Action Levels for Lead in Juice: Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2019-D-5609 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

April 2022

Table of Contents

Contains Nonbinding Recommendations

Draft-Not for Implementation

Action Levels for Lead in Juice: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

I. Introduction

FDA is committed to reducing lead in food to the extent feasible. FDA's *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. This guidance provides information to industry on the action levels for lead in juice. The action levels for lead in juice in this document would, if finalized, replace the current level of 50 parts per billion (ppb) described in the Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance (Juice HACCP Guidance), First Edition (Ref. 1). FDA considers the action levels described in this guidance to be achievable by industry (or you) when measures are taken to minimize the presence of lead.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidance means that something is suggested or recommended, but not required.

II. Background

Juice[2] can become contaminated with lead through sources such as produce used to make juice (Ref. 1) and old lead-containing equipment, such as old lead-soldered machinery (Ref. 2). 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. Even low lead exposure can harm children's health

[1] This guidance has been prepared by the Office of Food Safety, Division of Plant Products and Beverages in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] As stated in 21 CFR 120.1(a), "juice" means "the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree."

and development, specifically the brain and nervous system. Neurological effects of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Lead exposures also may be associated with immunological, cardiovascular, renal, and reproductive and/or developmental effects (Ref. 3). Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time (Ref. 4). FDA has taken actions to address lead in juice, a food commonly consumed by young children.

In 1993, we established an emergency action level of 80 ppb and above for lead in juice packed in lead soldered cans as a measure to limit the presence of lead in juice while we undertook rulemaking to revoke the prior sanctions for lead soldered cans and ultimately prohibit their use for packing food (58 FR 17233).[3]

In 1999, the Joint World Health Organization (WHO)/Food and Agriculture Organization (FAO) Expert Committee on Food Additives (JECFA) released a toxicological assessment for lead which maintained the provisional tolerable weekly intake (PTWI) for lead of 25 micrograms per kilogram body weight (μg/kg bw) but noted that foods with high levels of lead remain in commerce. In 2001, the Codex Alimentarius Commission (Codex), an international food standards organization, established a maximum level (ML) of 50 ppb for lead in ready-to-drink fruit juices, including fruit nectars, that are in international trade. FDA concurred with the Codex ML and adopted 50 ppb as the recommended level not to be exceeded for lead in juice in the Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance (Juice HACCP Guidance), First Edition (FDA, 2004).

In 2011, JECFA reassessed the safety of lead and withdrew the PTWI for lead. JECFA further concluded that "it was not possible to establish a new PTWI [for lead] that would be considered to be health protective" (Ref. 5). JECFA concluded that in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources and, if appropriate, to identify methods for reducing dietary exposure that are commensurate with the level of risk reduction (Ref. 5).

In 2012, Codex initiated work to reevaluate the previously established MLs for lead in multiple commodities in the Codex General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) (Codex Stan 193-1995) (Ref. 6), prioritizing review of MLs for foods (such as juice) that are highly consumed by children.

This work, led by the U.S., as a member of Codex, resulted in the reduction of the lead ML for fruit juices in general from 50 ppb to 30 ppb and for grape juice from 50 ppb to 40 ppb. The ML for fruit juices made from berries and other small fruits was retained at 50 ppb. This analysis was based on the achievability of lower MLs following review of international data on lead in fruit juices.

Because no safe level of lead exposure has been identified for children's health, in 2018, FDA developed interim reference levels (IRLs) for dietary lead to replace FDA provisional tolerable total daily intakes (PTTDIs) (Ref. 4) which had been developed in the early 1990's. FDA used

[3] In the *Federal Register* of June 27, 1995 (60 FR 33106), we issued a final rule to prohibit the use of lead solders in the construction of food cans. The rule is codified at 21 CFR 189.240.

the Centers for Disease Control and Prevention (CDC) reference value of 5 µg/deciliter (dL) blood lead[4] level, the level at which public health interventions should be initiated for children, and dietary conversion factors calculated by the Environmental Protection Agency to derive IRLs of 3 µg/day for children and 12.5 µg/day for women of child-bearing age (WOCBA), respectively. The IRL for WOCBA is protective against possible fetal lead exposure in women who are not yet aware that they are pregnant (Ref. 4).

In 2021, FDA initiated the *Closer to Zero* action plan that identifies actions we will take to reduce exposure to toxic elements, including lead, from foods eaten by babies and young children (Ref. 7). The plan outlines an iterative approach for achieving continual improvements over time, reducing children's exposure to lead and other toxic elements from food through activities such as setting action levels. FDA will identify IRLs for certain toxic elements as appropriate and may use the IRLs to help inform the development of action levels. The plan commits to consulting with stakeholders, including on the achievability of reducing toxic element levels, and notes the importance of minimizing the potential for unintended consequences on the availability of nutritious foods for children.

