U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Appendix 1: BPOM Procedures for Radionuclide Scanning and Product Testing, Updated: October 31, 2025

Radionuclide Scanning

All food products subject to the Yellow List of Import Alert #99-52, destined for export to the United States, will be screened, prior to loading on shipping containers, by scanning with a handheld Radioisotope Identification Device (RIID), which shall comply with ANSI N42.34 2021 or equivalent standards. Operators must follow RIID manufacturer instructions. A RIID with a 5.1 x 5.1 cm (2" x 2") NaI(Tl) scintillation crystal, or larger, capable of discriminating between gamma and neutron radiation, and quantifying gamma photons with an energy of 0.662 MeV, must be used. Alternative scanning instruments such as high purity germanium detectors, detector arrays, or portal monitors may be considered, provided they have comparable sensitivity to detect gamma emitting radionuclides and determined appropriate by FDA.

Product Scanning Procedure using RIIDs:

1. Ensure that the RIID manufacturer's calibration, background reference, and stabilization processes are satisfactorily completed.
2. Position the detector end of the RIID within 2 cm of the top left or right corner of one side of each of the pallets for each container.
3. Using a zig-zag motion, slowly scan the pallet from top to bottom and end to end. Total scan time for each side of the pallet should be at least three (3) minutes. (Count time will be dictated by detector efficiency at 0.662 MeV.)
4. Record RIID readings to include initials of the individual from the Indonesia government agency that is scanning, date, time, isotope, dose, and units, in a written logbook. Include processor name, address, USFDA FEI number, product description, product lot number, and master cartons per pallet or total pieces.
5. Repeat the scan for the remaining three (3) sides of the pallet. Record readings for each side of the pallet.
6. Segregate pallets with readings above background for Cs-137 or other radionuclides, except for Potassium-40 (K-40). **Pallets with readings above background levels on any side of the pallet are NOT eligible for export to the United States unless each case on the pallet is scanned. Any cases that are above background are NOT eligible for export to the United States**.

   Note: Alternative scanning procedures may be considered upon FDA review and acceptance. Consult with FDA for scanning procedures for non-palletized product**.**

   Notify FDA in the event of a reading(s) above background for Cs-137 or other radionuclides, except for Potassium-40 (K-40). Refer to Appendix 2 for communication protocol.

Finished Product Testing in Addition to Scanning:

1. Collect a sample from the first container prepared by each manufacturer/processor. After this initial sample, collect one sample for every 8-10 containers from the same manufacturer/processor. Follow FDA Compliance Program Guidance Manual 7304.019, Toxic Elements In Food and Foodware, and Radionuclides In Food – Import and Domestic, "Radionuclides in Food" section. Document manufacturer/processor name, address, and USFDA FEI number, product description, product lot number, master cartons per pallet, and name of the individual from the Indonesia government agency collecting the sample. Note: Shipments smaller than 1 container count as 1 container for the purposes of sampling frequency.
2. Submit the sample for Cs-137 analysis to an ISO/IEC 17025 accredited laboratory (details are available in the FDA Compliance Program Guidance Manual 7304.019, Toxic Elements In Food and Foodware, and Radionuclides In Food – Import and Domestic, "Radionuclides in Food" section Part IV (analytical section).

   Analytical results for any sample above the Limit of Quantitation for Cs-137 cited in the "Laboratory Requirements" section renders the shipment NOT eligible for export to the United States.

   Notify FDA of any sample results that detect samples above LOQ for Cs-137. Refer to Appendix 2 for communication protocol.

Laboratory Requirements

- Laboratory must be ISO/IEC 17025 accredited or as determined appropriate by FDA.
- Recommended laboratory method is WEAC-RN-Method.3.0 (Determination of Gamma-Ray Emitting Radionuclides in Foods by High-Purity Germanium Spectrometry). Alternative methods must be reviewed by FDA prior to use.
- The laboratory's radionuclide testing methods must fall within the scope of its ISO/IEC 17025 accreditation.
- Report results in Bq/kg.
- Cs-137 Limit of Quantification (LOQ): <8 Bq/kg.
- Negative Results = <8 Bq/kg