



 CULTIVATING A HEALTHIER
FUTURE



EXPORTING WITH CONFIDENCE

Speakers

Tim Birmingham, Almond Board of California

Anthony Sagariballa, The Almond Company

Abhijeet Kulkarni, Almond Board of California

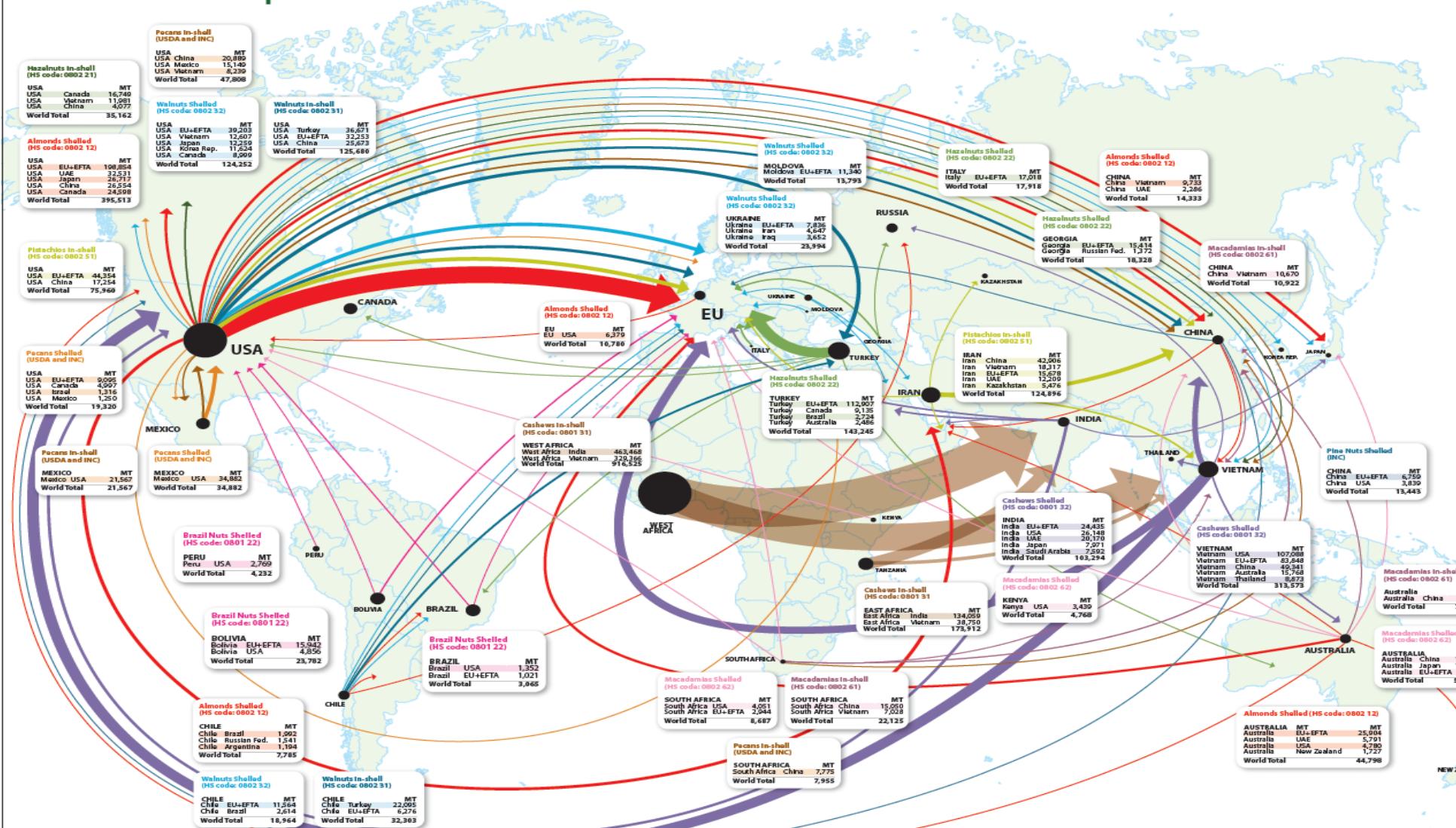
Exporting with Confidence

December 11, 2025



From California to the World

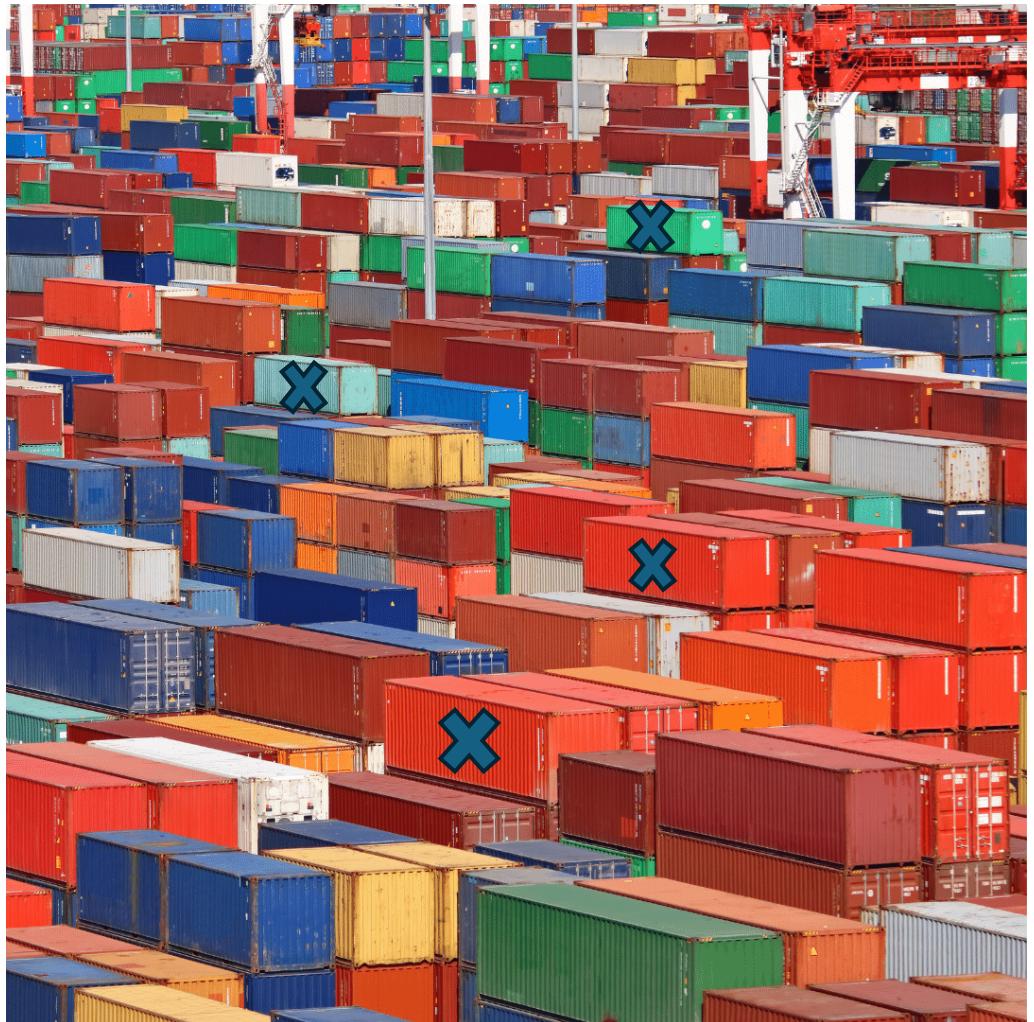
Tree Nut Export Flows



Shipping Stats

1.975 billion lbs exported
(Crop Year 2024-25)

45,000 20T containers



What is a Rejection?

