U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

June 1, 2023

Steve Whittaker
Seattle/King County Hazardous Waste Management Program (S/KC)
201 S. Jackson Street, Suite 5600
Seattle, WA 98104

Dear Dr. Whittaker

This letter is in response to your emails dated May 16 and 17, 2023, requesting FDA's guidance on current achievable limits of detection/quantitation for lead testing in 4% acetic acid leachate from cookware, in the context of a request from Amazon.com, Inc. (Amazon). We understand that S/KC is requesting FDA guidance on current achievable limits of detection/quantitation so that you may convey to Amazon an appropriate testing limit for lead in cookware that would be sold on their platform. You also state that anything you recommend would need to be readily achievable by commercial analytical labs. Below we provide our interim considerations for action levels for lead in food intended for consumption by young children and our recommendations for testing cookware for leachable lead, which you may convey to Amazon.

Legal Framework and Safety Concern for Cookware that Leaches Lead

First, we will provide information regarding the legal framework and public safety concern for cookware that leaches lead. Please note, currently, there is no FDA guidance limit for leachable lead from cookware; the marketing in interstate commerce, including importation, of cookware that exhibits *any level* of leachable lead upon testing is prohibited. Cookware that leaches lead into 4% acetic acid solution placed in the cooking reservoir is an indication that lead is reasonably expected to become a component of food cooked in such cookware. Neither lead nor lead containing materials (e.g., metals, solder) are permitted under FDA regulations for use in contact with food. Therefore, lead, or a component material containing lead in cookware, is an unsafe food additive, and cookware that leach lead are adulterated under section 402(a)(2)(C)(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). Offering an adulterated product for sale in interstate commerce, including importation to the U.S., is a prohibited act under the FD&C Act. Oral ingestion of lead in even small amounts is a known safety hazard and food cooked in cookware such as pressure cooker products would be expected to be served to small children as well as eaten by women of child-bearing age and those who may be breastfeeding infants. Fetuses, infants, and children are particularly vulnerable to the potential harmful effects from lead exposure because of their smaller body sizes, metabolism, and rapid growth. There is no level of exposure to lead that has been determined to be safe.

Therefore, neither lead, nor a component material containing lead, should be present, either intentionally or unintentionally, in cookware whereby the lead is reasonably expected to migrate

to food. Cookware should contain no component such as lead-containing brass, solder, or aluminum sourced from recycled aluminum parts that may contain lead, where lead is reasonably expected to migrate to food under the intended conditions of use of the cookware. Firms may be able to obtain a letter of guaranty as defined under Section 303 of the FD&C Act and described in 21 CFR 7.12 and §7.13 from suppliers whereby they ensure that lead is not present in cookware such that it may migrate to food. Firms may also require supporting documentation from such suppliers that may include, for example, certificates of analysis indicating that lead is not present in materials used to manufacture the cookware.

Recommendations for Testing Cookware for Leachable Lead

FDA's current method of analysis (MOA) of lead in acetic acid leachate from cookware, which should be considered an interim method, is a modified version of FDA Elemental Analysis Manual (EAM) Method 4.6 Inductively Coupled Plasma Optical Emission Spectrometric Determination of Cadmium and Lead Extracted from Ceramic Foodware (https://www.fda.gov/media/95170/download). For cookware, the only modification to this MOA is, instead of a 24-hour extraction at 22 °C ± 2 °C, the extraction conditions include a 2-hour boil followed by cooling and holding at room temperature for a total of 24-hours. All other method details remain the same. Our current estimate of the limit of quantitation (LOQ) for this method is in the 50 – 100 ppb range, and we believe this range is readily achievable in commercial labs. We expect the level of lead leached into 4% acetic acid under the above testing conditions will be exaggerative of any level of lead that would migrate to food cooked in the cookware. However, analytical methods with lower LOQs may be preferable to further reduce the risk of lead leaching into food from the cookware. FDA has other analytical methods, such as EAM 4.7, which utilizes ICP/Mass Spectrometry (ICP/MS) for analyzing for lead in food, with lower LOQs, however, FDA has not validated this method for use to analyze for lead in 4% acetic acid leachate from cookware.

For the testing protocol for leach testing cookware for lead, our recommendation to firms intending to market cookware in interstate commerce in the U.S. (which includes the importation of cookware), would be to use the protocol described in the above modified EAM 4.6 method, or similar methods.

For the analytical method and instrumentation to analyze lead in acetic acid leachate, we recommend firms find the methods and instrumentation that are currently available to them and have the lowest practicable reporting limits (LOQs), **not to exceed 100 ppb**. For example, lower LOQs may be achievable using analytical methods such as described in FDA's EAM 4.7 referenced above. For another example, S/KC provided FDA a description of the analytical method used by the University of Washington, which measured lead in acetic acid leachate from cookware provided by S/KC and apparently achieved lower LOQs utilizing ICP/MS. The University of Washington described utilizing modified versions of certain EPA analytical methods. Testing using analytic methods with the lowest practically achievable LOQs will provide better assurance that the cookware is safe. Furthermore, in the future, FDA may determine and issue guidance limits for lead in leachate from cookware, compliance with which may require testing using analytical methods with lower LOQs than 100 ppb.

Once firms decide on an available analytical method with a lowest practically achievable LOQ not to exceed 100 ppb and begin testing, **if a quantifiable level (at or above the LOQ of the method utilized) of lead is detected in the acetic acid leachate of a cookware product, indicating a reasonable expectation that lead will migrate to food from the cookware, the cookware should not be marketed in the U.S.** FDA recommends that all cookware that may contain lead be tested via a suitable method prior to marketing the product.

Please feel free to share this letter or any of its contents with Amazon.com, Inc. and any other firms involved in the marketing or sale of cookware. Firms may also send an email to FDA's Office of Regulatory Affairs/Office of Regulatory Science ORAORSPrivateLabImportAlerts@fda.hhs.gov to ask for guidance on testing cookware for leachable lead.

Firms may contact FDA's Office of Food Additive Safety: premarkt@fda.hhs.gov for any questions about the regulatory status of cookware, lead, and the content of this letter.

Sincerely,

Paul S. Honigfort -S

Digitally signed by Paul S. Honigfort -S
Date: 2023.06.01 17:30:18 -04'00'

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