



U.S. FOOD & DRUG
ADMINISTRATION

In-Country Assessment Report: Certifying Entity Implementation of the Cesium-137 Import Certification for Shrimp & Spice Products from Indonesia

**Import Certification Program
(MFQAA & BPOM)**

Human Foods Program

Executive Summary

In early August 2025, the U.S. Food and Drug Administration (FDA) detected Cesium-137 (Cs-137), a radioactive contaminant, in shrimp imported from PT. Bahari Makmur Sejati and subsequently in cloves imported from PT Natural Java Spice, both based in Indonesia. Based on information available regarding the risk of potential contamination with Cesium-137, FDA issued Import Alert 99-52 on October 3, 2025, and, effective October 31, 2025, began requiring import certification (IC) under section 801(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(q)) for shrimp and spice products originating from certain regions of Indonesia. To implement the IC program, FDA designated Indonesia's Marine and Fisheries Quality Assurance Agency (MFQAA) as the Certifying Entity (CE) for shrimp and the Indonesian Food and Drug Authority (BPOM) as the CE for spices. Each CE is required to provide shipment-specific assurances that covered products are free of Cs-137 contamination prior to export to the United States.

From May 4–8, 2026, FDA conducted an in-country assessment of both CEs' implementation of the IC procedures set forth in Appendices 1–3 of their respective CE designation letters (see [Reference section](#)). The assessment encompassed opening and closing meetings with CEs, onsite evaluations of CE performance at six shrimp processing establishments and five spice processing establishments spanning the provinces of Banten, West Java, and East Java, and visits to three servicing laboratories (BRIN, BAPETEN, and BUSPM) responsible for Cs-137 analytical testing. FDA evaluated core operational areas for each CE: radionuclide scanning and product testing, communication protocols and verification practices, and the issuance and submission of certificates. This report documents FDA's methodology, findings, and conclusions from that assessment, as well as each CE's responses and actions taken in response to FDA's assessment.

FDA's assessment determined that both MFQAA and BPOM are substantially meeting the responsibilities of their respective CE designation letters. One item requiring correction was identified for each CE: MFQAA was compositing samples across multiple containers in a manner inconsistent with the sampling requirements of Appendix 1, and BPOM was scanning pallets for 10 minutes (2.5 minutes per side), falling short of the required minimum of 12 minutes (3 minutes per side). Both CEs responded promptly, revised their procedures, and communicated the corrections to their respective regional offices and field staff. FDA has reviewed these revisions and considers both items addressed acceptably.

In addition, FDA identified four program improvement opportunities for MFQAA and nine for BPOM, encompassing certificate management practices, scanning device documentation, calibration and instrument QC procedures, sample result reporting, and laboratory result tracking. Both CEs provided substantive responses to all improvement opportunities, which FDA also considers satisfactorily addressed. All three servicing laboratories, BRIN, BAPETEN, and BUSPM, were found to fulfill the testing laboratory and method requirements defined in Appendix 1, with no deficiencies identified. Based on the integrity of each CE's certification program and FDA's evaluation of their revisions, FDA will maintain MFQAA and BPOM as the Certifying Entities for shrimp and spice products, respectively, exported to the United States under the Cs-137 import certification program. FDA will continue to monitor CE program implementation and provide updates as necessary.

Table of Contents

Executive Summary	2
Introduction	4
Assessment Summary	5
Shrimp Certifying Entity	6
MFQAA Program Implementation Assessment.....	6
Record Review.....	6
Program Implementation Deficiencies.....	6
Program Improvement Opportunities.....	7
Conclusion.....	8
Spice Certifying Entity	9
BPOM Program Implementation Assessment.....	9
Record Review.....	9
Program Implementation Deficiencies.....	9
Program Improvement Opportunities.....	10
Conclusion.....	14
Laboratory Assessments	14
References	15
Shrimp Certifying Entity.....	15
Spice Certifying Entity.....	15

