UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC

FSIS DIRECTIVE

9040.5

10/4/16

PROCEDURES FOR EVALUATING AND VERIFYING IMPLEMENTATION OF CORRECTIVE ACTIONS IN RESPONSE TO DETAINED OR REJECTED EXPORT PRODUCT

I. PURPOSE

This directive provides instructions to personnel in the Import and Export Policy Development Staff (IEPDS) within the Office of Policy and Program Development (OPPD) and personnel in District Offices (DO) within the Office of Field Operations (OFO) responsible for evaluating and verifying whether exporting U.S. establishments have implemented corrective actions after FSIS is notified that exported product from the United States failed to meet importing country requirements. The actions described in this directive are taken under the authority of the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA) and ensure ongoing compliance with international agreements, equivalence determinations, and regulatory requirements.

II. BACKGROUND

A. A foreign governments' Central Competent Authority (CCA) inspects shipments of meat, poultry, and egg products exported from the United States at the port of entry (POE) into the foreign country. If the foreign CCA determines that a consignment does not meet its requirements, the consignment may be rejected or detained. When FSIS is notified of a POE violation by the CCA of an importing country, FSIS will investigate the issue and report any corrective actions to the foreign CCA.

B. Exporting establishments that do not provide corrective actions that OFO and OPPD evaluate and deem adequate/effective will be de-listed; this will prevent the establishments from exporting to the country where the POE violation occurred.

C. Examples of POE violations or deficiencies include, but are not limited to, the following categories:

- 1. Microbiological contamination;
- 2. Chemical residues that exceed minimum residue limits (MRLs) (e.g., antibiotic or growth promotant residues);
- 3. Adulteration or presence of foreign material (e.g., urine, hair, bile, dirt, feces, milk);
- 4. Misbranding (e.g., incorrect, inaccurate, or non-compliant labeling, including labeling with undeclared allergens);
- 5. Presence of product that is off-condition or otherwise unfit, past use-by or expiration dates;
- 6. Discrepancies with export certification documents or export stamps; and

7. Ineligible product (e.g., product that does not meet Agricultural Marketing Service (AMS) Export Verification (EV), Process Verified Program (PVP) or Quality Systems Assessment (QSA) program criteria, or product that does not meet the importing country's additional requirements as stated in the Export Library).

III. IEPDS ACTIONS WHEN NOTIFIED BY THE IMPORTING COUNTRY THAT PRODUCT DOES NOT MEET REQUIREMENTS

A. IEPDS is to initiate an investigation when it receives notification of a rejected or detained export consignment. Notification may come from the importing country's CCA, the appropriate foreign Embassy in the United States, the Foreign Agricultural Service (FAS), or from the exporter.

B. IEPDS is to gather all of the relevant information on the POE violation, analyze it, and provide an evaluation to the DO where the establishment listed on the export certificate is located and to the Executive Associate for Regulatory Operations (EAROs) to which the DO reports. IEPDS is to include the following information in the notification to the DO and EARO:

- 1. The establishment name and number;
- 2. Any written documentation from the importing country's CCA explaining the reasons for rejection or detention;
- 3. The export certificate serial numbers and the export certificates, if available;
- 4. The container numbers or seal numbers; and
- 5. The actions the importing country has taken as a result of the POE violation.

C. If the importing country indicates the establishment in the United States is prohibited from exporting to that country until the violation is resolved; IEPDS is to update the eligible plant list in the Export Library for that country accordingly within 24 hours of receiving notification.

D. IEPDS is to document all POE violations reported by importing countries in the IEPDS shared electronic database.

E. If there is an export certification issue, IEPDS is to determine if a replacement certificate will correct the import deficiency. If a replacement certificate can resolve the issue, IEPDS is to notify the EARO and DO and advise them to issue a corrected replacement certificate following the procedures outlined in <u>FSIS</u> <u>Directive 9000.1</u>, *Export Certification*.

F. If IEPDS determines the POE deficiency identified by the importing country is the result of a failure to conform to an AMS- QSA, EV program or PVP program, IEPDS is to immediately advise AMS' Grading and Verification Division of the issue. Depending on the deficiency, AMS may conduct a separate investigation and IEPDS is to request a copy of this investigation.

G. If IEPDS believes the country that imported product from the establishment in the United States is applying a new requirement or incorrectly applying an existing requirement, IEPDS is to contact the Office of International Coordination (OIC) to open a dialogue with the importing country to seek clarification of the existing requirements or to establish the need for official notification of a new requirement.

H. If the exported product needs to be returned to the United States, and the return process has not already been completed, IEPDS is to communicate this to the EARO, DO and the exporter. IEPDS is to advise the U.S. exporter that the product should be returned as per instructions in <u>FSIS Directive 9010.1</u>, *Export Products Returned to the United States*, and by completing <u>FSIS Form 9010-1</u>, *Application for the Return of Exported Product to the United States*, for final disposition.

