GUIDANCE DOCUMENT

Guidance for Industry: Safety of Imported Traditional Pottery Intended for Use with Food and the Use of the Term "Lead Free" in the Labeling of Pottery/Proper Identification of Ornamental and Decorative Ceramicware

NOVEMBER 2010

Final

Docket Number:
FDA-2010-D-0571 (https://www.regulations.gov/docket/FDA-2010-D-0571)

Issued by:
(/regulatory-information/search-fda-guidance-documents/guidance-industry-safety-imported-traditional-pottery-intended-use-food-and-use-term-lead-free)
Center for Food Safety and Applied Nutrition

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I. Introduction

FDA is issuing this guidance to industry to address our concerns about the safety and labeling of imported traditional pottery, including imported Mexican terra cotta pottery, and the use of the term "Lead Free" in the labeling of pottery. Further, this guidance reminds industry of FDA's requirements for labeling ceramicware that is solely intended for ornamental or decorative use to ensure that it is not used for food-handling purposes that could result in the ceramicware contaminating the food.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

FDA has received recent reports from local and state agencies that pieces of traditional pottery imported into the United States from several manufacturers in Mexico that are labeled as "Lead Free" in fact contain levels of extractable lead. In some cases, these levels are comparable to levels found in lead glazed pottery and, in others, they are in excess of the action levels for extractable lead in ceramic foodware set forth in Compliance Policy Guide (CPG) Sec. 545.450 Pottery (Ceramics); Import and Domestic – Lead Contamination.[2] FDA's own investigations have confirmed some of these reports.

This information suggests that some manufacturers of non-lead glazed (NLG) pottery have not implemented practices to ensure that NLG pottery will not become contaminated with lead during its manufacture. Products that are labeled as "Lead Free" or in any other fashion that represents that lead

was not used in the product, but that contain levels of extractable lead that indicate contamination, could face regulatory action. FDA recommends that manufacturers, importers, and distributors of imported traditional pottery take the actions recommended in this guidance as a means to help ensure that their products are not contaminated with lead during the manufacturing process and that their products are properly labeled.

III. Safety of Imported Traditional Pottery Intended for Use with Food and the Use of the Term "Lead Free" in the Labeling of Pottery

Lead compounds, such as lead oxide, have historically been used in glaze formulations to regulate the melting properties of other glaze components and to enable the use of a broad firing temperature range in the production process. However, when fired at inadequate or uncontrolled temperatures, the lead is not fully incorporated into the glaze structure and is available to leach into food in quantities that may pose a health hazard to consumers.

FDA is aware of ongoing efforts by potters in Mexico and other countries to convert from lead glazed to NLG-based production methods for traditional pottery, a category of ceramicware produced using a low fire process and an earthenware ceramic body with culturally distinct decorative patterns. FDA has looked positively upon efforts by foreign governments and private organizations to promote conversion to NLG pottery production methods because they lessen the risk of food safety hazards historically associated with lead in traditional pottery that is used for food-handling purposes. In our interactions with the government of Mexico, with private organizations that have assisted potters in converting to NLG-based production methods, and with potters that have converted to NLG-based production

methods, we have learned of the following key practices that have been implemented by some pottery manufacturers to help prevent lead contamination of NLG pottery:

- All NLG pottery is made and packed in a separate building from any lead glazed items produced at the same site by the manufacturer.
- If lead glazed items are manufactured in another building at the site, the manufacturer has established and adheres to practices to ensure that no lead is introduced into the production area for NLG pottery, such as from utensils that have been used for handling lead glazes.
- If lead glazed items were previously manufactured in the facility, the manufacturer has modified the kilns (e.g., replaced the insulation) and carried out other cleanup in the facility as necessary to ensure that no lead contamination of the present production will occur due to the use of lead in the previous production. The efficacy of the kiln modification and plant cleanup has been confirmed by testing the NLG pottery using a quantitative extraction test method, such as those discussed in FDA's CPG referenced earlier in this document.
- The facility has trained its employees in practices that ensure the avoidance of lead cross-contamination in the production of pottery.

FDA recommends that parties involved in the manufacture, importation, and distribution of imported NLG traditional pottery for sale in the United States incorporate these key practices to help ensure that the pottery has been produced in such a manner that it will not become contaminated with avoidable lead. This is consistent with a longstanding goal of

FDA, which is to reduce the public's exposure to lead from food and products used in food- handling to the maximum extent practicable.

Furthermore, any food contact substance, including those used in glazed pottery, that meets the definition of a food additive in section 201(s) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 321(s)), must comply with the requirements set forth in section 409 of the Act (21 U.S.C. 348) to be marketed in the U.S. That is, it must be authorized for such use by a notification or regulation under Title 21 of the Code of Federal Regulations (21 CFR). In the CPG referenced earlier in this document, FDA set forth criteria that it will use in determining whether to recommend legal action against ceramicware that contains levels of extractable lead. Specifically, the levels of extractable lead should not exceed the action levels in the CPG when the ceramicware is tested according to the methods prescribed in the CPG. FDA considers this CPG to be applicable to all forms of ceramicware, including NLG ceramicware. If the amount of extractable lead in ceramicware exceeds the action levels in the CPG, FDA may consider the ceramicware to be adulterated under section 402(a)(2)(C) of the Act (21 U.S.C. 342(a)(2)(C)) because it bears or contains an unsafe food additive, and subject to enforcement action.

In addition, ceramicware that contains extractable lead when tested according to the method prescribed in the CPG should not be labeled as "Lead Free." If ceramicware bearing the term "Lead Free" in its labeling contains extractable lead, FDA may consider the use of the term "Lead Free" in the labeling to be false and misleading, and therefore the ceramicware misbranded under section 403(a)(1) of the Act (21 U.S.C. 343(a)(1)).

IV. Proper Identification of Ornamental and Decorative Ceramicware

FDA has received reports of imported traditional pottery that either bears a stick-on label stating that the item is not for food use or that bears this message on its packaging, but not on the item itself. Ornamental and decorative pottery labeled in such a manner may pose a food safety hazard if it contains extractable lead that could contaminate food and users assume that the pottery is safe to be used for food-handling purposes after the packaging is discarded and/or the stick-on label is removed.

FDA reminds firms of its requirements addressing ornamental and decorative ceramicware set forth in 21 CFR 109.16, which states that ceramicware that appears to be suitable for food use will be considered by FDA to be for food use unless it bears: (1) a conspicuous stick-on label on a surface clearly visible to consumers that states one of the messages provided in 21 CFR 109.16(b)(1)(i); and (2) a conspicuous and legible permanent statement of the message selected from 21 CFR 109.16(b)(1)(i) on the exterior surface of the base. FDA reminds firms that ceramicware purporting to be decorative or ornamental, but that does not meet the requirements of 21 CFR 109.16, could be subject to regulatory action if it contains extractable lead that could contaminate food. Firms making and selling ornamental or decorative ceramicware in the U.S. must ensure that their products comply with 21 CFR 109.16 as appropriate.

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

[2] Compliance Policy Guide (CPG) Sec. 545.450 Pottery (Ceramics); Import and Domestic – Lead Contamination (/media/71764/download)

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