Introduction

In early August 2025, the U.S. Food and Drug Administration (FDA) detected the radionuclide Cesium-137 (Cs-137) in a sample of frozen shrimp imported from Indonesia, specifically from the firm PT. Bahari Makmur Sejati. In response, FDA added the firm to [Import Alert 99-51](#) "Detention Without Physical Examination of Human Food Products That Appear To Have Been Prepared, Packed Or Held Under Insanitary Conditions Resulting in Chemical Contamination" for chemical contamination and issued a public safety alert advising consumers, distributors, and retailers not to eat, sell, or serve the affected products. Subsequently, through continued screening efforts, FDA also detected Cs-137 in a sample of cloves from PT Natural Java Spice, resulting in the firm's products being added to the same import alert. Products from PT. Bahari Makmur Sejati and PT Natural Java Spice remain prohibited from entering the U.S. market until each firm adequately demonstrates that the conditions giving rise to the appearance of the violations have been resolved.

In response to these findings, FDA issued [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)" on October 3, 2025, announcing the agency's intent to implement import certification under section 801(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(q)) for certain foods from certain regions of Indonesia. Effective October 31, 2025, FDA began requiring import certification (IC) for shrimp and spice products from those regions, marking the first use of this Congressional authority to address ongoing food safety concerns while facilitating continued trade of safe products.

To implement this IC program, FDA designated two Indonesian government agencies as Certifying Entities (CEs):

- **Marine and Fisheries Quality Assurance Agency (MFQAA)**, under the Ministry of Marine Affairs and Fisheries (MMAF), designated as the CE for shrimp and shrimp products (effective October 31, 2025).
- **Indonesia's Food and Drug Authority (BPOM)**, designated as the CE for spice products (effective November 3, 2025).

Each CE is responsible for providing shipment-specific assurances that covered products are not contaminated with Cs-137 prior to export to the United States, in accordance with the protocols and data requirements outlined in their respective designation letters and accompanying appendices (see [Reference section](#)).

As part of FDA's oversight responsibilities, the agency conducted an in-country assessment to evaluate both MFQAA's and BPOM's implementation of the IC procedures outlined in Appendices 1–3 of their respective CE designation letters. In addition to evaluating each CE's operational procedures, the assessment also included an evaluation of the servicing laboratories utilized by each CE for Cs-137 analytical testing. The assessment focused on three core operational areas: radionuclide scanning and product testing, communication protocols and verification practices, and the issuance and submission of certificates. FDA's in-country assessment activities were guided by an audit plan and basic

instructions and checklists developed to promote consistency in FDA's evaluation of the requirements of Appendices 1–3.

The in-country assessment commenced with an opening meeting on May 4, 2026, between U.S. FDA and Indonesia's Coordinating Ministry of Food Affairs (CMFA) Cesium Task Force, the designated CEs (MFQAA and BPOM), BAPETEN, and BRIN. The meeting served to welcome participants, discuss the purpose of the visit, outline FDA's expectations, and address questions from the CMFA.

FDA's objectives for the in-country assessment included meeting with each CE to observe their processes for certificate issuance and the coordination of scanning and sampling activities with industry. The assessment included onsite visits to between five and six locations per commodity (shrimp and spices) and three servicing laboratories to evaluate each CE's implementation of the IC procedures outlined in Appendices 1–3, with feedback provided on any corrections needed.

Assessment Summary

FDA met with MFQAA and BPOM at their respective HQ offices in Jakarta on May 4, 2026, and with the MFQAA Regional Office in Surabaya on May 6, 2026, to discuss and assess their certification programs and processes. Onsite assessments were conducted across different geographical locations, spanning the province of Banten, West Java and East Java, to evaluate any variations in the application of IC program implementation across regions. Specifically, FDA observed MFQAA and BPOM conducting scanning and sampling of shipments of shrimp and spices being exported to the US at several processing facilities over three days across each geographical location. FDA also obtained and reviewed records of each agency's procedures, all of the records associated with 10 issued certificates selected by FDA, and all of the records associated with the observed scanning and sampling activities and shipments. FDA's findings are based on review of these records and observations during onsite evaluations.

