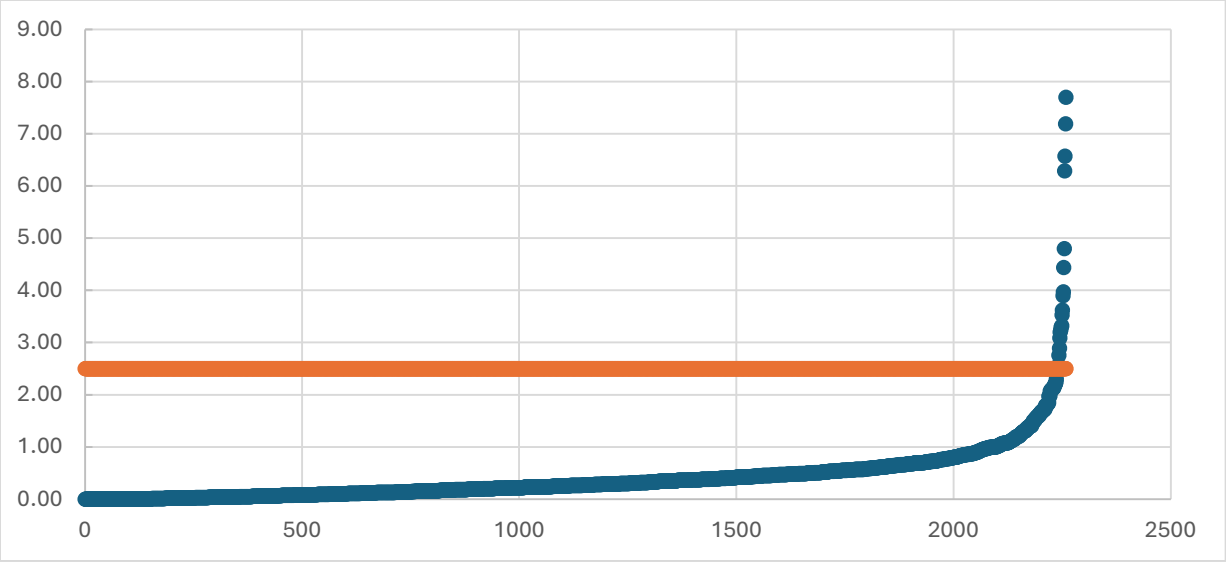

Figure 3: Lead concentration data distribution (mg/kg) in dried culinary herbs.

Table 2. Effect of the implementation of hypothetical MLs for lead on culinary herbs, based on UB approach.

ML (mg/kg)	Mean levels (mg/kg)	Sample rejection (%)	Intake reduction (%)
No ML	0.433	0.0	0.0
3.0	0.378	1.7	12.7
2.5	*0.372*	*1.9*	*14.1*
2.0	0.359	2.7	17.1
1.5	0.335	4.4	22.6
1.0	0.295	8.9	31.9

For barks like cinnamon and cassia, the proposed ML of 2.5 mg/kg would result in 4.1% of the products being rejected. If the ML were 1 mg/kg instead, the rejection rate would be 23.5% and triple the reduction of dietary lead intake.