Definition of Rejection: Consignment that is denied entry into the destination market.

This could be for a variety of reasons....regulatory, customs, phytosanitary, etc.

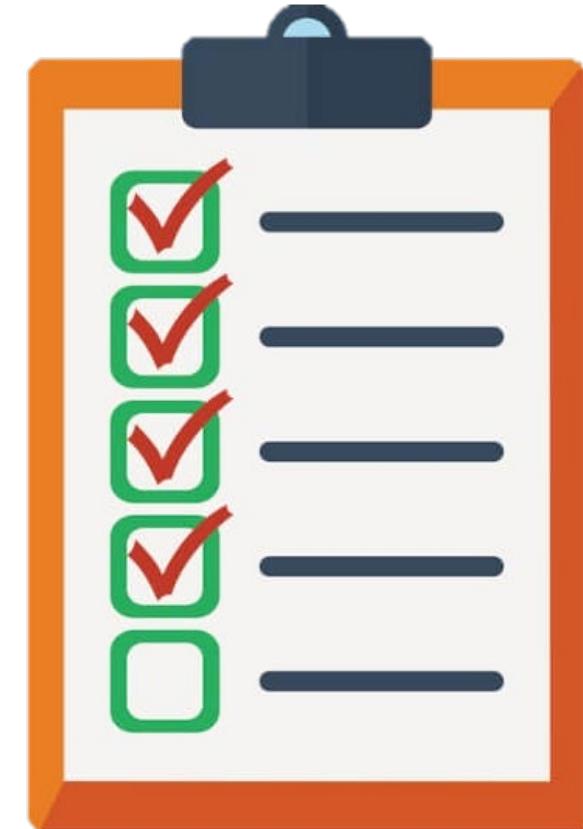
- Tim's talk on Goods Return will cover steps that must be taken to bring a rejected shipment back to the U.S.



Understanding Import Regulations

Preparation is the Key

- Importing country may have specific requirements
 - Phytosanitary Certificate (Japan, S. Korea, Morocco)
 - Import country registration (China, Turkey)
 - Labeling (India)
 - Shipping documents



Phytosanitary

Welcome External Access User
[Close PExD](#)

 Phytosanitary Certificate Issuance & Tracking System (PCIT)

Phytosanitary Export Database (PExD)

Need Help 

[View Country Information](#)

[Additional Export Data](#)

[Ineligible Commodities](#)

[View PExD Reports](#)

Notice: Certifying officials accessing the system without logging into PCIT may have [limited document visibility](#).

Welcome to the Phytosanitary Export Database (PExD) System. PExD contains phytosanitary import requirements of U.S.-origin commodities to foreign countries. This information may be retrieved by users with access to the Phytosanitary Certificate Issuance and Tracking (PCIT) system.

[Refresh Messages](#)

Messages

Messages List

General:
Fri Oct 08 00:00:00 CDT 2021 -

****Effective Immediately:**** All replacement phytosanitary certificates will require the following additional declaration.

"This certificate replaces and cancels [Phytosanitary certificate number], issued on [date], due to [reason for issuing new PPQ Form 577 or 579]."

View Country Information

Select the country you would like to view information on. Items marked asterisk are required.

***Country:**

Then select the type of information you would like to view on the selected country.

[USDA](#) | [APHIS](#) | [Export Program Manual](#) | [Export Certification Specialists List](#) | [Help/Contact Us](#)

Phytosanitary

Welcome External Access User [Close PExD](#)

 Phytosanitary Certificate Issuance & Tracking System (PCIT)

Phytosanitary Export Database (PExD) [Need Help](#) 

View Country Information
Commodity
Foreign Points of Contact
Harmful Organisms
Definitions
Points of Entry
General Requirements
Supporting Documents
Additional Export Data
Ineligible Commodities
View PExD Reports

The Republic of Korea 

Commodity

Enter the commodity botanical name to find the Commodity Summary for your specified country. Click here for [search tips](#) on finding your specific commodity. Items marked ***** are required.

Note: You must use the botanical name of the commodity you wish to find. To view all commodity summaries listed for the country enter *. Only commodities with data will be displayed.

***Commodity:** [Search](#) [Select One](#)

Search By: Prunus dulcis Prunus sp.

***Part:** [Select All](#)

List of Parts		
<input type="checkbox"/> Hulls	<input type="checkbox"/> In shell nuts	<input type="checkbox"/> Plants
<input type="checkbox"/> Pollen	<input checked="" type="checkbox"/> Shelled nuts	<input type="checkbox"/> Shells

If the part you are looking for is not returned, click here to view General Requirements.

Phytosanitary

The Republic of Korea



Commodity Summary

Important Notes:

- **10/02/2025:** As of October 9, 2025 (shipping date), host material from the Oriental Fruit Fly quarantine areas in the Jurupa Valley quarantine area established in Riverside and San Bernardino Counties, California were added to the import suspension areas. Host material is prohibited. All shipments of host fruits from CA should be accompanied by a PC with an AD that, "The shipment has been produced and packed in an area outside of the quarantine areas for fruit flies."
- **12/04/24:** APHIS was informed that the following OFF "Q" areas in California were removed from the import suspension areas as of December 3, 2024 (shipping date of consignment). The OFF "Q" areas removed are Santa Clara County, Contra Costa County, and San Bernardino County and the adjacent Riverside County.
- **12/05/23:** As of December 6, 2023 (shipping date), host material from the Queensland Fruit Fly quarantine areas in Ventura County and adjacent Los Angeles County, CA, were added to the import suspension areas. Host material is prohibited. All shipments of host fruits from CA should be accompanied by a PC with an AD that, "The shipment has been produced and packed in an area outside of the quarantine areas for fruit flies."
- **12/01/23:** As of December 5, 2023 (shipping date), host material from the quarantine areas in Leimert Park area in Los Angeles County, CA, were added to the import suspension areas. Host material is prohibited. All shipments of host fruits from CA should be accompanied by a PC with an AD that, "The shipment has been produced and packed in an area outside of the quarantine areas for fruit flies."
- **09/12/22:** As of September 15, 2022 (shipping date), host material from the quarantine areas in Valley Central Area, San Diego County, CA, were added to the import suspension areas. Host material is prohibited. All shipments of host fruits from CA should be accompanied by a PC with an AD that, "The shipment has been produced and packed in an area outside of the quarantine areas for fruit flies."
- **04/22/20:** NEW SOD UPDATE: As of April 16, 2020, Korea has lifted the SOD restriction on propagative material such as nursery stock (including root stocks), cuttings and scions, etc. (except seeds and fruits) and wood (including logs) with bark of *P. ramorum* host plants and associated plants from 6 states (Indiana, Missouri, Iowa, Illinois, Kansas, and Nebraska). **Oklahoma is still considered a regulated area.** *P. ramorum* host logs and associated host with bark from Oklahoma will need to be bark free or have the following AD present on the PC: "The shipment was inspected and found free of *Phytophthora ramorum*." The State and County or origin must appear on the PC.
- **11/20/18:** As of November 16, 2018 (PC issuance date), the shipment of host fruit from the Mexfly (*Anastrepha ludens*) quarantine area in Laredo City, Webb County, TX, is prohibited.