A closeout meeting was held with each respective CE following the in-country assessment, during which preliminary findings, including items requiring correction, were shared. Overall, one item requiring correction was identified for both MFQAA and BPOM. Additionally, opportunities for improvement were identified and shared with each CE. The CEs were asked to provide a response within 30 days, and those responses have been incorporated into this report.

Based on the integrity of the Cs-137 certification programs and FDA's assessment below MFQAA and BPOM remain the CEs for shrimp and spice shipments exported to the US, respectively. The CE responses to the items requiring correction were adequate and also addressed the opportunities for improvement FDA identified.

Shrimp Certifying Entity

MFQAA Program Implementation Assessment

FDA evaluated MFQAA's fulfillment of the responsibilities of Appendices 1-3 as described above. Specifically, FDA met MFQAA at their HQ and Regional Office and observed demonstrations of the certificate process and records systems at these offices. FDA also conducted an onsite evaluation of their scanning and sampling operations at 6 selected establishments spanning the provinces of Banten and East Java.

Record Review

MFQAA submitted records that documented their procedures for scanning and product testing, communication protocols and verification practices, and the issuance of certificates (specified in Appendices 1-3). FDA requested, reviewed, and verified all records associated with a selection of ten (10) certificates issued and all records associated with the certificates issued for the shipments that were observed being scanned and sampled during the in-country evaluation.

Program Implementation Deficiencies

Onsite assessment identified one program implementation deficiency, described below alongside MFQAA's implemented corrections.

1. Sampling Procedure

During FDA's meeting with MFQAA at the Surabaya Regional Office, MFQAA described their sample process which included collecting a sample from each container for each manufacturer/processor and then compositing the samples taken from 10 consecutive containers/processor for analysis. Samples may represent multiple shipments, which are held pending analytical results.

[Appendix 1, Finished Product Testing in Addition to Scanning](#), states in part, "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." The requirement is to collect a sample from only the 8th or 9th or 10th container, as applicable, not from each container.

MFQAA Correction: MFQAA revised the sampling procedure to conduct sampling from a maximum of ten (10) scanned containers, with one individual sample collected from a single selected container representing the scanned containers and no longer composites samples.

MFQAA informed all regional offices of this revision through Letter No. B.2326/BPPMHKP.4/TU.210/VI/2026 dated 26 June 2026, effective 29 June 2026.

FDA considers this item satisfactorily addressed and closed.

Program Improvement Opportunities

Four program improvement opportunities were identified during the in-country program assessment, which are described below alongside MFQAA's responses.

1. Certificate Process

MFQAA issues draft certificates that exporters share with their U.S. customers for review. When changes are requested — by the customer or shipping company — the exporter submits revision requests to MFQAA. Draft certificates have been submitted to FDA by importers that appeared to be final, with signature, and lacked a draft designation. Discrepancies were found when compared to a final MFQAA certificate submitted directly to FDA and required reconciliation.

Recommendation: FDA recommended clearly distinguishing draft from final certificates and requested a copy of any revision of their SOPs. A process to replace corrected certificates was shared with MFQAA via email on June 2, 2026.

MFQAA Response: MFQAA changed their procedures to add "DRAFT" and only signs the final certificate to submit to the exporter. The submitter is responsible for uploading the final certificate to the FDA. To ensure consistent implementation of this procedure, MFQAA conducted an online session for all regional offices on 8 July 2026.

FDA acknowledges that MFQAA's revisions satisfactorily address this item.

2. Acquisition Status

FDA had questions regarding scanning device configuration for acquisition. After interviewing MFQAA scanning operators and reviewing photos taken during stabilization, background measurement, and pallet scanning, FDA determined that MFQAA was operating the devices correctly in acquisition mode per manufacturer instructions.

