UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

9010.1
Revision 2

1/25/22

UNITED STATES EXPORTED AND RETURNED PRODUCTS

I. PURPOSE

This directive provides instructions and procedures for the Office of Field Operations(OFO), Recall Management and Technical Analysis Division (RMTAD), inspection program personnel (IPP), and Office of Investigation, Enforcement and Audit (OIEA) to follow when meat, poultry, and egg products bearing the mark of inspection are exported from and subsequently returned to the United States (U.S.). This directive provides program area responsibility for coordinating the return of U.S. exported product. FSIS is reissuing this directive to provide updated instructions to FSIS personnel that define program responsibilities and activities when U.S. exported products are returned to the U.S.

II. CANCELLATION

FSIS Directive 9010.1 Revision 1, *United States Exported and Returned Products*, 9/5/2007

III. BACKGROUND

A. As set out in 9 CFR 327.17, 381.209, 557.17, and 590.965, meat, poultry, and egg products exported from and then returned to the U.S. are exempt from FSIS import inspection requirements applied to foreign product but still must be approved by FSIS to return to U.S. commerce. Depending on the product and its condition, RMTAD may approve or deny the product's return to U.S. commerce, or defer its decision until the product has been reinspected at an official FSIS establishment. U.S. meat, poultry and egg products returning to the U.S. must meet requirements defined by the Animal and Plant Health Inspection Service (APHIS) as well as FSIS.

B. RMTAD will make decisions concerning U.S. returned product based on a number of factors in order to determine whether such product is safe and not adulterated or misbranded. These factors include but are not limited to: (1) the general condition of the product, (2) the conditions under which the product has been held, (3) whether a chain of custody has been maintained and can be demonstrated for the period of time the product was outside the U.S., and (4) the duration of time the product has been outside of the U.S.

IV. FSIS FORMS ASSOCIATED WITH THIS DIRECTIVE

A. FSIS Form 9010-1 Application for the Return of Exported Products to the United States – RMTAD will consider the information provided by the applicant on this form as part of the decision making process when determining whether the product will be approved to re-enter the U.S., and whether the product will require reinspection at an official FSIS establishment. The form is available on-line at: https://www.fsis.usda.gov/inspection/inspection-forms?combine=9010.

B. FSIS Form 9010-2 U.S. Exported and Returned Product Facility for Reinspection Concurrence – In the event RMTAD requires reinspection, RMTAD is to use this form to request concurrence with the reinspection location from the District Office (DO). The DO is to use this form to document and send its concurrence to RMTAD.

V. PROCEDURES FOR DETERMINING APPROVAL FOR ENTRY, REINSPECTION, OR RELEASE INTO COMMERCE

A. RMTAD is to receive FSIS Form 9010-1, a copy of the export certificate, and any additional information submitted by the applicant to determine whether to approve the product's return to the U.S., to deny the product's return to the U.S., or to require reinspection at an official FSIS establishment in order to gather additional information to make its decision. If reinspection is required, the application for return must be accompanied by a copy of the establishment's written plan for handling the returned product. RMTAD is to return incomplete applications to the applicant and may request additional information, if needed. Applications are submitted by email at USReturnedExports@usda.gov.

B. To determine whether FSIS may approve a product for return to the U.S., RMTAD will ask questions and gather information to determine the current condition of the product and its labeling as well as information necessary to determine whether the product remained under control for the entire time it was outside of the U.S. Information suggesting the entire shipment is adulterated or that control of the product was lost while outside the U.S. will result in denial of the request to return such goods. Questions may include but are not limited to:

1. What are the circumstances necessitating return?
2. What is the condition of the product and its packaging?
3. How long has the product been out of the U.S.?
4. Where has the product been since it was exported from the U.S.?
5. Under what conditions has the product been held, including temperature logs if appropriate??
6. What has been the chain of ownership of the product?
7. Is there an equivalence determination of the country from where the product is being held and returned?
8. If the product is not being returned from a country determined to have a food safety system equivalent to that of the U.S., was documentation provided to establish a sufficient level of confidence in the integrity of handling, storage, and control of the product?
9. Was the product ever abandoned or subject to possible criminal activity such as theft or break-in?
10. Is the product label in compliance with U.S. regulations?
11. Was the product refused entry by a foreign government, and, if so, what were the circumstances behind the refusal? The applicant is to provide a copy of all documentation issued by the foreign government regarding the official refused entry notification and lab analysis (if applicable).
12. Is the product in its original packaging; have any of the outer containers (e.g., carton, package, or combo, as shipped from the U.S.) been opened?
13. Has the product entered commerce in the foreign country?

14. Was the product ever removed from the original cargo container?

15. Is the original U.S. seal intact?

16. Are there any specific food safety concerns associated with the return of this product?

17. What is the applicant's intentions with the product after it has returned (and U.S. requirements have been met)?

NOTE: The applicant is responsible for ensuring that returned product also meets APHIS requirements

C. RMTAD will forward each application content to APHIS.

D. RMTAD may also contact program areas, such as the Office of Public Health Science (OPHS); Office of Policy and Program Development (OPPD); OIEA; or the Significant Incident Preparedness and Response Staff (SIPRS) for assistance in determining whether to allow the product return or to require reinspection.

E. When RMTAD determines, based on its review of the complete application package, that the returned product is safe and not adulterated or misbranded, and can be allowed back into the U.S. and released directly into commerce, RMTAD is to document the decision on FSIS Form 9010-1 and return the application to the applicant.

