U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

November 3, 2025

Prof. Taruna Ikrar, M.D., M.Biomed, Ph.D.
Chairperson, Indonesian Food and Drug Authority (BPOM)
Jl. Percetakan Negara No. 23
Jakarta 10560, Indonesia

Dear Prof. Taruna Ikrar,

FDA appreciates the collaboration with the Indonesian Food and Drug Authority (BPOM) to ensure the safety of spices imported into the U.S. from Indonesia. We look forward to continuing to work together with BPOM to develop control strategies for cesium-137 (Cs-137) contamination in spices in support of Indonesian spice producers.

As stated in Import Alert #99-52, "Detention Without Physical Examination of Certain Human Food Products From Certain Regions In Indonesia Subject To The Requirement of Import Certification Per Section 801(q)," the FDA has made the determination that Cs-137 is a known safety risk in spice products from Indonesia and that there is a known safety risk associated with certain regions of origin in Indonesia within the meaning of Sections 801(q)(2)(A) and (B) of the U.S. Food, Drug, and Cosmetic Act, respectively. Potential Cs-137 contamination sources include radioactive contamination discovered in Serpong, Banten Province in 2020, ongoing investigations revealing airborne radioactive debris from metal smelting facilities, and contamination risks identified in the island of Java and the Province of Lampung in the island of Sumatra. FDA suggests spice producers in these regions exporting their products to the U.S. identify Cs-137 as a hazard requiring a preventive control in their food safety plans and develop and implement preventive controls for Cs-137.

Nature of the Hazard

FDA's determination that there is a known safety risk associated with certain regions of origin in Indonesia and the identification of Cs-137 in cloves (spices) requires spice producers from the Island of Java and the Province of Lampung on the Island of Sumatra on Import Alert #99-52 to develop control strategies for this hazard.

Radiological hazards may result from naturally occurring radionuclides, such as radium in well water, or from accidental contamination, e.g., contamination arising from accidental

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5001 Campus Drive
College Park, MD 20740
www.fda.gov

release from a nuclear facility, damage to a nuclear facility from a natural disaster, contamination from improper disposal of radioactive equipment, and release from smelting of steel with radioisotope contamination.[1]

Radiological hazards rarely occur in foods.[2] Radiological hazards can become incorporated into food through the use of water that contains radionuclides during food manufacturing/processing, or through airborne contamination.[1] According to published reports, there is the potential for radionuclides to transfer to certain plants through uptake from contaminated soil through plant roots.[3]

Spice producers' Cs-137 Control Program

FDA recommends all impacted spice producers consider and follow FDA's recommendations regarding the following elements in developing and implementing their Cs-137 control programs:

Root-Cause Analysis

Completion of a root cause analysis is a critical step to help mitigate and prevent future contamination events. Spice producers should take note of the outcomes of root cause investigations conducted by national and/or international regulatory bodies. FDA suggests producers identify potential Cs-137 points of entry into spice production and processing facilities and potential Cs-137 points of introduction into spice products.

Food Safety Plan

The Food Safety Modernization Act (FSMA) Final Rule for Preventive Controls for Human Food[4] requires covered food facilities to have a written food safety plan (FSP) in place that includes an analysis of hazards and risk-based preventive controls to minimize or prevent the hazards identified as requiring a preventive control. The FSP includes:

- Hazard analysis

[1] Radiocesium contamination at a steel plant in Ireland, Health Phys. 1996, 70(4), 568-72

[2] Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food | FDA

[3] Classification of Soil Systems on the Basis of Transfer Factors of Radionuclides from Soil to Reference Plants | IAEA

[4] FSMA Final Rule for Preventive Controls for Human Food | FDA

- Preventive controls
- Management components including monitoring, corrective action, and verification
- Supply chain program
- Recall plan

Depending on the outcome of a hazard analysis, a known or reasonably foreseeable ("potential") chemical hazard could be addressed by a program that includes:

- Current Good Manufacturing Practice (cGMP)[5] measures and other prerequisite programs;
- One or more preventive controls (and associated preventive control management components (i.e., monitoring, corrective actions and corrections, verification, and associated records)). Preventive controls for chemical hazards could include, as appropriate to the facility and its spices and spice products:
    - Process controls – i.e., procedures, practices, and processes to ensure the control of parameters during operations and the maximum or minimum value, or combination of values, to which any parameter must be controlled to significantly minimize or prevent a hazard requiring a process control (see 21 CFR 117.135(c)(1)); and
    - A supply-chain program for those raw materials and other ingredients for which you have identified a chemical hazard that is controlled before receipt of the raw material or other ingredient (see part 117, subpart G)[5]; or
- A combination of cGMP measures and other prerequisite programs and one or more preventive controls (and associated preventive control management components).

cGMP measures

FDA suggests spice producers pay particular attention to the cGMP requirements in 21 CFR Part 117, Subpart B. Examples of practices that the spice producer may implement to protect food from Cs-137 contamination include:

- Ensuring that persons working in direct contact with food, food-contact surfaces, and food-packaging materials conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food (21 CFR 117.10(b)), such as:

  - Washing hands thoroughly in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated;
  - Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials; and
  - Scanning employees with an appropriate radioisotope identification detector (RIID) prior to entering the processing area(s) of the facility.