Recommendation: FDA recommended MFQAA consider notating the spectrum acquisition / acquire mode setting being used for the scanning device on the Specification of Scanner section of the Scanning Form (Decree 27 of 2026, Chapter V, Documents and Format).

MFQAA Response: MFQAA revised its scanning procedure and scanning form by adding an "Acquisition Mode" field to the scanning form.

FDA acknowledges that MFQAA's revisions satisfactorily address this item.

3. Background Measurements and Calibration

MFQAA operators followed automated calibration and background measurements, but procedures were unclear around documentation of this process.

Recommendation: FDA recommended MFQAA continue to follow the manufacturer's process for calibration, stabilization, and background measurement and reinforce standardized documentation of background measurements.

MFQAA Response: MFQAA disseminated the revised procedure to all regional offices on 8 July 2026 reinforcing the standardization of background value measurements and modified Cs-137 sampling procedures.

FDA acknowledges that MFQAA's revisions satisfactorily address this item.

4. Sample Results Reporting

Sample results are not directly reported from the laboratory to MFQAA. BRIN sends sample analysis results to the exporter but not directly to MFQAA. Appendix 2 requires MFQAA report samples that detect Cs-137 to FDA.

Recommendation: FDA recommended MFQAA ensure results for all samples submitted to BRIN are shared with MFQAA.

MFQAA Response: MFQAA developed the procedure for the Determination of Cesium-137 laboratory testing, which regulates the requirement and procedures for determining Cesium-137 testing laboratories and the obligation of the designated testing laboratories to report to the DG of MFQAA:

- i. SOP for cesium-137 testing.
- ii. Method verification results.
- iii. Test result report issued by the laboratory.

FDA acknowledges that MFQAA's revisions satisfactorily address this item.

Conclusion

FDA's in-country assessment of MFQAA's implementation of the import certification program for shrimp and shrimp products found that MFQAA is substantially meeting the responsibilities set forth in Appendices 1–3 of its CE designation letter.

MFQAA corrected one item for sampling and implemented four program improvements related to draft certificate management, scanning device acquisition mode documentation, background measurement

and calibration practices, and the direct reporting of laboratory sample results. FDA has reviewed MFQAA's revisions and considers the items satisfactorily addressed.

Based on the integrity of MFQAA's certification program and the agency's timely and substantive response to FDA's findings, FDA will maintain MFQAA as the Certifying Entity for shrimp and shrimp products exported to the United States under the Cs-137 import certification program. FDA will continue to monitor MFQAA's implementation of the program and conduct additional assessments as needed.

Spice Certifying Entity

BPOM Program Implementation Assessment

FDA evaluated BPOM's fulfillment of its responsibilities as set forth in Appendices 1-3 and as described above. Specifically, FDA met with BPOM at their HQ Office and observed a demonstration of the certificate process and records systems. FDA also conducted an onsite evaluation of BPOM scanning and sampling operations at 5 selected establishments spanning the province of West Java and East Java.

Record Review

BPOM submitted records documenting their procedures for scanning, sampling and analysis, reporting, certification and record keeping as specified in Appendices 1-3. FDA requested, reviewed and verified all records associated with a selection of ten (10) certificates issued and all records associated with the certificates issued for the shipments FDA observed being scanned and sampled during the in-country evaluation.

Program Implementation Deficiencies

Onsite assessment identified one program implementation deficiency, described below alongside BPOM's implemented corrections.

1. RIID Scan Time for FLIR R425

For the FLIR R425, FDA established a standard total scan time for each side of the pallet of at least three (3) minutes (count time will be dictated by detector efficiency at 0.662 MeV); however, BPOM operators scanned pallets for a total of 10 minutes (2.5 minutes per side).