Prunus dulcis

Commodity Parts:

- [Shelled nuts](#)

Shelled nuts

Last Updated: January 12, 2022

→ Phytosanitary Certificate (PC) is required.

[\[Return to Top of Page\]](#)

Phytosanitary

European Union*



Austria; Belgium; Bulgaria; Croatia; Cyprus; Czech Republic; Denmark; Estonia; Finland; France; Germany; Greece; Hungary; Ireland; Italy; Latvia; Lithuania; Luxembourg; Malta; Montenegro; Netherlands; Poland; Portugal; Romania; Slovakia; Slovenia; Spain; Sweden; Switzerland; The Republic of Moldova; United Kingdom-Northern Ireland

*Note: Although not European Union member countries, Montenegro, Switzerland and United Kingdom-Northern Ireland follow the European Union requirements.

Commodity Summary

Important Notes:

Note:

- Users must use the most current document, located under General requirements, Supporting documents, for *Additional Declarations - Propagative Plant Parts and Soil and Growing Media*, for plants for planting not listed in a summary
- Users must use the most current document, located under General requirements, Supporting documents, *Additional Declaration glossary*, to define all Additional Declarations
- Users must list Additional Declarations on phytosanitary certificates exactly as they appear in a commodity summary

Prunus dulcis

Commodity Parts:

- Shelled nuts

Shelled nuts

Last Updated: December 16, 2019

Commodity is unrestricted.

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Phytosanitary

County Ag Commissioner

India



Commodity Summary

Important Notes:

12/12/19: For shipments of kiln dried and heat treated lumber, the treatment date must be indicated on the treatment certificate. It must also be included in the DISINFESTATION AND/OR DISINFECTION TREATMENT section of the phytosanitary certificate.

08/05/16: Export Services has been notified that India's plant protection organization has amended their regulations to remove the import permit requirement from hundreds of commodities. ES is updating PExD, but it may take some time as each affected commodity must be updated individually.

Prunus dulcis

Commodity Parts:

- [In shell nuts](#)

In shell nuts

Last Updated: January 12, 2022

Phytosanitary Certificate (PC) is required.

Treatments

MB or Phosphine. If a phosphine/carbon dioxide mixture is used, such as Eco2Fume, it must meet the same schedule as stated below. When conducting any phosphine treatment, the commodity temperature must always be at or above 5 degrees Celsius (41degrees Fahrenheit). Please consult the treatment label for phosphine tablets and pellets.

Treatment Table 1

Fumigation - Methyl bromide			
Concentration	Temperature	Duration	Comments
1 pounds / 1000 ft ³	69.8 and above °F	24 Hours	
1.5 pounds / 1000 ft ³	60.8 - 69.7 °F	24 Hours	
2 pounds / 1000 ft ³	51.8 - 60.7 °F	24 Hours	
2.5 pounds / 1000 ft ³	50 - 51.7 °F	24 Hours	

Fumigation - Phosphine			
Concentration	Temperature	Duration	Comments
40 g / 1000 ft ³	5-9.9 C	10 Days	
40 g / 1000 ft ³	10-14.9 C	8 Days	
40 g / 1000 ft ³	15-19.9 C	4 Days	
40 g / 1000 ft ³	20-24.9 C	3 Days	
40 g / 1000 ft ³	25.0 + C	2 Days	

Additional Declaration

The shipment was inspected and found free of *Ephestia elutella*, *Ephestia kuehniella*, and *Plodia interpunctella*.

Registration Requirements

- Almond Certain countries require US exporters to register in a database
- Almond China (Decree 248) – GACC registration
- Almond Turkey
- Almond Your buyer or broker will be a good source
- Almond USDA GAIN reports



Required Report: Required - Public Distribution

Date: April 20, 2022

Report Number: CH2022-0038

Report Name: Food and Agricultural Import Regulations and Standards Country Report

Country: China - People's Republic of

Post: Beijing

Report Category: FAIRS Annual Country Report

Prepared By: FAS China Staff

Approved By: Adam Branson

Report Highlights:

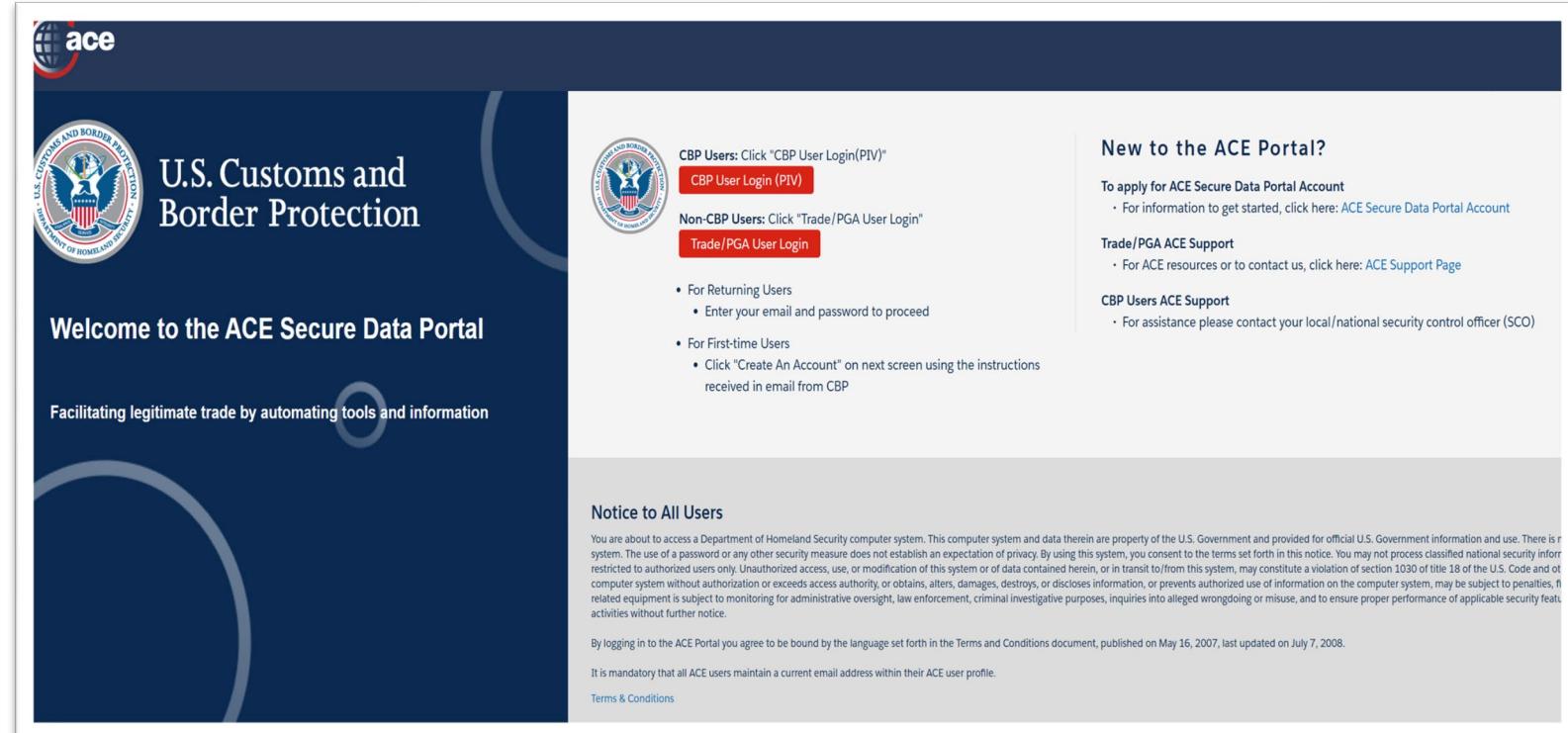
This report presents regulations and standards applicable to food and agricultural imports, including changes to existing standards. In 2021, China released several regulations and standards, including the revised Administrative Measures on Import and Export Food Safety, revised Regulations on the Registration and Administration of Overseas Producers of Imported Food, regulations overseeing variety registration of major crops and the safety assessment of agriculture GMOs, and the full text of the National Food Safety Standard of Maximum Residue Limits for Pesticides in Food (GB 2763-2021). Given the dynamic nature of China's food regulations, U.S. exporters should verify the full set of import requirements with their China-based representatives or customers prior to shipping.