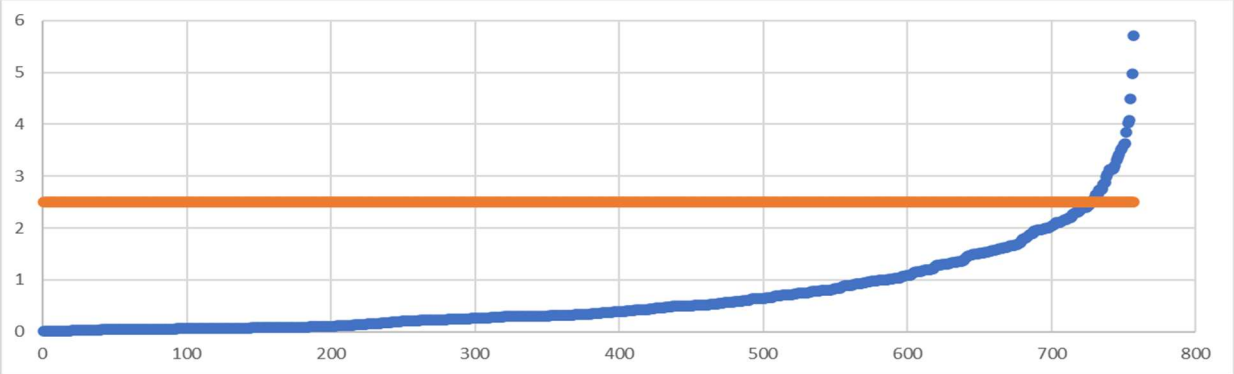

Figure 4: Lead data distribution (mg/kg) in dried bark.

Table 2. Effect of the implementation of hypothetical MLs for lead on dried bark (n=736), based on UB approach.

ML (mg/kg)	Mean levels (mg/kg)	Sample rejection (%)	Intake reduction (%)
No ML	0.67	0.0	0.0
3.0	0.59	2.6	12
2.5	0.56	4.1	17
2.0	0.49	8.2	28
1.5	0.40	14.8	41
1.0	0.30	23.5	55

With these MLs, the woman consuming cinnamon and dried culinary herbs at the modest would have a blood lead level of 3.6 µg/dL at age 30. This is still more than the level at which the ACOEM would advise women who are or may become pregnant to avoid occupational lead exposure that would elevate the BLL greater than or equal to 3.5 µg/dL.

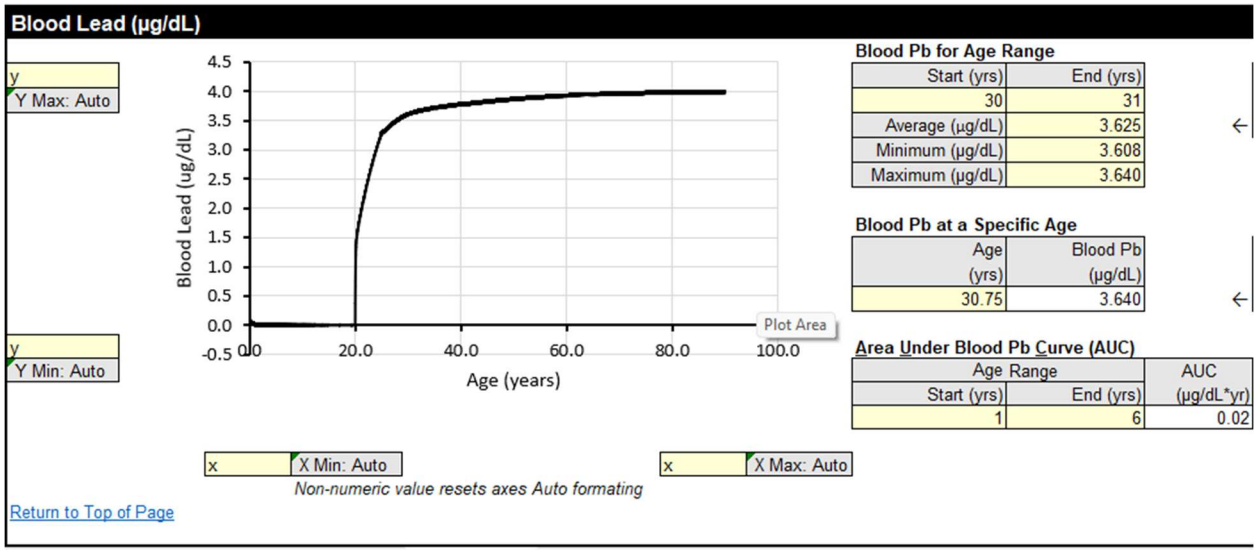

Figure 5: Daily consumption of 0.2 grams per day of cinnamon at ML and 4.45 grams per day of herbs with ML of 1 mg/kg

For more information, please contact Tom Neltner at tneltner@unleadedkids.org or 317-442-3973.