IV. OFO ACTIONS WHEN NOTIFIED BY IEPDS THAT PRODUCT DOES NOT MEET IMPORT REQUIREMENTS

A. Upon receiving the information from IEPDS that exported product has been rejected or detained by an importing country, the DO is to notify the appropriate Inspector-In-Charge (IIC) and establishment management within two business days that a POE violation has been received. The IIC is to direct the establishment to conduct and document an investigation to identify the cause of the deficiency and propose corrective actions.

B. The IIC is to document in a memorandum of information (MOI) to the establishment. The MOI is to include the IIC's assessment of the establishment's investigation findings and the adequacy of the proposed corrective actions. If the IIC makes a determination that the proposed corrective actions will not prevent the POE violation from recurring, he or she will note this finding in the MOI and inform the establishment that FSIS will not certify the effected exports until new corrective actions are proposed and the IIC determines that they are adequate. The IIC will send a copy of the MOI, the report documenting the establishment investigation, and the establishment's proposed corrective actions through their supervisory chain to the DO who will then provide a copy to IEPDS.

C. If the establishment does not provide investigation results and corrective actions within 10 days of its notification by the DO of a POE violation, the IIC is to report that fact to the DO. The DO is to notify establishment management of the need to perform the investigation and report the investigation findings and corrective actions within five days or risk losing export eligibility for that country.

D. If the establishment's investigation indicates that FSIS was responsible for, or contributed to, certifying product that did not meet the importing country's requirements, the DO will determine if FSIS is effectively performing export certification tasks and handle accordingly.

E. The DO is to report the investigation findings and proposed corrective actions to IEPDS and its respective EARO within 15 business days of receiving notification from IEPDS of the POE violation from the importing country.

V. DOCUMENTATION OF CORRECTIVE ACTION REVIEWS

IEPDS is to:

- 1. Evaluate the establishment's proposed corrective actions and consult other program areas as needed;
- 2. Document the corrective actions in the IEPDS shared electronic database and evaluate the corrective actions to ensure that they are thorough, appropriate, and effective;
- 3. Contact the establishment, the DO, and the IIC as often as necessary to provide advice, gather additional information, or clarify current information. The IEPDS is to copy the appropriate District Manager (DM) or Deputy District Manager (DDM) when corresponding with the IIC; and
- 4. Communicate the status of the corrective actions evaluation to the EARO and DO within 10 business days after receiving the corrective actions. If the corrective actions are deemed thorough, appropriate and likely effective, IEPDS is to communicate that to the DO and EARO and provide a status on the response to the importing country. If the corrective actions are deemed inadequate, IEPDS is to also communicate that information to the DO and EARO.

VI. ADVISING FOREIGN COUNTRIES OF THE RESULTS OF THE CORRECTIVE ACTION REVIEW

A. When implementation of the corrective actions has been verified by the IIC and DO, the IEPDS will prepare a letter or other appropriate form of communication to the importing country. The letter will state what corrective actions have been taken to resolve the POE violation and, if applicable, request that the foreign country remove any restrictive action(s).

B. The Assistant Administrator of OPPD will review and clear the letter. The letter may be reviewed and cleared by other program areas if requested. Once approved, the OIC will sign and transmit the letter to the foreign country CCA.

VII. CHARGING FOR VOLUNTARY REIMBURSABLE SERVICE

The DO, at its discretion, may designate a non-bargaining unit employee (e.g. Enforcement Investigations and Analysis Officer – (EIAO)) or Front Line Supervisor (FLS), if the IIC is a bargaining unit employee, to document the establishment investigation and verification of the adequacy/likely effectiveness of the proposed corrective actions. The time expended by the designated non-bargaining unit employee or IIC on the establishment investigation, assessing the adequacy/effectiveness of corrective actions, and verifying the implementation and effectiveness of the corrective actions is to be charged to the establishment as voluntary reimbursable services for export certification by the DO. In addition, all travel time by a designated employee other than the assigned IIC is to be charged to the establishment as voluntary reimbursable services for export certification.

VIII. DATA ANALYSIS

Each year, the Data Analysis Staff within the Office of Data Integration and Food Protection or IEPDS is to report the number of the past year's POE violation incidents identified by importing countries.

IX. QUESTIONS

Refer questions regarding this directive to IEPDS through <u>askFSIS</u> or by telephone at 1-855-444-9904. When submitting a question, use the Submit a Question tab and enter the following information in the fields provided.

Subject Field: Enter Directive 9040.5

Question Field: Enter question with as much detail as possible.

Product Field: Select **Export** from the drop-down menu.

Category Field: Select Detained Product Cases from the drop-down menu.

Policy Arena: Select International (Import/Export) from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: Refer to FSIS Directive 5620.1, Using askFSIS, for additional information on submitting questions.

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