

REGULATORY PROCEDURES MANUAL – CHAPTER 9

SUBCHAPTER: GUIDANCE CONCERNING RECOMMENDING CUSTOMS' SEIZURE AND DESTRUCTION OF IMPORTED HUMAN AND ANIMAL FOOD THAT HAS NOT BEEN RECONDITIONED

This draft guidance represents FDA's current thinking on recommending U.S. Customs Service's seizure and destruction of imported human and animal food that has not been reconditioned. This draft guidance does not create or confer any rights for, or on, any person and does not operate to bind FDA, the U.S. Customs Service or the public. This draft guidance is being distributed for comment in accordance with the FDA's regulation on Good Guidance Practices (21 CFR 10.115).

Comments and suggestions regarding this document should be submitted by [date] to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. After [date] submit comments to Joseph L. McCallion, Division of Import Operations and Policy (HFC-170), 5600 Fishers Lane, Rockville, MD 20857. For questions regarding this document contact Joseph L. McCallion, (301) 443-6553.

(NOTE: For the purpose of this subchapter, "food" includes both animal food and human food, including food-related items and dietary supplements subject to regulation by FDA.)

The following draft guidance DOES NOT apply to any food that has been successfully reconditioned after detention. Reconditioning proposals should be considered under guidance procedures found in Chapter 9, Regulatory Procedures Manual.

PURPOSE: To ensure that imported food that poses a significant risk to public health is not distributed or exported and subsequently re-imported into the U.S.

BACKGROUND: Food products refused entry into the United States may be offered subsequently for re-importation, either by unscrupulous importers who choose to circumvent the import regulatory system, or by importers who are simply unaware of the previous refusal. Once FDA has determined that food is imported contrary to law, the United States Customs Service (Customs) has the authority, under 19 U.S.C. 1595a(c), to seize the food. Once the seized food is forfeited under Customs

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procedures, it may be destroyed. If the costs of storage during the forfeiture process are disproportionate to the value of the seized product, destruction may be ordered prior to the completion of the forfeiture. (19 U.S.C. 1612(b) and 19 CFR 162.48)

FDA and Customs have worked together on numerous cases to seize and destroy imported products regulated by FDA. This guidance serves to delineate FDA's procedures for collecting information, analyzing public health risk, recommending seizure, and coordinating destruction of the violative imported food by Customs.

GUIDANCE: When a violative imported food appears to represent a significant risk to public health and is not successfully reconditioned, districts should submit a recommendation for destruction to the appropriate Center (Center for Food Safety and Applied Nutrition (CFSAN) or Center for Veterinary Medicine (CVM)) with a copy to the Division of Import Operations and Policy (DIOP) in ORA Headquarters.

CFSAN/CVM should forward approved recommendations to DIOP. DIOP should recommend seizure, forfeiture, and destruction by Customs of violative imported food that poses a significant risk to public health.

Product Criteria:

The product violation should represent a significant risk to health such as those covered by Class I recall. Class I recall is defined in 21 CFR 7.3(m)(1) as "... a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death". Examples of such violations include (but are not limited to):

1. Ready-to-eat product contaminated with salmonella, listeria monocytogenes, or other pathogens.
2. Underprocessed Low Acid Canned Food (LACF) or Acidified Food (AF) products.
3. Product containing undeclared or excessive levels of ingredients or contaminants known to cause adverse reactions; e.g. undeclared sulfites, eggs, peanut protein, some colors.
4. Contaminated or counterfeit infant formula.

Procedures:

When the district detains a product that appears to represent a significant risk to public health and the:

1. Importer attempts to distribute the product without appropriate FDA release; or
2. Importer fails to respond to the Notice of FDA Action (Detention) within 30 calendar days; or
3. Importer requests immediate issuance of a Refusal, i.e., the importer did not apply for authorization to recondition; or
4. Application for authorization to recondition is denied; or
5. The product is not successfully reconditioned;

the district should refer the destruction recommendation in 3 working days to CFSAN's Office of Field Programs, Import Branch (HFS-606) or CVM's Division of Compliance (HFV-230) with a copy to DIOP (HFC-170) for evaluation of the destruction recommendation. (See attached Recommendation for Referral to Customs for Destruction.)

(NOTE: Reconditioning proposals should be approved on the condition that the importer will destroy rejected or discarded product.)

Within 5 working days of receipt of the recommendation, CFSAN/CVM should assess the significance of the risk posed by the product by using established procedures similar to those used to classify recalls. Immediately after CFSAN/CVM completes its assessment, it should notify DIOP (HFC-170) of its analysis and should provide a statement that includes the proposed charge and the reason that the product appears to pose a significant risk to public health.