Label Requirements

- 悚 Label requirements vary by country
- 悚 Product Name
- 悚 Packer Name
- 悚 Country of Origin
- 悚 Quantity
- 悚 Allergen statement
- 悚 Lot Code
- 悚 Specific symbols/declaration

Shipping Documents

- 菩提螺 BOL
- 菩提螺 Invoice
- 菩提螺 HS Code (080212/080211)
- 菩提螺 Certificate of Origin (Tariff related)
- 菩提螺 Electronic Export Information (EEI) filing (> \$2500)



The screenshot shows the login page of the ACE Secure Data Portal. The page has a dark blue header with the "ace" logo and the U.S. Customs and Border Protection seal. The main content area is also dark blue and features the text "U.S. Customs and Border Protection" and "Welcome to the ACE Secure Data Portal". Below this, it says "Facilitating legitimate trade by automating tools and information". On the right side, there are two sections: "CBP Users: Click "CBP User Login(PIV)" and "CBP User Login (PIV)" (with a red button) and "Non-CBP Users: Click "Trade/PGA User Login" and "Trade/PGA User Login" (with a red button). Below these are two lists of instructions: one for returning users and one for first-time users. At the bottom, there is a "Notice to All Users" section with a detailed legal notice, a "Terms & Conditions" link, and a "Notice to All Users" link. The right side of the page is a white sidebar with sections for "New to the ACE Portal?", "To apply for ACE Secure Data Portal Account", "Trade/PGA ACE Support", and "CBP Users ACE Support".

New to the ACE Portal?

To apply for ACE Secure Data Portal Account

- For information to get started, click here: [ACE Secure Data Portal Account](#)

Trade/PGA ACE Support

- For ACE resources or to contact us, click here: [ACE Support Page](#)

CBP Users ACE Support

- For assistance please contact your local/national security control officer (SCO)

Notice to All Users

You are about to access a Department of Homeland Security computer system. This computer system and data therein are property of the U.S. Government and provided for official U.S. Government information and use. There is no expectation of privacy. By using this system, you consent to the terms set forth in this notice. You may not process classified national security information or data. Unauthorized access, use, or modification of this system or of data contained herein, or in transit to/from this system, may constitute a violation of section 1030 of title 18 of the U.S. Code and of other laws. Computer system without authorization or exceeds access authority, or obtains, alters, damages, destroys, or discloses information, or prevents authorized use of information on the computer system, may be subject to penalties, fines, and other legal action. Related equipment is subject to monitoring for administrative oversight, law enforcement, criminal investigative purposes, inquiries into alleged wrongdoing or misuse, and to ensure proper performance of applicable security features without further notice.

By logging in to the ACE Portal you agree to be bound by the language set forth in the Terms and Conditions document, published on May 16, 2007, last updated on July 7, 2008.

It is mandatory that all ACE users maintain a current email address within their ACE user profile.

[Terms & Conditions](#)

Teamwork



Key Regulatory Issues

- Exceeding pesticide MRLs – DDVP/PBO (EU/Korea)
- Aflatoxin exceedance (EU/Japan)

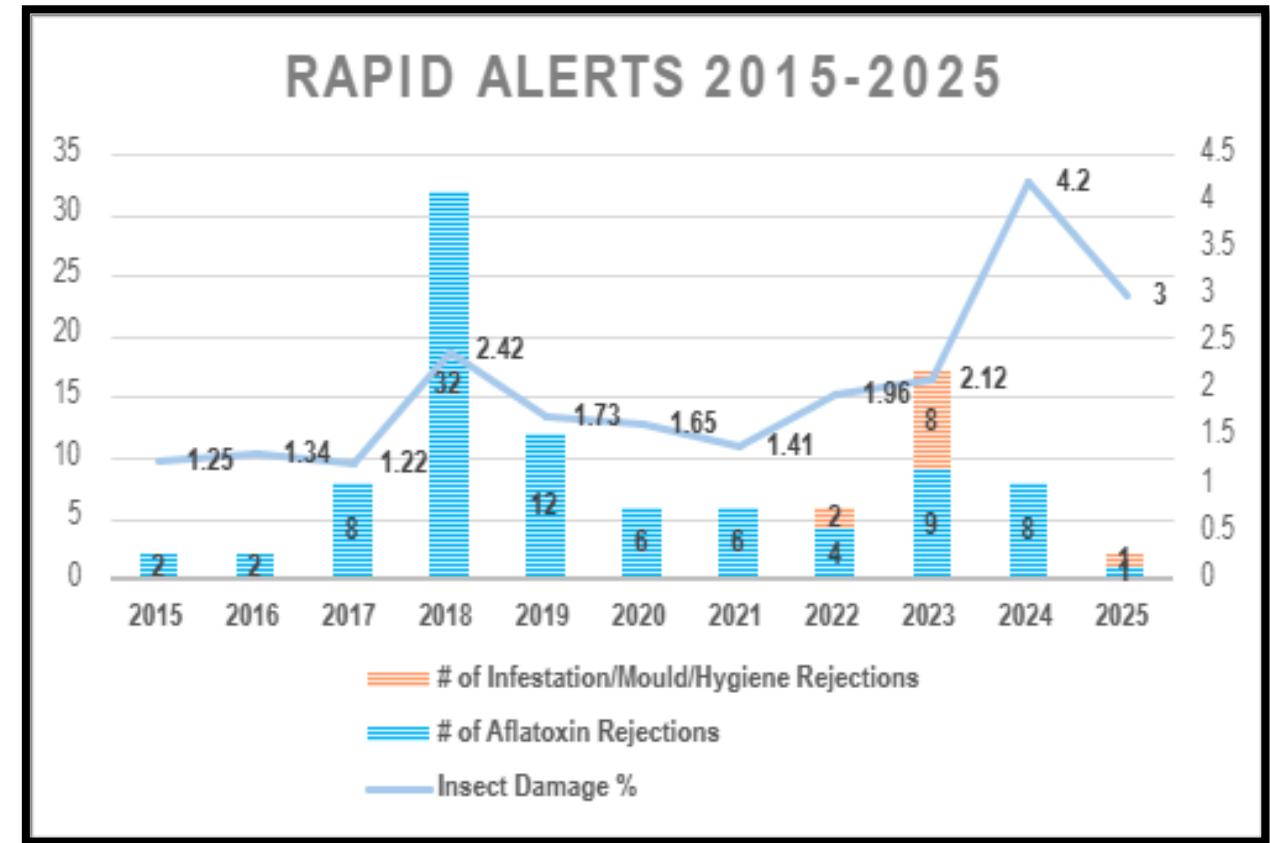


Source: Cardinal Professional Products



Rejections in the EU

- 🥜 Pre-Export Check (PEC) agreement with EU.
- 🥜 # of Rejections is low on a percentage basis.....