Sincerely,

Tom Neltner

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EDF
ENVIRONMENTAL DEFENSE FUND
Finding the ways that work

January 20, 2022

Lauren Posnick Robin, ScD
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SUBJECT: Comments for the 15th Session of the CCCF on MLs for lead in certain food categories

Dear Dr. Robin:

The Environmental Defense Fund appreciates the opportunity to comments on the U.S. position on the issues to be discussed at the upcoming session of the Codex Committee for Contaminants in Food (CCCF) regarding maximum levels (MLs) in foods. EDF has more than 2.5 million members and a staff of over 1000 scientists, economists, policy experts, and other professionals around the world. Guided by science and economics, we find practical and lasting solutions to the most serious environmental problems. Our Healthy Communities Program seeks to safeguard human health by reducing exposure to toxic chemicals and pollution, including via our food.

We strongly urge the U.S. to vigorously push to lower MLs of lead to be as low as possible, especially for foods consumed by infants, children, and women of reproductive age; and to work towards achieving continual improvements over time. This position would be consistent with the FDA/USDA Closer to Zero Action Plan designed to drive down lead, cadmium, and arsenic levels in children's food to reduce children's cumulative dietary intake of these neurotoxic elements.

Several of the CCCF proposed MLs are unacceptable. For example:

- For some foods (including but not limited to foods intended for infants and children) the proposed MLs would fail to achieve any reduction in lead exposure, or only very small reductions, which is clearly contrary to the objective of the Closer to Zero Action Plan.
- For ready-to-eat foods intended for infants and children, a single serving at the proposed ML would actually exceed FDA's maximum daily intake for lead from food in a single serving, which is completely unacceptable.

The adoption of lower MLs for some foods could be facilitated by creating sub-categories of foods, based on the distribution of data in document CX/CF 2/15/7, and establishing separate MLs for these sub-categories, as opposed to proposing one ML for the entire category. This would advance the Closer to Zero Action Plan's objective.

We also recommend that the US propose that CCCF request that the Codex Committee on Methods of Analysis and Sampling (CCMAS) re-evaluate the approved methods for lead in foods for infants

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and young children and remove methods that are insufficiently sensitive to support MLs needed to better protect children's health.

We commend the U.S. draft position of not supporting several of the proposed MLs for lead, because they are too high. We also agree with several other points outlined in the U.S. draft position on lead, such as to clarify the types of products included in the analysis of rejection rates, since further stratification might facilitate the establishment of lower MLs. However, in other cases the U.S. would be supporting MLs for foods that are widely consumed by children that are higher than proposed, even when the rejection rates are under 5%, and there is no public health justification for this position.

The US and CCCF have shown a willingness to allow a rejection rate of almost 10% for other contaminants. For total aflatoxins in peanuts, CCCF is considering MLs with rejection rates higher than the 0-5% range customarily followed by CCCF, and that the U.S. draft position states that the U.S. does not object to these (e.g., to a 9.7% rejection rate (15 ug/kg)). We can think of no more compelling case where rejection rates above 5% are needed for consumer health protection than lead, especially for foods that are important sources of exposure to infants, children, and women of childbearing age, given the significant detrimental health effects of lead exposure for those groups.

The U.S. must ensure that MLs as low as possible are proposed and finalized as rapidly as possible. We urge the U.S. to take an active role in developing these more protective MLs.

Background and Public Health Rationale

As you know, multiple authorities, including the U.S. Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), the FAO/WHO Joint Expert Committee of Food Additives (JECFA), and others agree that there is no known safe blood lead level. These and other authorities further agree that fetuses, infants, and children are the most sensitive to lead, and that even blood lead concentrations as low as **5 ug/dl** may be associated with decreased intelligence in children, behavioral difficulties, and learning problems.

