U.S. Goods Return Procedures[i]

Consignments of almonds rejected in Europe for exceeding EU aflatoxin limits have several alternatives:

- *Request a retest*
- *Reprocessing in Europe*
- *Ship to another non-EU country/returned to U.S.*
    - *European authorities may require confirmation from the non-EU country's authorities that the goods will be accepted upon arrival*
    - *Almonds rejected in Japan must be returned to the U.S.*
- *Destroyed or diverted to non-food use*

The following procedures outline the goods return process and can be applied to all almond shipments returned to the U.S. including those rejected for aflatoxin in the export market.

While the Consignment is in the Foreign Port

Before the Goods Can Be Returned to the U.S.

If the consignment will be returned to the U.S., some European authorities require confirmation that the goods will be accepted on arrival in the U.S. USDA and FDA have expressed a preference to work through the Almond Board of California rather than responding to individual requests. FDA has confirmed that ABC can respond to specific inquiries, and has provided a letter to ABC which outlines the U.S. regulations related to aflatoxin. Handlers who are requested to provide the letter to European authorities need to provide ABC with the information below. ABC will prepare a letter incorporating the details provided, attaching the letter provided by FDA.

- Container number
- Shipping date/date of arrival
- Product description
- eVASP certificate number
- European aflatoxin results (a copy of the official lab results – Japanese authorities do not always provide this)
- Packer name
- Port of Return
- Contact details for European port authority (name, organization, fax number/email address)

Please send this information to Caroline Stringer at cstringer@almondboard.com or call 209.343.3256.

IMPORTANT: ABC will send the letter directly to the European import authorities, with a copy of the letter to the FDA/CFSAN office in Washington, DC and the FDA District office (Alameda). A copy is also provided to the handler. Handlers can forward copies to interested parties (for example, their brokers in Europe).

FDA Inspection Process

Before Arrival in the U.S.

- The representative[1] responsible for filing for entry to the U.S. should provide the European aflatoxin analysis results and the Goods Return letter ABC provided to European authorities when submitting entry documents to FDA. At the time the representative files these documents, an Entry Number is created by the representative.
- Japanese authorities do not always provide documentation to the exporter.

[1] The representative responsible for filing for entry to the U.S. is referred to by several different names depending on the organization. FDA, for example, calls this individual the "filer" while other organizations call this individual the "broker." In this document, the individual will be referred to as the representative.

- Prior to arrival at the U.S. port, handlers should provide ABC with the Entry Number for the consignment; this will be relayed to the FDA District office. This will facilitate FDA's ability to tie the returning consignment with the Goods Return letter – and, may help expedite FDA clearance.
- Even if the returned consignment tested below the U.S. aflatoxin limit, FDA may detain the consignment for further screening. Providing the aflatoxin analysis from the foreign laboratory prior to arrival of the goods may help keep it from being detained.

Before the consignment arrives, FDA screens the documents using a computer program known as OASIS (Operational and Administrative System for Import Support). Once the consignment arrives, it may be inspected and detained by FDA's Compliance division even if the consignment was not flagged by OASIS.

Upon Arrival in the U.S.

- If the returning consignment tested above the U.S. aflatoxin limit (20 ppb total) at the foreign port, the handler may be required to provide a reconditioning plan* to bring the consignment into compliance with U.S. standards without FDA performing sampling or analysis.
    - Do not provide this documentation until it is requested by FDA; ABC suggests preparing the reconditioning plan beforehand and keeping it on file until it is requested.
    - Once approved by FDA, the consignment is reconditioned under FDA supervision and released for circulation once it is demonstrated that the consignment conforms to U.S. aflatoxin limits.
- If the consignment is detained, FDA will send out a "Notice of FDA Action."** FDA may request the foreign laboratory results and/or analysis from a private laboratory*** to prove that the consignment complies with FDA standards.
    - The consignment can be stored at the handler's warehouse with FDA approval while awaiting release.
    - The FDA may also sample the consignment using its own lab for analysis
        - Should the consignment be found noncompliant, FDA will send a "Notice of Detention and Hearing."
        - The Notice will provide a date by which the importer must present testimony or evidence that the consignment is compliant (usually, private lab analysis results****).
    - If, upon review by FDA, the testimony or evidence is acceptable, FDA sends a "Notice of Release."**

