U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Appendix 2: MFQAA 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.