- Utilizing appropriate quality control operations to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable (21 CFR 117.80(a)(2)), such as by:
  - Scanning with an appropriate RIID potential points of entry of Cs-137 in the processing facility, daily, during pre-operations (pre-op.) and at adequate frequency during production. Air intake and other areas in the H-VAC/ventilation system (including air filters), loading docks, and doors and windows are some examples of potential points of ingress.
  - Scanning of food contact surfaces (FCS) using an appropriate RIID, daily, during pre-op., and at adequate frequency during production. The spice producer should carefully select representative FCS for daily monitoring. Rotational/randomized scanning of a larger pool of representative FCS may also be acceptable.

- Providing adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces (21 CFR 117.20(b)(6)). Examples of adequate controls the spice producer may implement to protect food from Cs-137 contamination include the installation of air filtration systems and/or maintaining positive air pressure in the facility.

- Ensuring that buildings, fixtures, and other physical facilities of the plant are maintained in a clean and sanitary condition and must be kept in repair

adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials (21 CFR 117.35(a)). Additionally, all food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food (21 CFR 117.35(d)). For example, adequate general maintenance would consist of conducting cleaning at a sufficient frequency that protects interior facilities and fixtures from Cs-137, before and during production.

- Utilizing chemical, microbial, or extraneous-material testing procedures where necessary to identify sanitation failures or possible allergen cross-contact and food contamination (21 CFR 117.80(a)(5)).

- Inspecting, segregating, or otherwise handling raw materials and other ingredients to ascertain that they are clean and suitable for processing into food and storing them under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration (21 CFR 117.80(b)(1)). An example of an appropriate treatment of raw materials and ingredients is the routine inspection by scanning using a RIID of all incoming materials, ingredients, and their storage areas for the presence of radionuclides. FDA suggests the spice producer may scan raw packaging materials and other ingredients determined to pose a Cs-137 hazard with a RIID prior to acceptance for use in the facility to ensure the hazard is controlled.

Preventive controls

FDA suggests that all spice producers in the Island of Java and Province of Lampung on the Island of Sumatra listed on Import Alert #99-52 identify Cs-137 as a chemical (radiological) hazard requiring a preventive control.

In developing appropriate preventive controls to address Cs-137, spice producers should assess their facilities and manufacturing operations to identify the most likely routes of contamination with Cs-137. For those routes of contamination, the spice producer should elevate the most relevant cGMPs mentioned earlier in this letter to a preventive control through the establishment of written control procedures and maintenance of records

demonstrating implementation of the written control procedures.

FDA suggests that such a preventive control program could elevate the following cGMPs, among others, to preventive controls: cleaning food-contact surfaces and using a RIID to scan food contact surfaces and ventilation equipment, and any other identified potential points of entry in the facility. FDA suggests the spice producer's critical limits ultimately ensure that food contact surfaces not be found to emit gamma rays above the natural background level at an energy of 661KeV. Spice producers should follow all RIID manufacturer instructions. At a minimum, FDA suggests that verification activities include RIID calibration at an adequate frequency as established by the equipment manufacturer.

A preventive control program for Cs-137 could also include establishment of a supply-chain program to ensure that incoming raw materials and other ingredients are not contaminated with Cs-137. The supply-chain program could include approving raw material and ingredient suppliers, written procedures for receiving raw materials and other ingredients, supplier verification activities such as scanning raw materials and other ingredients with a RIID prior to acceptance for use in the facility, and records documenting the performance of these activities. If it is found that a raw material or other ingredient contains Cs-137 above background levels, the facility would be expected to take corrective actions such as rejecting the product and working with the supplier to determine and address the cause of the contamination.

Additionally, FDA suggests the spice producer scan finished products with a RIID to verify the overall efficacy of the controls for Cs-137. For both raw materials and finished product, FDA suggests the spice producer's critical limits ensure that finished products not be found to emit gamma rays above the natural background level at an energy of 661KeV. Spice producers should follow all RIID manufacturer instructions. At a minimum, FDA suggests that verification activities include RIID calibration at an adequate frequency as established by the equipment manufacturer.

The producer should also periodically pull random representative samples of lots of raw materials and finished products for Cs-137 analysis by a third-party testing laboratory. The FDA Compliance Program 7304.019C may be used to determine the quantity of samples and number of subsamples for laboratory analysis

Ultimately, the hazard should be controlled in the packaged spices and spice products offered for export to the U.S. The control may be implemented for the smallest unit of sale, the master cartons, totes, sacks or the palletized finished product.

Recall plan: FDA suggest that spice producers have a written recall plan that describes the procedures to perform a recall for Cs-137 contaminated products.

Closing

Thank you for your cooperation in this matter. If you have any questions about this letter, please contact Darlene Krieger. We welcome a conversation with you about the information and FDA suggestions provided in this letter and the outcome of your follow-up activities. We look forward to working with you further on this matter.

Sincerely,

Donald A. Prater -S

Digitally signed by Donald A. Prater -S
Date: 2025.11.03 15:14:22 -05'00'

Donald A. Prater, DVM
Principal Deputy Director for Human Foods
U.S. Food and Drug Administration
5001 Campus Drive, RM 3C103
College Park, Maryland 20740

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