In 2012, the CDC recommended health practitioners use a blood lead reference value (BLRV) of **5 ug/dL** for intervention, which was based on the 97.5 percentile of NHANES distributions using 2007-2008 and 2009-2010 data. In 2021, CDC updated the BLRV from 5 ug/dL to **3.5 ug/dl** to identify children with higher levels of lead in their blood compared to most children. This level is based on the 97.5 percentile of blood lead values among U.S. children ages 1-5 years from the 2015-2016 and 2017-2018 National Health and Nutrition Examination Survey (NHANES) cycles. As CDC explains, it is not a health-based standard or a toxicity threshold.

Because there is no apparent threshold for lead toxicity, that lead exposure is cumulative, and food is not the only source of lead, every effort must be made to reduce children's lead exposure as much as possible, from all sources (see (AAP, WHO, EFSA, JECFA, CDC). JECFA states, "although a few micrograms per day may have a negligible impact on IQ without other exposures, such a dietary exposure may be a concern when other lead exposures push total exposure to the steeper part of the curve." (p. 467)

However, even three micrograms a day (3 ug/day) is significant; this has been calculated by the U.S. Food and Drug Administration (FDA) as a maximum daily intake for lead from food, called the Interim Reference Level (IRL), or the amount of dietary lead intake that would be required to reach a blood lead level of 5 ug/dl including a 10x safety factor. As FDA scientists state, the IRL for children and women of childbearing age (WOCBA) is below the lead exposure JECFA considers to be

negligible for lead's effect on IQ (i.e., 0.3 ug/kg bw/day, associated with a population decrease of 0.5 IQ points).

Furthermore, as part of its Closer to Zero plan, FDA will need to update its IRL to take into account CDC's recently updated BLRV as it established action levels for foods.

Food can be a significant source of exposure to lead and is the major source of exposure for some populations – including 80% of U.S. children between 1 and 2, as well as other populations (e.g., the European population.) JECFA has estimated that mean dietary exposures for children aged about 1-4 years range from 0.03 to 9 ug/kg per day.

In other words, mean dietary exposures for young children as estimated by JECFA are greater than FDA's IRL for lead. In the US, an estimated 2.2 million children exceeded the FDA's maximum daily intake as calculated based on the agency's Total Diet Study 2014-2016 results.[1] This number underscores the urgency and importance of lowering lead levels in food.

EDF previously calculated, using FDA's Total Diet Study data from 2014-2016, that approximately 2.2 million children in the United States already consume over the FDA IRL.

In addition, if lead were eliminated from children's food, the estimated benefits to US society in increased lifetime earnings would be at least $27 billion based on our 2017 analysis.

To address MLs where analytical method limitations appear to be blocking progress on the adoption of lower MLs, the US should propose that CCCF request that the Codex Committee on Methods of Analysis and Sampling (CCMAS) re-evaluate the approved methods for lead in foods for infants and young children and remove methods that are insufficiently sensitive. The inductively coupled mass spectrometry (ICP-MS) Elemental Analytical Method 4.7 has been validated by FDA for analysis of total lead in food with an limit of quantification (LOQ) of 11 micrograms per kilogram (µg/kg) and widely available on commercial market at a reasonable cost. EDF coordinated a proficiency testing program and identified more than ten commercial laboratories around the world can do better and are capable of quantifying lead at 6 µg/kg.

Although CCCF generally sets MLs to correspond with a rejection rate of 5% or less, this approach fails to consider the public health threat posed by lead and the facts described above. WHO has identified lead as one of ten chemicals of major public health concern needing action by Member States to protect the health of children and women of reproductive age.

Furthermore, some of the proposed MLs are associated with very low rejection rates, and this is unacceptable. The proposed MLs will not result in meaningful reductions in lead exposure, to those most at risk. As noted above, for total aflatoxins in peanuts, CCCF is considering MLs with rejection rates higher than 5%, and the U.S. draft position states that the U.S. does not object to a ML of 15 ug/kg, which is associated with a 9.7% rejection rate. The U.S. has previously taken the position that MLs for lead in food should be established on a case-by-case basis. Other countries, such as Japan, have taken a position that violation rates above 5% would be acceptable if the ML is not sufficient for consumer health protection. We can think of no more compelling case where rejection rates above 5% are needed for consumer health protection than the case of lead, given the significance of lead exposure for infants, children, and women of childbearing age.