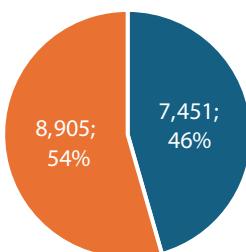


NOTE Lack of PEC documents is not grounds for rejection (EU)

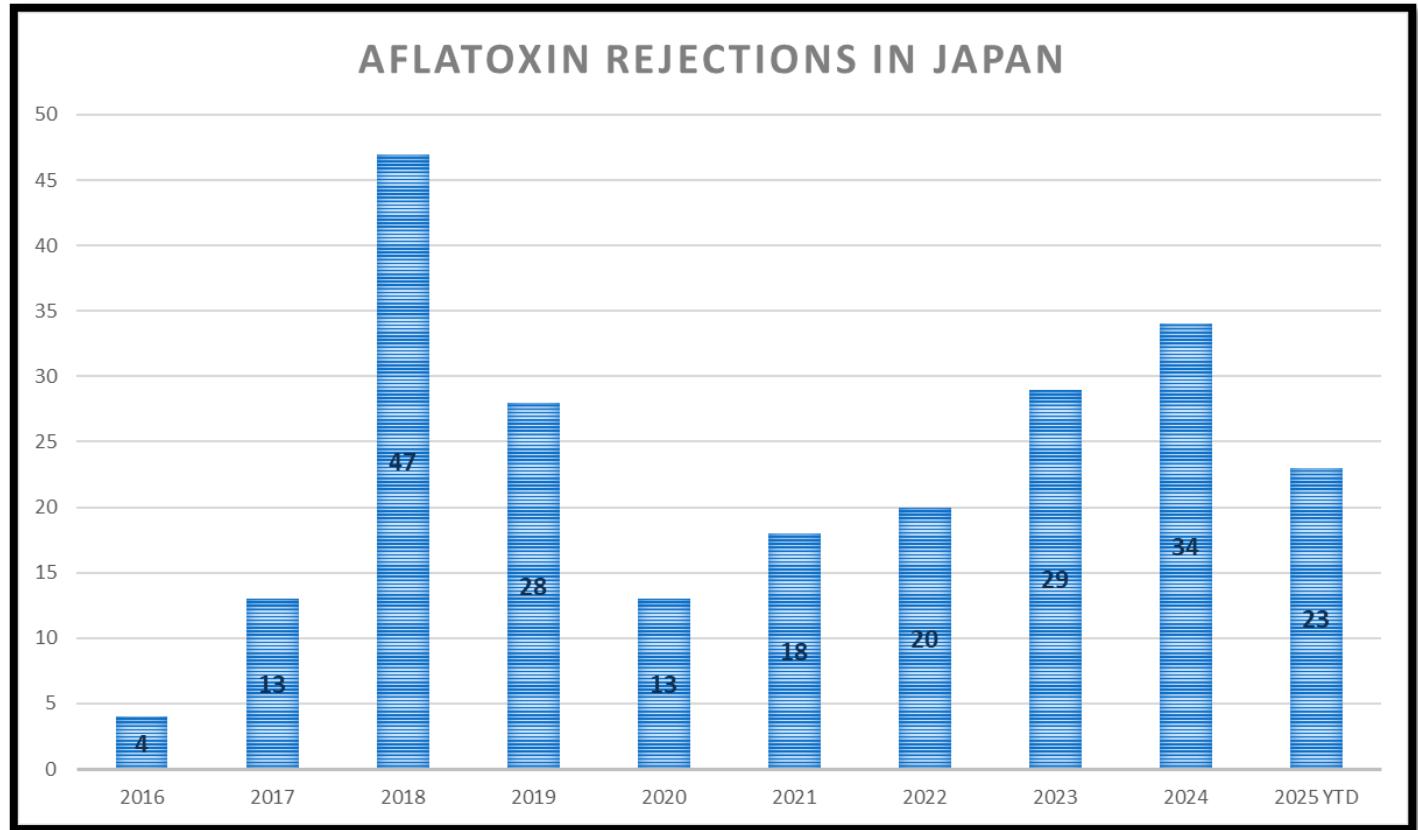
Rejections in Japan

- Japan was inspecting at 100% level.
- USDA-MHLW Agreement on Pre-testing (April 2025).
- < 4% inspections on arrival (4/1/26).
- Local reprocessing option (in progress) in Yokohama.

