
Appendix 2: BPOM Communication Protocol & Verification Practices for Cesium-137 (Cs-137) Detection, Updated: October 31, 2025

This protocol establishes standardized communication procedures between Certifying Entities (CEs) and the U.S. Food and Drug Administration (FDA) when cesium-137 (Cs-137) is detected during product scanning or sampling operations. The communication protocols below are required to provide assurances that food products are not contaminated with Cs-137.

1. Product Not Eligible for Export to the U.S Due to Cs-137 Scanning Results

If a product, lot, or portion of a shipment is not eligible for export to the U.S. due to contamination with Cs-137 based on scanning results as described in *Appendix 1: Procedures for Radionuclide Scanning and Product Testing*, submit the following information via email to the designated FDA inbox **HFP-ImportCertification-Cesium@fda.hhs.gov** weekly:

1. Product Identification: Product name, brand, manufacturer, FEI#, lot/batch numbers
2. Detection Details: Scanning equipment used, detection levels (units), detection date and time
3. Product Status: Quantity of affected product and confirmation that product has been rejected and quarantined
4. Shipment Information: Total quantity and description of shipment including any portion that was not impacted. Include container number, entry information, and estimated date of arrival in U.S.
5. Immediate Actions Taken: Quarantine measures and product disposition.

2. Detection of Cs-137 in Product Sample from Laboratory Analysis

If a product, lot, or shipment sample detects Cs-137 based on the criteria described in *Appendix 1: Procedures for Radionuclide Scanning and Product Testing*, submit the following information via email to the designated FDA inbox weekly regardless of whether it was shipped to the US:

1. Product Identification: Product name, brand, manufacturer, FEI#, lot/batch numbers
2. Sample Identification: Sample ID, collection date, sampling methodology used
3. Laboratory Information: Testing facility name and address, accreditation status
4. Laboratory Results: Quantitative results (Bq/kg), method of analysis, detection limits
5. Product/Shipment Status: Current location and quarantine measures/disposition of contaminated product. Total quantity and description of shipment.

Analytical results for any sample above the Limit of Quantitation for Cs-137 cited in the “Laboratory Requirements” section of Appendix 1 renders the shipment NOT eligible for export to the United States.

3. Data Submission and Retention Requirements

3.1: RIID Scanning Data Submissions

a. For the first 500 certificates issued by the CE:

Submit the scanning data elements described in *Appendix 3: Procedures for Radionuclide Scanning and Product Testing* for every 25 certificates issued (or 4% of the first 500 certificates).

b. For subsequent certificates issued by the CE:

Submit the scanning data elements described in *Appendix 1: Procedures for Radionuclide Scanning and Product Testing* for every 100 certificates issued (or 1% of certificates issued).

3.2. Random Record Requests

- a. All scanning and product testing conducted for shipment certification by the CE are subject to random record requests by the FDA.
- b. CE will provide requested records within 10 business days of receiving an FDA record request.

3.3. Record Retention:

- a. CE will maintain all RIID scanning data and finished product testing records for a minimum of 2 years.