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[1] Spungen, JH. 2019. Children's exposures to lead and cadmium: FDA total diet study 2014-2016. Food Additives and Contaminants: Part A 36:893-903 https://doi.org/10.1080/19440049.2019.1595170

Specific Comments on Proposed MLs and the U.S. Draft Position

Our comments are focused especially on foods that may contribute significantly to exposure of infants, children, and women of childbearing age.

RTE meals for infants and children

The proposed ML for ready-to-eat (RTE) meals for infants and children of 0.05 mg/kg of food corresponds to a lackluster rejection rate of 1.0%. The proposed ML is unacceptable especially since this is a food specifically marketed for infants and young children. We strongly agree with the U.S. draft position to not support this proposed ML, given the significance of lead exposure for fetuses, infants, and young children.

We understand that the 0.05 mg/kg was chosen in order to comply with guidelines set out in the Codex Procedural Manual that advise that the ML be established so that the LOD is less than or equal to 1/5 of the ML and the LOQ is less than or equal to 2/5 of the ML. However, more robust analytical methods are available, and the public health imperative to reduce lead levels in infants and children should take precedence over these "guidelines," (to quote the Codex Procedural Manual). After all, the main purpose of Codex proposals, to again quote the Codex Procedural Manual, is "protecting the health of the consumers and ensuring fair practices in the food trade."

Using the FDA-established interim reference level of 3 µg/day, a single serving of ready-to-serve dinners (stews or soups) for young children of 170 grams and the proposed ML of 0.05 mg/kg in a 170 gram RTE stew or soup would result in a lead intake of 8.5 ug—over 2.8 times the IRL, from a single serving:

0.05 mg/kg x 0.17 kg = 0.0085 mg, or 8.5 ug, per serving.

Even a ML of 0.02mg/kg would exceed the FDA IRL – from this single serving alone. A ML of 0.02 mg/kg corresponds to a 5.7% rejection rate, according to CX/CF 22/15/7. The next lower ML considered, 0.01 mg/kg, corresponds to a 14.8% rejection rate.

We support the U.S. position to clarify whether ready-to-eat meals are limited to jarred foods and purees or if they include a variety of multi-ingredient meals, and for the electronic working group (EWG) to analyze these separately, as analytical methods for single ingredient vs. multiple ingredient products have different limits of detection (LODs) and quantitation (LOQs), and a separate analysis may facilitate lower MLs for single ingredient products.

Cereal-based products for infants and children

Similarly, the proposed ML for cereal-based products for infants and children is 0.05 mg/kg, which corresponds to a rejection rate of only 1.3%, with two sub-categories, those containing fruit, and those containing milk, associated with a 0% rejection rate. This is unacceptable, especially since these are products marketed to infants and children. The next lower ML considered, 0.04 mg/kg, results in a rejection rate of 10.1% for the category, as well as all subcategories.

According to the European Food Safety Authority (EFSA), cereal products contribute most to dietary lead exposure.

We agree with the US draft position to not support this ML. The U.S. should urge that public health considerations take priority over the 5% rejection rate that CCCF is accustomed to using. If the committee is unable to agree to a proposed ML of 0.04 or lower because the rejection rate is above

5%, at the very least, an intermediate value between 0.04 and 0.05 (e.g., 0.045 mg/kg) should be established, and the ML revisited as soon as possible to consider a lower level.

Separate MLs could also be developed for sub-categories of cereal-based products, based on the distribution of data in CX/CF 2/15/7, if that would facilitate acceptance of lower MLs by the Committee. We also agree that the data should be analyzed separately for dry cereal vs. jarred cereal, as this may allow development of lower MLs.