In response to the 2011 JECFA conclusion, the Codex adoption of lower MLs for fruit juices based on achievability, as well as FDA's development of IRLs and the *Closer to Zero* plan, FDA reevaluated the 50 ppb lead level recommended in the current Juice HACCP Guidance (Ref. 1). Given that no safe level of lead exposure from food has been identified by JECFA (Ref. 5), FDA's reevaluation has focused on review of U.S. data to determine if lower levels of lead in juice were achievable and if lower levels would reduce lead exposures in vulnerable populations.

III. Action levels

Based on our review of lead levels in juice samples that were collected by FDA after the 50 ppb level for juice was established in 2004, in consideration of the IRL for lead of 3 µg/day for children, and in accordance with 21 CFR 109.6, we are establishing an action level for lead of 10 ppb for apple juice on a single-strength (ready-to-drink) basis and an action level for lead of 20 ppb for other single-strength juice types, including juice blends that contain apple juice (Ref. 8). The lower action level for apple juice is based on the fact that apple juice is the most commonly consumed juice type by young children in the U.S. For apple juice, an action level of 10 ppb is estimated to reduce dietary exposure to lead for children by 46% at the 90th percentile consumption level (see Ref. 8). For other fruit and vegetable juice types, an action level of 20 ppb is estimated to reduce dietary exposure to lead for children by 19% at the 90th percentile consumption level. Though not binding, these action levels are intended to encourage manufacturers to maintain lead levels in juices below the action levels, thus reducing risks associated with dietary lead exposures. The establishment of these action levels for lead in juice is consistent with FDA's longstanding policy of reducing consumers' lead exposure. Therefore, it is important that HACCP controls are considered to minimize the presence of this contaminant. The action is focused on juice, a product consumed frequently by infants and children, who are more sensitive than adults to the neurodevelopmental effects of lead exposure. The action levels

[4] The reference value of 5 µg/deciliter (dL) blood lead was updated in 2021 by the CDC. Additional information is available at: https://www.cdc.gov/media/releases/2021/p1028-blood-lead.html.

differ from international levels established by Codex, as the action levels reflect data from samples in the U.S. (from both import and domestic products in the marketplace), while Codex levels are based on international data.

Consistent with 21 CFR 109.4, these action levels define the levels of lead contamination that may cause the juice products described in this guidance to be regarded as adulterated. We intend to consider these action levels, in addition to other factors, when considering whether to bring enforcement action in a particular case. When this draft guidance is finalized, we intend to update the Juice HACCP Guidance (Ref. 1) to reflect the new action levels.

FDA recommends that the juice industry continue to work to lower the lead concentrations in juices to the extent possible under current good manufacturing practices. As part of our *Closer to Zero* plan, we intend to further engage with stakeholders on proposed action levels, including the achievability of such levels, and the feasibility of further reducing the presence of lead in food. After action levels are finalized, we plan to monitor the levels of lead in food and children's exposure to lead from food to assess whether to adjust the action levels for lead in juice.

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them in person at this location between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. FDA, 2004. Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition; Final Guidance. Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-hazard-analysis-critical-control-point-hazards-and-controls-guidance-first.*
2. Codex Alimentarius, 2021. Revision of the Code of Practice for the Prevention and Reduction of Lead Contamination in Foods in Report of the 14th Session of the Codex Committee on Contaminants in Foods (REP21/CF). Available at: https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCCF&session=14.
3. HHS, National Toxicology Program, 2012. NTP Monograph on Health Effects of Low-Level Lead. Available at: https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead_newissn_508.pdf.
4. Flannery, B.M., L.C. Dolan, D. Hoffman-Pennesi, A. Gavelek, O.E. Jones, R. Kanwal, B. Wopert, K. Gensheimer, S. Dennis, S. Fitzpatrick, 2020. U.S. Food and Drug Administration's interim reference levels for dietary lead exposure in children and women of childbearing age. Reg. Toxicol. Pharmacol. 110:1-20.

5. WHO/FAO Joint Expert Committee on Food Additives, 2011. Evaluation of Certain Contaminants in Food, 73rd Report of the World Health Organization/Food and Agriculture Organization of the United Nations Joint Expert Committee on Food Additives. WHO Technical Report Series 960. Available at https://apps.who.int/iris/bitstream/handle/10665/44515/WHO_TRS_960_eng.pdf?sequence=1.
6. Codex Alimentarius, 2021. General Standard for Contaminants and Toxins in Food and Feed, CXS 193-1995. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B193-1995%252FCXS_193e.pdf.
7. FDA, 2021. Closer to Zero: Action Plan for Baby Foods. Available at https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods.*
8. FDA, 2022b. Draft Supporting Document for Establishing FDA's Action Levels for Lead in Juice. Available at https://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/draft-supporting-document-establishing-fdas-action-levels-lead-juice.*