BPOM Correction: BPOM determined that the deviation was attributable to an error in a supporting document utilized during the verification process, which incorrectly stated that the required scanning time for the FLIR R425 was 2.5 minutes per side. BPOM revised its scanning

protocol procedure to clearly specify the required scanning time and detector settings for each instrument and committed to providing documentation on RIID settings prior to scanning to demonstrate compliance with the three-minute-per-side requirement. BPOM provided FDA with a corrected procedure.

FDA has reviewed BPOM's revisions and considers this item satisfactorily addressed and closed.

Program Improvement Opportunities

Nine program improvement opportunities were identified during the in-country program assessment, which are described below alongside BPOM's responses.

1. Sample Results References

Sample results referenced on certificates did not correspond to the shipment. BPOM certificates frequently referenced laboratory results for different shipments in the attestation statement. BPOM explained that it referenced sample dates for the first sample of every set of 8-10 container shipments from that manufacturer/processor in order to satisfy the sampling requirements of Appendix 1.

Recommendation: The sample date included in the attestation statement of the certificate should reflect the actual product that is part of the shipment. FDA recommended BPOM consider including a statement such as “sample not required” or provide similar language.

BPOM Response: BPOM provided a revised attestation statement to accurately reflect whether sampling occurred or was needed or include reference to the applicable previous shipment. Corrections applied to single and multiple product shipments.

FDA acknowledges that BPOM's revisions satisfactorily address this item.

2. Tracking Sample Frequency

BPOM appears to rely on the exporter to maintain records (e.g., “stock card”) of when shipments require sampling. Although BPOM explained and demonstrated they can track sampling at the HQ-level, the field inspector is responsible for verifying the sample schedule during the firm visit.

Recommendation: FDA recommended BPOM establish a process for routine sample tracking checks prior to issuance of certificates.

BPOM Response: BPOM has established a sampling monitoring matrix to ensure periodic tracking of export shipments and to determine when re-sampling is required, which is accessible to all BPOM officers, and captures key shipment information including the exporter name,

product name, date of last sampling, Cs-137 Certificate of Analysis (CoA) number, container number, Shipment Specific Certificate (SSC) number, and other relevant details.

FDA acknowledges that BPOM's revisions satisfactorily address this item.

3. Duplicate Certificates

Two certificates appeared to correspond to the same lot and product (157155; 157858). BPOM indicated that this was a typographical error, and the firm had to re-submit a new certificate.

Recommendation: FDA recommended that BPOM establish a process to flag a re-issued or replacement certificate after submission to FDA.

BPOM Response: BPOM committed to enhancing its existing certificate monitoring system and to promptly notify FDA of any certificate revisions should they occur in the future.

FDA acknowledges that BPOM's revisions satisfactorily address this item.

4. Certificate Lot Code

Product lot codes listed on several certificates did not match the respective lot codes referenced in the corresponding BRIN laboratory reports provided for review and were missing certain elements.

Recommendation: FDA requested that BPOM review these certificates and explain the discrepancies.

BPOM Response: BPOM provided detailed information regarding discrepancies and revised the attestation statement in the certificate to clearly indicate whether the sample tested corresponds to the applicable Certificate of Analysis (CoA) or not.

FDA acknowledges that BPOM's revisions satisfactorily address this item.

5. Instrument Calibration

The detailed procedures for calibration and instrument QC checks were not described in BPOM's procedure and calibration activity records were not maintained.

Recommendation: FDA recommended that BPOM establish written standardized procedures describing the calibration steps, required calibration frequency, QA checks, and specifications to be incorporated within the scanning procedure, and that BPOM work with BAPETEN and the equipment manufacturer's representative to develop additional training on equipment use, troubleshooting, and maintenance.

BPOM Response: BPOM, in collaboration with BAPETEN, revised the scanning protocol to include detailed steps for calibration and functional testing, with results of calibration and functional tests to be recorded in the logbook. Formal training on scanning activities occurred in October 2025, and troubleshooting issues were addressed on an ongoing basis through coordination between BPOM and BAPETEN during scanning activities. A dedicated formal training program specifically covering troubleshooting procedures was subsequently conducted on July 1–2, 2026. In addition, BPOM revised the logbook record containing a calibration section, screenshots of the instrument calibration process, revised scanning procedures inclusive of calibration instructions, and calibration information for four RIID instruments.