Sugar-based candies

EDF strongly urges the US to rethink its position supporting an ML of 0.1 mg/kg for all candy types (higher than what has been proposed for most candy types), since candy is a food especially consumed by children, and since it would achieve no reductions in lead exposure from soft candies and only minimal reductions in lead exposure from hard candies (1.1% rejection rate) and gummy and jelly (1.3%).

The proposed ML of 0.05 mg/kg for hard candies, gummies and jellies results in rejection rates of 5% or less, and there is no public health justification for the U.S. supporting a higher ML. The proposed ML for soft candies, 0.07 mg/kg, which results in a rejection rate of 2%, is not acceptable for this food widely consumed by children. The rejection rate would be 10.2% at 0.06 mg/kg, according to the data presented in CX/CF 22/15/7.

The U.S. should urge that public health considerations take priority over the 5% rejection rate that CCCF is accustomed to using, for these foods consumed by children. If the committee is unable to agree to a proposed ML of 0.06 or lower because the rejection rate is above 5%, at the very least, an intermediate value between 0.06 and 0.07 (e.g., 0.065 mg/kg) should be established.

Sugars and honey

We urge the U.S. to modify its position for sugars (white and refined, brown, and raw). The unfortunate reality is that children consume large amounts of added sugars, and the proposed ML of 0.1 mg/kg for all types of sugar results in no reduction in exposure to lead from refined sugar, only very low reductions in exposure for white sugar (0.78 rejection rate) and raw sugar (1.6%), and modest reductions from brown sugar (3.2%).

If the committee is unable to agree to a ML of 0.09 or lower for sugar (white and refined, brown, and raw) since the rejection rate is above 5%, at the very least, an intermediate value between 0.09 and 0.1 (e.g., 0.095 mg/kg) should be established, and the ML revisited as soon as possible to consider a lower level. Again, if setting separate MLs for different types of sugar would facilitate the acceptance of lower MLs within the Committee, the U.S. should support that.

We also disagree with the US position favoring a higher ML (0.1 mg/kg) than proposed (0.06 mg/kg) for honey. The proposed ML results in a rejection rate of 4.4%, and there is no public health justification for supporting a higher level.

Syrups and molasses

Instead of the proposed ML of 0.1 mg/kg for corn and maple syrups, which results in a 0% rejection rate for corn syrup, we urge the US to support the establishment of a separate ML for corn syrup. The only other MLs considered are 0.05 mg/kg (associated with a 3.5% rejection rate) and 0.01 (associated with a 7.0% rejection rate). Given the frequent occurrence of corn syrups in food, especially foods consumed by children, an ML as low as possible should be considered.

Spices from bark
EDF supports the US position calling for a lower ML for spices from bark than proposed (2.5 mg/kg) since cinnamon is used heavily in children's foods.

Rhizomes, bulbs and roots (excluding garlic)
We agree with the U.S. position of not supporting the proposed ML of 3.5 mg/kg for rhizomes, bulbs, and roots (excluding garlic), and to differentiate between ground and whole samples, removing any adulterated ground samples from the analysis of rejection rates. We also agree that a lower ML could be set for the whole category if turmeric were excluded. We would further suggest that the US support excluding ginger from the category.

So instead of the proposed ML of 3.5 mg/kg (3,500 ppb) for "spices, dried rhizomes, bulbs, and roots, excluding garlic," lower reductions in lead could be achieved by establishing MLs no higher than 3 or 3.5 mg/kg for turmeric and for ginger, and no higher than 1.5 mg/kg for spices, dried rhizomes, bulbs and roots, excluding turmeric, ginger, and garlic. (Retaining the proposed ML of 0.4 mg/kg for garlic).

A 2018 Morbidity and Mortality Weekly Report study found that contaminated spices, as well as herbal remedies and ceremonial powders, might represent an important source of childhood lead exposure, especially for those whose parents are from Southeast Asia.

Thank you for considering our comments.

Sincerely,

Tom Neltner

Tom Neltner, PhD, JD
Senior Director, Safer Chemicals Initiative
Environmental Defense Fund

Lisa Y. Lefferts

Lisa Y. Lefferts, MSPH
Environmental Health Consultant