

Contains Nonbinding Recommendations

Draft Compliance Policy Guide

Compliance Policy Guidance for FDA Staff¹

Draft Guidance Levels for Radionuclides in Domestic and Imported Foods

This draft guidance document is being distributed for comment purposes only.

Draft released for comment on January 13, 2004.

Comments and suggestions regarding this draft document should be submitted by March 14, 2004 to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket number 2003D-0558. For questions regarding this draft document contact Paul South (HFS-306) Center for Food Safety and Applied Nutrition (CFSAN), (301) 436-1640.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
January, 2004**

¹ This draft guidance has been prepared by the Office of Plant and Dairy Foods and Beverages in the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. This draft guidance represents the Agency's current thinking on its enforcement process concerning the adulteration of food with radionuclides.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.

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Sec. 560.750 Guidance Levels for Radionuclides in Domestic and Imported Foods (CPG 7119.14)

*Additional copies are available from:
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**U.S. Department of Health and Human Services
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Sec. 560.750 Draft Guidance Levels for Radionuclides in Domestic and Imported Foods (CPG 7119.14)

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I. INTRODUCTION

The purpose of this document is to present guidance levels for radionuclide activity concentration, called derived intervention levels (DILs), which FDA has adopted to help determine whether domestic food in interstate commerce or food offered for import into the United States presents a safety concern. This draft Compliance Policy Guide (CPG), if finalized, will rescind and replace CPG Sec. 560.750 Radionuclides in Imported Foods – Levels of Concern (CPG 7119.14).

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

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cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

In the Federal Register of June 25, 1986 (51 FR 23155), after the Chernobyl nuclear accident, FDA issued a Compliance Policy Guide (CPG) Sec. 560.750 Radionuclides in Imported Foods – Levels of Concern (CPG 7119.14) (hereinafter 1986 FDA guidance), which establishes guidance levels called “Levels of Concern” (LOCs) for radionuclide activity concentration in food offered for import. FDA staff considers the 1986 guidance levels when deciding whether to recommend detention of food offered for import into the United States. In the Federal Register of August 13, 1998 (63 FR 43402), FDA announced the availability of a new document entitled “Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations to State and Local Agencies” (hereinafter 1998 FDA document). The 1998 FDA document provides broader and more current information regarding radionuclides in food, and recommends new guidance levels for radionuclide activity concentration in food called Derived Intervention Levels, or DILs.

III. DISCUSSION

In this draft CPG, FDA has adopted DILs that were recommended in the 1998 FDA document as guidance levels for radionuclide activity concentration in food offered for import. FDA also has adopted these same guidance levels for radionuclide activity concentration for domestic food in interstate commerce. Previously, FDA had not established guidance levels for radionuclide activity concentration for domestic food in interstate commerce. In addition, the

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scope of coverage of the 1986 FDA guidance, which included food accidentally contaminated with radionuclides, has been expanded in this draft CPG to food that is accidentally or intentionally contaminated with radionuclides. These changes were made to ensure that FDA staff has appropriate guidance to address an incident involving food accidentally or intentionally contaminated with radionuclides, whether in domestic interstate commerce or offered for import. This draft CPG, if finalized, will rescind and replace the 1986 guidance (i.e., CPG Sec. 560.750 Radionuclides in Imported Foods – Levels of Concern (CPG 7119.14)). The 1998 FDA document is unaffected by this CPG. Consistent with the terminology used in the 1998 FDA document, guidance levels for radionuclide activity concentration in this draft CPG are called DILs. DILs is an internationally used term that will replace the previous FDA term “Levels of Concern” (LOCs).

IV. REGULATORY ACTION GUIDANCE

FDA uses DILs to help determine whether domestic food in interstate commerce or food offered for import into the United States presents a safety concern. FDA determines whether foods contain unsafe levels of radionuclides on a case-by-case basis, considering the totality of the circumstances and the extent to which those circumstances depart from the assumptions that underlie the derivation of DILs. The DILs adopted in this draft CPG are not binding on FDA, the regulated industry, or the courts. In any given case, FDA may decide to initiate an enforcement action against food with concentrations below the DILs or decide not to initiate an enforcement action against food with concentrations that meet or exceed the DILs. A district is to contact CFSAN/Office of Compliance/Division of Enforcement (HFS-605) for a preliminary

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assessment regarding the use of a DIL in a given case. The DILs that FDA may use to help determine whether foods contain unsafe levels of radionuclides are listed in the following table:

Derived Intervention Levels (DILs) for Each Radionuclide Group for Food in Domestic Commerce and Food Offered for Import^{a,b}

Radionuclide Group	DIL
	(Bq/kg)
Strontium-90	160
Iodine-131	170
Cesium-134 + Cesium-137	1200
Plutonium-238 + Plutonium-239 + Americium-241	2
Ruthenium-103 + Ruthenium-106 ^c	$\frac{C_3}{6800} + \frac{C_6}{450} < 1$

^aThe DIL for each radionuclide group is applied independently. Each DIL applies to the sum of the concentrations of the radionuclides in the group at the time of measurement.

^bApplicable to foods as prepared for consumption. For dried or concentrated products such as powdered milk or concentrated juices, adjust by a factor appropriate to reconstitution, and assume the reconstitution water is not contaminated. For spices, which are consumed in very small quantities, use a dilution factor of 10.

^cDue to the large differences in DILs for Ruthenium-103 and Ruthenium-106, the individual concentrations of Ruthenium-103 and Ruthenium-106 are divided by their respective DILs and then summed. The DIL for the Ruthenium group is set at less than one. C_3 and C_6 are the concentrations, at the time of measurement, for Ruthenium-103 and Ruthenium-106, respectively.

SPECIMEN CHARGES:

For legal actions based on analytical determination that radionuclides are present in the food:

Domestic seizure:

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The article is adulterated within the meaning of 21 U.S.C. section 342(a)(1) in that it bears or contains an added poisonous or deleterious substance, namely radionuclides, which may render the article injurious to health.

Import detention:

The article is subject to refusal of admission pursuant to 21 U.S.C. section 381(a)(3), in that it appears to be adulterated within the meaning of 21 U.S.C. section 342(a)(1) because it bears or contains an added poisonous or deleterious substance, namely radionuclides, which may render the article injurious to health.

For legal actions based on evidence that the situation or environment associated with the food may have caused the food to be contaminated with radio nuclides:

Domestic seizure:

The article is adulterated within the meaning of 21 U.S.C. section 342(a)(4) because it was prepared, packed, or held under insanitary conditions in which contamination with radionuclides may have rendered the article injurious to health.

Import detention:

The article is subject to refusal of admission pursuant to 21 U.S.C. section 381(a)(3), in that it appears to be adulterated within the meaning of 21 U.S.C. section 342(a)(4) because it was prepared, packed, or held under insanitary conditions in which contamination with radionuclides may have rendered the article injurious to health.