DIOP should concurrently review the documentation of the case. If the CFSAN/CVM assessment supports Customs seizure and destruction of the product and the documentation is appropriate, DIOP should notify the district and Customs headquarters of the recommendation within 3 days of receipt of the concurrence to seize and destroy the product. The district should NOT issue an FDA Notice of Action (Refusal) covering the product.

Within 5 days of receipt of the recommendation, Customs HQ should direct its field office to proceed with the seizure. Within 5 days of receipt of the recommendation, the FDA district should contact the appropriate Customs field office, provide the appropriate office with a copy of the DIOP recommendation, and offer any applicable assistance, including suggestions for appropriate methods of destruction (e.g. landfill, incineration, etc). DIOP's referral to Customs HQ should state that the product is an importation that is inadmissible into the United States and should include the Center's assessment that the product poses a significant risk to public health. The referral also

should include supporting documentation. (See attached Recommendation for Referral to Customs for Destruction.)

Customs should:

1. Notify FDA when the seizure is accomplished;
2. Notify FDA of misdeclaration or substitution discovered during the seizure;
3. Destroy the product; and
4. Notify FDA of any circumstance that prevented the seizure or destruction.

No FDA Notice of Action (Refusal) should be issued for products to be seized by Customs. Once the product is destroyed, close out the OASIS record by entering a Release, with a narrative note stating that the product was destroyed by Customs and the date the destruction was accomplished.

If the CFSAN/CVM assessment does not support Customs seizure or for some other reason the destruction recommendation is denied, DIOP will communicate that decision to the district. The district may then issue the Notice of FDA Action (Refusal).

RECOMMENDATION FOR REFERRAL TO CUSTOMS FOR DESTRUCTION

TO: CFSAN, Office of Field Programs, Division of Enforcement and Programs, Import Branch (HFS-606) [for animal food products: CVM, Office of Surveillance and Compliance, Division of Compliance (HFV-230)]

CC: Division of Import Operations and Policy, ORO, ORA (HFC-170)

FROM: _____ District (HFR-)
Contact: _____ Phone: _____

DATE: _____

PRODUCT: _____

REASON FOR DETENTION: _____

ANALYTICAL RESULTS(include quantitative results, when appropriate):

Copies attached: FDA _____ Private _____

Label attached _____

RELATED ACTION:

Attempted distribution without FDA release:

Failed to respond to Notice of FDA Action (Detention) within 30 days:

Requests immediate refusal for exportation (attach request):

FDA-766 denied (attach denial and FD-766):

Unsuccessful reconditioning (attach FDA-766):

ENTRY NUMBER: _____

IMPORTER (name, address, FEI, SNN/Tax ID): _____

LOCATION OF GOODS: _____

CFSAN/CVM RESPONSE

To: DIOP

DATE: _____

CONCUR: _____

Applicable charge: _____

Public health risk: _____

DO NOT CONCUR: _____

REASON: _____

CFSAN/CVM Contact _____

Phone/FAX: _____

Cc: HFR: _____

Attachment: Supporting Documentation

REFERRAL FOR DESTRUCTION

TO: US Customs Service
Other Government Agency Branch
FDA Liaison

DATE:

FROM: US Food and Drug Administration
Division of Import Operations and Policy
Customs Liaison (301) 594-1218

SUBJECT: Request for US Customs Seizure/Forfeiture/Destruction

The following product(s) have been found to be inadmissible into the United States per 21 U.S.C. 381, and pose a significant risk to public health. Documentation of inadmissibility and health risk is attached. A representative label is attached.

Please consider Customs seizure/forfeiture/destruction of this product(s) and notify this office when the product has been seized. Please notify this office of any instance of misdeclaration or substitution discovered during accomplishment of the seizure. Also notify this office of any circumstance that prevents the seizure or destruction from occurring.

Thank you for your assistance in protecting the public health.

ENTRY NUMBER:
ENTRY DATE:
PORT OF ENTRY:
IMPORTER ID:
DESCRIPTION OF GOODS:
QUANTITY:
LOCATION OF GOODS:
APPLICABLE CHARGE:
PUBLIC HEALTH RISK:
DISTRICT CONTACT/#/FAX:
FDA CFSAN/CVM CONTACT/#/FAX:
SUGGESTED METHOD OF DESTRUCTION:
Attachments: Supporting documentation and label

TO: DIOP
FROM: USCS

DATE:

Date seizure accomplished:
Discrepancies:

Reason(s) seizure not accomplished:
Customs Contact/#/FAX: