

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0558]

Compliance Policy Guide, Guidance Levels for Radionuclides in Domestic and Imported Foods, Availability; and Supporting Document, Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods, Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) entitled “Guidance Levels for Radionuclides in Domestic and Imported Foods.” This document is intended to make FDA offices and the industry aware of FDA’s guidance for enforcement concerning radionuclide activity concentration in domestic food in interstate commerce or food offered for import. This CPG rescinds and replaces CPG Sec. 560.750 Radionuclides in Imported Foods—Levels of Concern (CPG 7119.14). The agency also is announcing the availability of a final supporting document entitled “Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods.”

DATES: Submit written or electronic comments concerning the CPG or the final supporting document at any time.

ADDRESSES: Submit written requests for single copies of the CPG entitled “Guidance Levels for Radionuclides in Domestic and Imported Foods” and/or the final supporting document entitled “Supporting Document for Guidance

Levels for Radionuclides in Domestic and Imported Foods” to Paul South (see **FOR FURTHER INFORMATION CONTACT**). Send two self-addressed adhesive labels to assist that office in processing your request. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to these documents.

FOR FURTHER INFORMATION CONTACT: Paul South, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1640.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 14, 2004 (69 FR 2146), FDA announced the availability of a draft CPG entitled “Guidance Levels for Radionuclides in Domestic and Imported Foods,” and a draft supporting document entitled “Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods.” After considering comments received on these documents, FDA has finalized the CPG and supporting document. The CPG rescinds and replaces CPG Sec. 560.750 Radionuclides in Imported Foods—Levels of Concern (CPG 7119.14).

FDA received five comments on the draft CPG. The comments represented the views of individual consumers, a Federal agency, a State health department, and a foreign government. One comment was rejected because it was outside the scope of the draft CPG. The majority of comments supported the proposed guidance levels while a number of comments suggested changes or modification to other aspects of the draft CPG. After considering carefully

the comments received, the agency revised the draft CPG to include a reference to methods for radionuclide analysis of foods.

The CPG is being issued as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The CPG represents the agency's current thinking on its enforcement process concerning the adulteration of food with radionuclides. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the CPG entitled "Guidance Levels for Radionuclides in Domestic and Imported Foods," and/or the final supporting document entitled "Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods." Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the CPG, the final supporting document, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the CPG and final supporting document may be accessed from the home pages of the Center for

Food Safety and Applied Nutrition at <http://www.cfsan.fda.gov> and the Office of Regulatory Affairs at <http://www.fda.gov/ora/>.

Dated: July 22, 2004.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S