FDA acknowledges that BPOM's revisions satisfactorily address this item.

6. Scanning Procedures and Documentation

During scanning, “insufficient counts” results on the FLIR R425 instrument were observed several times, with inconsistencies in the documentation. One inspector documented the highest reading observed and another inspector documented the reading in the middle of the pallet.

Recommendation: FDA recommended BPOM consult the instrument manual or manufacturer for guidance on what to do when this happens and include these instructions in the scanning procedure.

BPOM Response: BPOM explained that, as stated in the identiFINDER R425 User Manual, an “Insufficient Counts” message may occur when insufficient data is acquired during a scan due to a low count rate, a condition that is expected when a sample emits radiation at a very low level. BPOM revised the scanning protocol (Chapter III, Point F) and updated the logbook template. BPOM also committed to a refresher training for inspectors to reinforce the standardized radiation scanning and documentation procedures.

FDA acknowledges that BPOM's revisions satisfactorily address this item.

7. Product Rejection Procedures

BPOM procedures for when to reject a product are unclear. BPOM’s “Scanning Protocol for Spice Products” procedure indicated that when radionuclides other than naturally occurring radionuclides (NORMS) are detected to re-scan the product. The procedure indicated to restart the instrument, recalibrate and re-scan three times. If still found the procedure instructed to segregate product and scan each master carton. If non-NORMS are detected the procedure indicates to re-scan all six sides three times and if still detected, segregate and notify BPOM for further action. The following steps included sampling product, however it was unclear if the product that was scanned was rejected at this stage or if it must also be sampled.

Recommendation: FDA recommended BPOM refer to Appendix 1 which includes instructions on when to reject product and include additional clarification when product should be rejected in their procedure.

BPOM Response: BPOM revised their Scanning Protocol procedures to clarify the criteria for rejection and the handling of products with confirmed detection of radionuclides above the background reference. The revised procedure specifies the steps, including re-scanning and instrument calibration, segregation and quarantine of affected products, scanning of individual master cartons, and laboratory analysis for radionuclide confirmation. It also establishes the disposal or waste management actions based on the laboratory results and applicable regulations.

FDA acknowledges that BPOM's revisions satisfactorily address this item.

8. Evaluation Procedures for Inconclusive Results

BPOM lacks procedures for evaluating inconclusive Cs-137 signals and levels below background. BPOM identified and ruled out a “false positive” Cs-137 signal detected during scanning. FDA reviewed and concurred with BPOM's steps that were taken to rule out contamination and notify FDA.

Recommendation: FDA recommended BPOM include a procedure for ruling out false positives or inconclusive readings.

BPOM Response: BPOM clarified that any pallet or case with radiation readings above background levels following completion of the scanning process is considered ineligible for export to the United States, in accordance with the requirements specified in Appendix 1. BPOM revised their Scanning Protocol procedures and added steps for handling inconclusive/false positive results.

FDA acknowledges that BPOM's revisions satisfactorily address these items.

9. Sample Results Reporting

Sample results are not directly reported from the laboratory to BPOM. Appendix 2 requires BPOM report samples that detect Cs-137 to FDA.

Recommendation: FDA recommended BPOM ensure they will be notified and obtain all final sample analysis results (certificate of analysis [CoA]) directly from the laboratory, including those that result in detection of Cs-137 or other isotopes and sample results for shipments that an exporter does not submit for certification.