If no notice is received from OASIS, the goods are still subject to further scrutiny by FDA's compliance division. Importers should not assume that since the consignment was not detained after inspection of the entry documents that it will be released for circulation once it arrives.

Note: If, upon review by FDA, the consignment is not allowed for import into the U.S., the importer has the option to destroy or re-export the consignment. FDA sends a "Notice of Refusal of Admission" and must witness destruction of the consignment; or Customs Border Patrol will oversee the re-export of the consignment. Exporters should work with their brokers or filers to complete the necessary steps for either process.

Important Notes and Links

The FDA's Import Program Overview Web site is currently under revision but can be found at http://www.fda.gov/ForIndustry/ImportProgram/ImportProgramOverview/default.htm.

If using a private lab, ask if the staff has experience with FDA-detained goods. If they already know the protocols, this can save a considerable amount of time and money.

* According to the FDA *Regulatory Procedures Manual March 2009*, Chapter 9, reconditioning plans must be submitted on a Form FD-766 Reconditioning Plan Proposal. These must be submitted in triplicate at a minimum and in quadruplicate if the handler wants a copy returned for records.

** According to the FDA *Regulatory Procedures Manual March 2009*, Chapter 9, all notices sent by the FDA are to be addressed to the representative, the importer of record, and the consignee designated on the entry documents. ABC understands that in most cases, FDA only notifies the representative. Handlers should expect either method of communication.

*** FDA may detain consignments to test for any number of food quality or safety issues in addition to aflatoxin. The general experience with almonds returned for

aflatoxin rejections is that they are detained for aflatoxin analysis but that does not mean that goods cannot be detained for inspection for other reasons.

**** **FDA does not defer to USDA-approved laboratories for VASP or VASP Protocols – the most significant difference is that FDA requires a 50 lb sample**. FDA's accepted sampling and analysis for aflatoxin in almonds differs from that of VASP. If private lab analysis results are provided to FDA, VASP protocols will not be recognized by FDA as sufficient for screening for aflatoxin. Handlers are encouraged to ask private lab managers if they have experience with testing FDA-detained goods before sampling.
For **complete guidelines**, please instruct private labs to use the following guidance documents:

- FDA Office of Regulatory Affairs (ORA) Laboratory Manual: Section 2 Chain of Custody – Sample Handling
- FDA Office of Regulatory Affairs (ORA) Laboratory Manual: Section 7 Private Laboratory Guidance
- FDA Office of Regulatory Affairs (ORA) Laboratory Manual Section 7 Mycotoxin Analysis
- FDA Inspections, Compliance, Enforcement, and Criminal Investigations Subchapter 4.5 – Sampling: Preparation, Handling, Shipping
- FDA Inspections, Compliance, Enforcement, and Criminal Investigations Chapter 6 – Mycotoxin Sample Sizes

FDA requires that private labs submit analytical worksheets or analytical packets with every submission no matter how many submissions to FDA they have made in the past. Should lab managers have any questions regarding what FDA will need in order to evaluate the results submitted, they should contact the FDA's Compliance Officer listed in the "Notice of Detention and Hearing." Anecdotal evidence suggests that emails are answered the fastest in most cases. If an email is sent to an FDA Compliance Officer, a copy should be sent to SanImportsCompliance@fda.hhs.gov as well.

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[i] This document has been reviewed by FDA's Import Operations Branch, San Francisco Office. For further information, please contact Caroline Stringer at 209.343.3256 or cstringer@almondboard.com.