Japan Imports (MT)
April 1 - July 31, 2025
MHLW Data

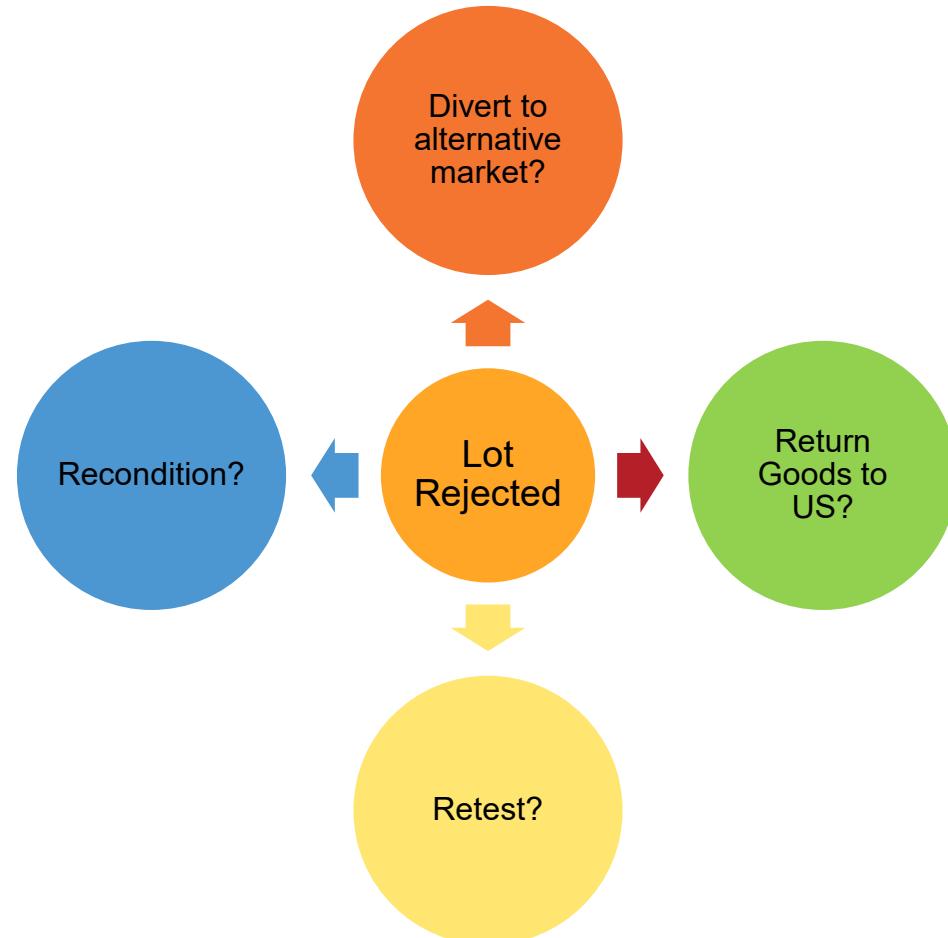


■ Protocol Shipments (MT)
■ Non-Protocol Shipments (MT)



What Are My Options?

- 🥜 Ultimately what you do with the product will be depend upon:
 - Specific Country Requirements
 - Practicality
 - Customer Needs
 - Costs



Addressing Aflatoxin Issues in Europe



REPROCESSING IN EUROPE

- Companies in Spain, Netherlands identified
- Handler Notice and FAQs have been distributed
- Spanish rejects reprocessed (Rotterdam and Spain)
- Staff continuing to visit authorities, ports, trade



PEC < 1% INSPECTION

- EU Commission Services issue an internal RASFF notice
- Confirms to Competent Authorities that the frequency of controls for U.S. almonds under Regulation (EU) 2015/949 are < 1%



U.S. GOODS RETURN

- Delays, inconsistencies raised with local FDA authorities
- ABC working with FDA offices in DC
- Reprocessing plan template drafted for discussion
- Engaging AMS re: MOU with FDA for USDA-approved labs

Typical Rejection Scenario:

- Almond Your consignment was PEC-certified in California
- Almond It leaves Port of Oakland on-time headed to Germany; your buyer is notified that all is well
- Almond The consignment arrives few weeks later in Hamburg, Germany
- Almond Hamburg Port Authorities inspect the load; samples are taken
- Almond The Aflatoxin lab results come back as **24 ppb**. Hamburg authorities detain the consignment
- Almond You get that dreaded email from your buyer. **You shout an expletive**, and then you call Abhi Kulkarni at the Almond Board
- Almond What happens next?

What Next?

- If there is an actual “Rapid Alert Border Rejection” that has been issued, ABC gets it from Brussels. We will contact the exporter if we did not hear from you first. Not all rejections become alerts
- With or without an Alert, ABC will need to collect as much detail from the Handler/trading company;
 - Container Number; Vessel; Date of Arrival in Foreign Port, (If PEC, #); EU lab reports
- We will review the requirements for each option you have and share any anecdotal information to help you decide what you want to do with the rejected consignment.
- As needed, ABC will liaise with U.S. Embassy in country of rejection to facilitate communications with port health officials
- Once completed, ABC will then communicate with the EU in Brussels as to the final disposition if there is a Rapid Alert published

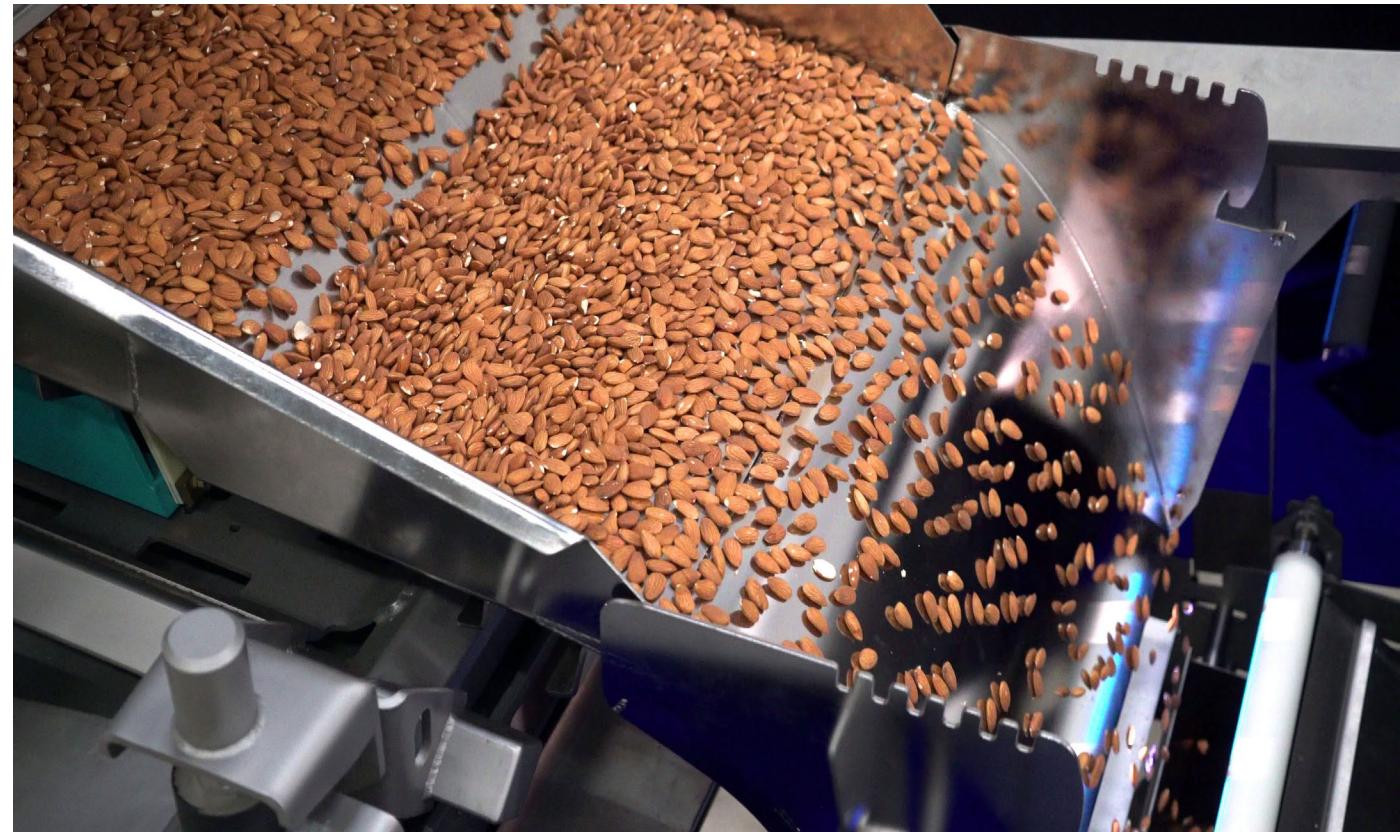
Estimated Costs of Rejection*—Reprocessing vs. Return to U.S.