BPOM Response: BPOM described the implementation of a procedure requiring all samples submitted for Cs-137 testing to BRIN and other designated laboratories be accompanied by

an official cover letter issued by BPOM. The cover letter instructs the laboratory to submit all final analytical results, including any detection of Cs-137 or other radionuclides, directly to BPOM. As a short-term measure, BRIN will provide BPOM with access to a shared folder containing CoAs. As a long-term solution, BPOM committed to developing an online platform through which BRIN can submit CoAs directly to BPOM; upon issuance, laboratories will submit CoAs to both their own application and the BPOM online platform.

FDA acknowledges that BPOM's revisions satisfactorily address this item.

Conclusion

FDA's in-country assessment of BPOM's implementation of the import certification program for spice products found that BPOM is substantially meeting the requirements set forth in Appendices 1–3 of its CE designation letter.

BPOM corrected one item for scanning pallets and implemented nine program improvements encompassing certificate discrepancies, documenting calibration and instrument QC procedures, inconsistent documentation of scanning results, unclear rejection criteria, written protocols for evaluating inconclusive radiological signals, and gaps in direct sample result reporting. FDA has reviewed BPOM's revisions and considers the items satisfactorily addressed.

Based on the integrity of BPOM's certification program and the agency's timely and substantive response to FDA's findings, FDA will maintain BPOM as the Certifying Entity for spice products exported to the United States under the Cs-137 import certification program. FDA will continue to monitor BPOM's implementation of the program and conduct additional assessments as needed.

Laboratory Assessments

As part of FDA's CE assessments, FDA evaluated laboratory requirements of Appendix 1. Specifically, FDA visited three laboratories utilized by MFQAA and BPOM, including the BRIN (National Research and Innovation Agency) laboratory on May 4th & 5th, 2026, the BAPETEN Environmental Laboratory on May 6, 2026, and the BUSPM laboratory on May 7, 2026. FDA evaluated laboratory operations related to Cs-137 analysis of finished products for each laboratory. Each laboratory provided FDA with their respective instrument and method SOPs, method validation documents, accreditation documentation, and training records.

All three laboratories maintain an ISO/IEC 17025-accredited radiochemistry facility capable of measuring gamma-emitting radionuclides. The laboratories routinely perform sample analysis for the Certifying Entities, with a gamma spectrometry method included in its accreditation scope. No deficiencies were identified with respect to Appendix 1 laboratory requirements. Opportunities for improvement recommendations were shared with each laboratory in-country.

Based on FDA's assessment, BRIN, BAPETEN, and BUSPM fulfill the testing laboratory and method requirements as defined in Appendix 1.

References

As referenced in this report, a letter designating certifying entities (CE) was sent to MFQAA and BPOM and included the following appendices that describe the requirements for scanning, sampling, reporting, and certificates.

Shrimp Certifying Entity

- Food and Drug Administration. (2025, October 31) [Notice Designating MFQAA Certifying Entity for Shrimp](#) [Letter]
- Food and Drug Administration. (2025, October 31) [Appendix 1: MFQAA Procedures for Radionuclide Scanning and Product Testing](#) [Appendix to letter]
- Food and Drug Administration. (2025, October 31) [Appendix 2: MFQAA Communication Protocol & Verification Practices for Cesium-137 \(Cs-137\) Detection](#) [Appendix to letter]
- Food and Drug Administration. (2025, October 31) [Appendix 3: MFQAA Required Data Elements & Submission of Certificates](#) [Appendix to letter]

Spice Certifying Entity

- Food and Drug Administration. (2025, October 31) [Notice Designating BPOM Certifying Entity for Spices](#) [Letter]
- Food and Drug Administration. (2025, October 31) [Appendix 1: BPOM Procedures for Radionuclide Scanning and Product Testing](#) [Appendix to letter]
- Food and Drug Administration. (2025, October 31) [Appendix 2: BPOM Communication Protocol & Verification Practices for Cesium-137 \(Cs-137\) Detection](#) [Appendix to letter]
- Food and Drug Administration. (2025, October 31) [Appendix 3: BPOM Required Data Elements & Submission of Certificates](#) [Appendix to letter]