F. When RMTAD determines, based on its review of the form and supporting documentation, that the safety of the product cannot be assured, or that the product might be adulterated or misbranded, RMTAD is to deny return of the product, document the decision on FSIS Form 9010-1, and return the application to the applicant. RMTAD is to notify the applicant of their right to appeal the decision to the Deputy Director of RMTAD.

G. When RMTAD determines, based on its review of the complete application package, that the returned product needs to be reinspected or if RMTAD cannot make a determination based on the information provided in the application, RMTAD is to inform the applicant that they need to work with the establishment (designated in block 18 of FSIS Form 9010-1) to develop an action plan for the examination, possible testing, sorting, and/or presentation of the product for FSIS reinspection, and destruction of non-compliant product (including the method of destruction). RMTAD will verify that this plan includes:

1. A procedure for staging the shipment for IPP to verify documentation, count, and review the shipment for signs of tampering prior to any invasive manipulation of the product by the establishment;

2. Procedures the establishment will perform to keep this product separate from other product in the establishment and prevent commingling during storage, rework, and reinspection;

3. Procedures the establishment will perform to ensure the product is safe, wholesome, and not adulterated, and that addresses the reason for return;

4. A procedure for presenting the product to IPP after any rework is performed so that IPP may select verification samples; and

5. How condemned product will be disposed of.

H. RMTAD is to develop and provide an FSIS sampling plan in accordance with 9 CFR 318.2, 381.145, or 590.424 to be used by IPP for the reinspection. RMTAD is to send FSIS Form 9010-2 along with the applicant's plan and the FSIS sampling plan to the DO with jurisdiction over the establishment identified by the applicant when RMTAD determines that reinspection is necessary. RMTAD is to also forward a copy of FSIS Form 9010-1 and any additional information concerning the product to the DO. The DO is to assess the availability of FSIS resources and the suitability of the establishment to perform the activities referenced in the applicant's plan and facilitate the reinspection outlined in the FSIS sampling plan (e.g., area to open the cartons in a sanitary manner to prevent contamination).

I. If reinspection can occur without undue disruption of regular inspection activities at the establishment identified by the applicant and the establishment is determined suitable for the reinspection, the DO is to document its concurrence and return the FSIS Form 9010-2 to RMTAD.

J. After the DO's concurrence, RMTAD is to advise the applicant (with a copy to the DO) that they are authorized to return the product for reinspection. The product is to be transported to the establishment in accordance with 9 CFR 325.10. All the product's supporting documentation (copies are permitted), including FSIS Form 9010-1 and 9010-2, are to accompany the returned product to the establishment. The notification will include a recommended sampling plan with guidance for the organoleptic reinspection to be performed by IPP.

K. The DO is to direct the Inspector-in-Charge (IIC) at the establishment to perform the reinspection and advise him or her of the approximate date of arrival. RMTAD is to routinely check the status of each application to verify it has arrived in the U.S. and was reinspected at the establishment as required. If the product has arrived in the U.S. and has moved to a location other than the establishment noted on FSIS Form 9010-1, RMTAD is to contact the Compliance and Investigations Division (CID), OIEA, to initiate tracing or other appropriate investigatory activities. CID is to report its findings back to RMTAD.

L. If the DO does not concur with the request for reinspection at the establishment, RMTAD is to ask the applicant to identify an alternate establishment and to submit a revised FSIS Form 9010-1 (block 18) and an action plan from that establishment. RMTAD will repeat the steps above until the applicant provides an appropriate reinspection location and receives concurrence from the applicable DO.

VI. REINSPECTION PROCEDURES

A. RMTAD is to include a sampling plan, specific for the type of product returning, which includes instructions on the reinspection process. IPP at the establishment are to reinspect the product in accordance with the sampling plan and 9 CFR 318.2, 381.145, or 590.424, to determine whether it is not adulterated or misbranded and that there is no product tampering. The organoleptic reinspection process could include thawing or tempering if the product is frozen. If it is not possible to reinspect the samples the same day, IPP are to hold the sampled cartons under FSIS control.

B. After reinspection of the returned product, the IIC is to report the findings of the reinspection to the DO. The findings are to include, at a minimum:

1. Whether the IIC carton count and product verification results are acceptable;

2. The number of cartons randomly selected by the IIC for the reinspection;

3. Information on how the samples were thawed, tempered or otherwise prepared for the organoleptic reinspection;

4. Defects identified, if any;

5. Results of the organoleptic reinspection;

6. Number of damaged and/or condemned cartons; and

7. Other information to assist RMTAD in making the final disposition determination.

C. The DO is to report the findings of the reinspection via email to RMTAD at USReturnedExports@usda.gov. RMTAD is to determine, based on the findings of the reinspection, whether to approve the release of the product. RMTAD is to contact the DO for clarification of the findings as necessary. If the product meets FSIS requirements, RMTAD is to document the decision on FSIS Form 9010-1 and provide a copy to the applicant and the DO. The shipment is then released into commerce. If the product is found adulterated, mislabeled, or unwholesome, RMTAD is to deny the return, document the decision on Form 9010-1, and notify the applicant and the DO. The IIC is to retain the product and proceed as set out in 9 CFR 318.2, 381.145, or 590.424. Appeals specific to reinspection findings shall be submitted through the appropriate DO chain of command.

D. The shipment is to remain intact at the establishment until the applicant is notified by RMTAD that product may re-enter U.S. commerce.

VII. QUESTIONS

Refer questions regarding this directive or any other export questions to your supervisor or as needed to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select Export as the Inquiry Type.

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

Assistant Administrator
Office of Policy and Program Development