Reprocessing in the EU	Returning Consignment to the US
<u>Transportation</u> : Send load to Re-processor. (Cost will depend on distance, etc.). \$2000-3000	<u>Transportation</u> : Estimated up to \$8000 per container in just shipping costs to port in the U.S.
<u>Demurrage</u> (\$100-200 per day). Make sure buyer/importer makes logistics arrangements to avoid excessive delays.	<u>Demurrage</u> : (\$100-200 per day). Number of days will vary.
<u>Reconditioning</u> : \$1,200 (40,000 lbs. @\$0.03-0.04 cents)	<u>Reconditioning</u> : If required upon return. Cost will depend on reconditioning plan approved by FDA
<u>Retesting</u> : \$250-500, depending on how samples are taken, third-party involvement, etc.	<u>Retesting</u> : \$250-500, depending on how samples are taken, third-party involvement, etc.
<u>TOTAL</u> : \$3000-5000	<u>TOTAL</u> : \$8000-9000

* Based on estimates from industry

Tips for Reprocessing

- Make the decision **soon** to reprocess after a rejection is issued; the longer you wait, the more it will cost in demurrage, etc.
- Check with your buyer and other involved parties that they are willing to facilitate the reprocessing; confirm their ability to do so and potential time to reprocess
- Lost in the translation; details can be mis-interpreted; ok to call
- Contact the Almond Board for any additional assistance and background information



ABC Activities

- ABC continues to engage stakeholders (Ministries, Port Officials, trade) to address ongoing issues involving inspections, rejections, reprocessing snags
- Visits with EU authorities in The Netherlands, Brussels, as well as DC.
- Japanese MHLW staff along with ABC and FAS staff.
- Ongoing efforts to educate port officials and inspectors on the PEC program and quality controls.



Bringing the Goods Back

December 11, 2025

ALMOND BOARD OF CALIFORNIA



U.S. Goods Returned – Seems Like Jumping Through Hoops

FDA treats all goods entering U.S. Ports as Imports – Regardless of country of origin



- Almond icon: All Imports are subject to Customs Border Protection (CBP) and Food and Drug Administration Scrutiny
- Almond icon: All imported foods must be pure, wholesome, safe to eat, and produced under sanitary conditions
- Almond icon: Prior Notice (Advanced Notice) must be provided

U.S. Goods Returned: 3 Part Process

- Almond icon Get the product back onto US soil
- Almond icon Prepare & Submit a reconditioning plan
 - Only required if Detention Notice is received by FDA
- Almond icon Reconditioning – Carrying out the Plan

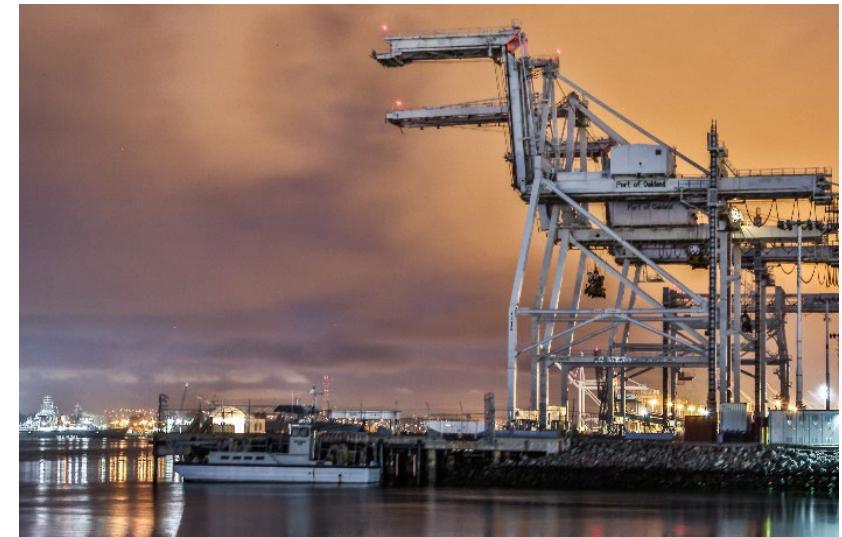
Note: If aflatoxin rejection >20PPB in foreign port expect and prepare for FDA detention notice “Notice of FDA Action” upon return



1. Getting the Product Back

A. Notify ABC

- 💡 ABC will issue official “Goods Returned Letter” to EU authorities for return to U.S. (if required)

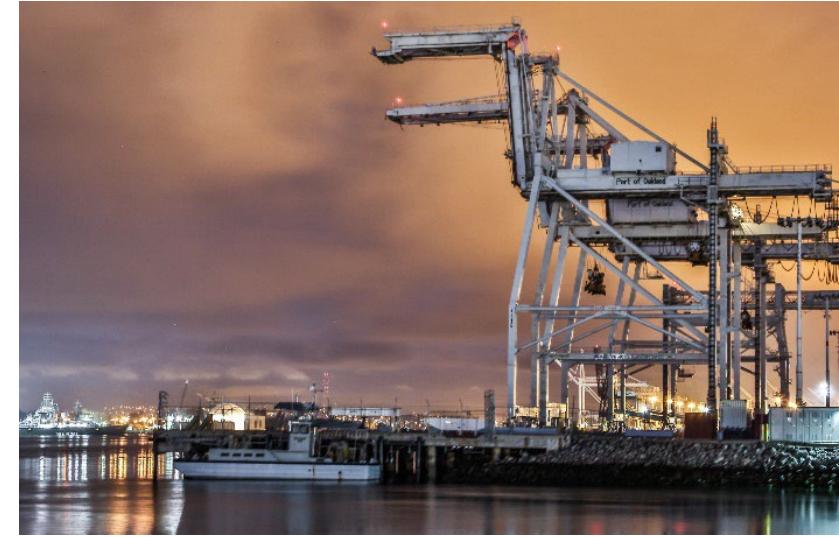


1. Getting the Product Back

B. Work with Customs Broker

⚠ Prior notice must be submitted to FDA

- Must be submitted and submission confirmed by FDA no less than 8 hours before arrival (by water)
- Submit through FDA Prior Notice System Interface (PNSI)- No more than 15 days before anticipated arrival or;
- Through CBP Automated Broker Interface of the Automated Commercial Environment (ABI/ACE) – No more than 30 days before anticipated arrival

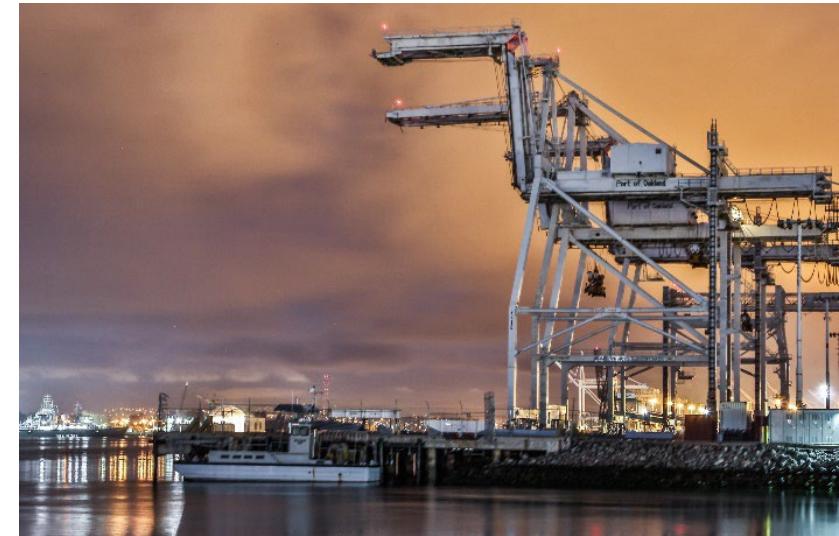


Tip: Prior notice may be submitted by any person with knowledge of the required information for the product/shipment; prior notice may be submitted on behalf of another person

