U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

October 20, 2025

Director General Ishartini

Indonesian Ministry of Marine Affairs and
Fisheries Quality Assurance Agency
Republic of Indonesia Jl. Medan Merdeka Timur No. 16
Jakarta Pusat, Indonesia 10110

Dear Director General Ishartini:

FDA appreciates the collaboration with Indonesia's Director General of the Ministry of Marine and Fisheries Quality Assurance Agency (MFQAA) to ensure the safety of shrimp imported into the U.S. from Indonesia. We look forward to continuing to work together with MFQAA to develop control strategies for cesium-137 (Cs-137) contamination in shrimp products in support of Indonesian shrimp processors.

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 shrimp products 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 shrimp processors in these regions exporting their products to the U.S. develop and implement controls for Cs-137 in their HACCP plans.

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 shrimp requires shrimp processors from the Island of Java and the Province of Lampung on the Island of Sumatra on Import Alert #99-52 ("impacted shrimp processors") to develop control strategies for this hazard.

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Shrimp Processor Cs-137 Control Program

FDA recommends all impacted shrimp processors 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 a future contamination event. Shrimp processors should take note of the outcomes of root cause investigations conducted by national and/or international regulatory bodies. FDA suggests that potential Cs-137 points of entry in the facility be identified.

HACCP Prerequisite Programs

According to FDA's HACCP Principles and Application Guidance, the production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. This has traditionally been accomplished through the application of current Good Manufacturing Practice (cGMP) requirements. These conditions and practices are considered to be prerequisite to the development and implementation of effective HACCP plans and provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food.

In addition to compliance with the regulatory requirements specified in Title 21 of the U.S. Code of Federal Regulations, Part 123 (21 CFR 123), FDA suggests processors pay particular attention to 21 CFR 123.11(b)(5) for protecting food from chemical, physical and biological contaminants. Examples of sanitation monitoring activities that the processor may implement to protect food from Cs-137 contamination include:

- Scanning with radioisotope identification detector (RIID) potential points of entry of Cs-137 in 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), daily, during pre-op. and at adequate frequency during production. The processor should carefully select representative FCS for daily monitoring. Rotational/randomized scanning of a larger pool of representative FCS may also be acceptable.

- Scanning should be conducted with appropriate equipment and the results documented.

In addition to compliance with all applicable cGMP regulatory requirements for the manufacturing of seafood, FDA suggests the processor pay particular attention to the following cGMP requirements under 21 CFR Part 117:

- Provide 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 processor 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.

- Buildings, fixtures, and other physical facilities of the plant must be 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)). An example of adequate general maintenance consists of conducting cleaning at a sufficient frequency that ensures interior facilities and fixtures are free from Cs-137, before and during production.

- The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for

employee sanitary facilities (21 CFR 117.37(a)). An example of an adequate water supply is one that is tested at an adequate frequency to ensure it is not contaminated with Cs-137.

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

- Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food (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.

The HACCP Plan

The processor shall have and implement a HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur (21 CFR 123.6(b)) and identify the preventive measures that the processor can apply to control those hazards. FDA suggests the processor's HACCP plan identify the chemical hazard (Cs-137) and include Critical Control Points (CCPs) (21 CFR 123.6(c)(2)) at raw materials receiving steps and at a finished product step. The processor may scan raw materials entering the facility with a RIID to ensure the hazard is controlled in all packaging materials and in all food ingredients. The processor may scan finished products with a RIID. The hazard should be controlled in the packaged food offered for export to the US. The control may be implemented for the smallest unit of sale, the master cartons, or the palletized finished product. Processors should follow all RIID manufacturer instructions.

FDA suggests the processor's critical limits at these critical control points (21 CFR

123.6(c)(3)) ensure that raw material and finished packaged products not be found to emit gamma rays above the natural background level at an energy of 661KeV.

The monitoring of the critical control (21 CFR 123.6(c)(4)) points shall include scanning and recording the results of each lot of raw materials and finished and packaged product using a RIID, or equivalent. Detectors should be capable of identifying specific isotopes and have sufficient sensitivity to detect background emissions. FDA suggests that processors download RIID detector results daily and the detector be used by a designated employee that is properly trained in the maintenance and use of radionuclide scanning and/or testing equipment.

FDA is not aware of reconditioning methods to remove Cs-137 from food. Therefore, the processors shall implement corrective actions (21 CFR 123.6(c)(5)) that ensure the product be rejected/destroyed when shrimp is found to be contaminated with Cs-137. For example, at receiving, the firm should reject the lot and discontinue use of the supplier until evidence is obtained that the cause of the contamination has been eliminated. If contamination is found in finished product, the impacted lots should be destroyed, production discontinued, and the source of the Cs-137 residue should be identified and eliminated.

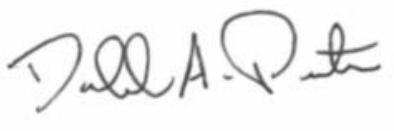
The processor shall include verification procedures and their frequency in the HACCP plan (21 CFR 123.6(c)(6)). FDA suggests, at a minimum, the following verification activities: (1) Equipment calibration at adequate frequency established by the equipment manufacturer, and (2) periodically pull random 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.

The processor shall provide for a record keeping system that documents the monitoring of the CCPs (21 CFR 123.6(c)(7)). FDA suggests the following record examples: Sanitation and cGMP records (21 CFR 123.11(c)), raw data recorded from RIID detector(s), RIID calibration records following manufacturers' instructions, laboratory verification testing results, standard operating procedures for RIID detectors, and employee training records for operation of RIID detectors.

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 continuing to work with you further on this matter.

Sincerely,



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This guidance represents the agency's current thinking on the hazards associated with fish and fishery products and appropriate controls for those hazards. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.