1. Getting the Product Back

C. Prepare for Detention Notice - “Notice of FDA Action”

- Handler will have a limited amount of time to submit a plan to bring the product into compliance after notice issued



Tip: Use transit time to translate official notices (e.g. aflatoxin analysis) to English and submit along with original to FDA through ITACS System

2. Prepare a (Detailed) Reconditioning Plan

- Fill out FDA Form 766 (Application for authorization to relabel or to perform other action of the FD&C Act)
- Prepare a detailed Reconditioning Plan in Addition to Form 766
- Submit both to FDA
 - Directly via email to FDA compliance officer as shown on the detention notice, or Through ITACS system

Tip: Details, Details, Details!!!

SUBMIT IN TRIPPLICATE (Submit in QUADRUPLE/ICATE if you desire copy returned to you.)

APPLICATION FOR AUTHORIZATION TO RELABEL OR TO PERFORM OTHER ACTION OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND OTHER RELATED ACTS

FORM APPROVED: OMB No. 0910-0025
EXPIRATION DATE: 7/31/2020

Public reporting burden time for this collection of information is estimated to average .25 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the address to the right:

An agency *may not* conduct or sponsor, and a person is *not required* to respond to, a collection of information unless it displays a currently valid OMB control number.

TO: DIRECTOR
Division,
Food and Drug Administration

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please do **NOT** send your completed form to the above PRA Staff email address.

Application is hereby made for authorization to bring the merchandise below into compliance with the Act.

CARRIER AMOUNT AND MARKS

Redelivery bond has been posted by the applicant. The merchandise will be kept apart from all other merchandise and will be available for inspection at all reasonable times. The operations, if authorized, will be carried out at:

_____ and will require about _____ days to complete. A detailed description of the method by which the merchandise will be brought into compliance is given in the space below:

We will pay all supervisory costs in accordance with current regulations.

FIRM NAME ADDRESS OF FIRM

APPLICANT'S SIGNATURE

ACTION ON APPLICATION

TO: (Name and Address)

DATE

Your application has been: Denied because: Approved with the following conditions:

Time limit within which to complete authorized operations: _____

When the authorized operations are completed, fill in the importer's certificate on the reverse side and return this notice to this office.

SIGNATURE OF DIVISION DIRECTOR

DIVISION

DATE

FORM FDA 768 (01/18)

(See Back)

FRONT

The “Detailed” Reconditioning Plan

Company Information

- Company name, address, contact, contact info, description

Returned Goods Background Information

- Product description, packaging description, pack date, ship date, returned date
- Pre-Shipment aflatoxin testing conducted (e.g. PEC sampling and testing)
 - Include sampling and testing records

Aflatoxin in Almonds Background Information (ABC provided Information)

- Brief description of aflatoxin contamination of almonds
- Description on efficacy of sorting for Aflatoxin Removal
- Description on efficacy of blanching for Aflatoxin Removal (If Using blanching)

Reconditioning Method

Post Reconditioning Compliance Verification (Aflatoxin Testing)

- Must demonstrate that reconditioned product meets US Regulatory Limits

Guide for Returning California Almonds to United States

United States Food and Drug Administration (FDA) is responsible for ensuring that US Goods Returned meet U.S. food safety regulatory requirements. If goods returned exceed U.S. regulatory limits handlers will need to prepare a detailed reconditioning plan describing steps that will be taken to ensure compliance. When sharing information with FDA, documents should be submitted through the Import Trade Auxiliary Communication System (ITACS). Follow up communications can take place directly with FDA once a compliance officer is assigned with the FDA local import. Local contact information can be found at: <https://www.fda.gov/media/105333/download>. Information on submitting through the ITACS system, including requesting an ITACS account can be found at <https://www.fda.gov/industry/import-systems/itacs>

The use of ITACS allows:

- The ability to check the status of FDA- regulated entries and lines.
- The ability to submit entry documentation electronically.
- The ability to electronically submit the location of goods availability for those lines targeted for FDA exam.
- The ability to check the estimated laboratory analysis completion date for sampled lines

Section 1. California Almonds - US Goods Returned Almond Handler Action Steps

1. Notify Almond Board of California (ABC) as soon as product is detained for failure to meet regulatory limits in the export country.
 - a. ABC has a MOU with FDA allowing ABC to issue the official U.S. Goods Returned Letter if needed/requested by foreign Port Authority.
2. Contact a customs broker licensed by U.S. Custom Borders Protection (Customs) to prepare and file the necessary customs entries documents and obtain an entry number. Refer to the FDA Entry Submission Process information at: <https://www.fda.gov/industry/entry-process/entry-submission-process#submit>
3. Prepare translations of official notices including sampling procedures and laboratory analysis reports from foreign language to English.
 - a. Submit copies of untranslated and translated documents to FDA through ITACS system
4. Prepare for FDA Notice of FDA Action (Detention Notice)
 - a. Once Customs has conditionally released the product, the importer (Handler) must wait to receive an FDA release or further notification
 - b. If the product appears to be out of compliance (e.g. aflatoxin rejection at >20PPB, FDA will issue a Notice of FDA Action (Detention Notice) after Customs has conditionally released the product. Note: All product is subject to FDA scrutiny. Product rejected in a foreign country at >10 PPB but less than U.S. regulatory limits of 20PPB may still be detained and inspected/tested for aflatoxin.
 - c. Once a Notice of FDA Action has been issued, the handler has a limited amount of time to submit a plan to bring the product into compliance

The “Detailed” Reconditioning Plan – Template Has Been Used Successfully

Standardized Template for Aflatoxin Reconditioning for California Almonds Returned to United States (Used in addition to FDA Form 766)		
A. COMPANY INFORMATION	A1. Company Name:	A2. Company Contact:
A3. Company Address:	A4. Contact Telephone #:	A5. Contact Email:
	A6. Company Description:	
B. PRODUCT INFORMATION	B1. Lot Code:	B2. Entry Number:
B3. Product Description:	B4. Packaging Description:	B5. Entry Date:
	B6. Packaging Labeling:	B7. Other ID:
B8. Product Current Location:	B9. Product Hold Status and Identification:	
C. RECONDITIONING PLAN / METHOD	C1. Reconditioning Facility Location:	
C2. Reconditioning Method (Check all that apply):		
<input type="checkbox"/> *Blanching <input type="checkbox"/> **Sorting for Insect Damage Removal <input type="checkbox"/> Other (Describe)		
<p>* Research conducted by United States Department of Agriculture, Agricultural Research Service has demonstrated that blanching can significantly reduce aflatoxin contamination in kernels. "Effect of Blanching on Aflatoxin Contamination in Almonds," B. Campbell, N. Mahoney: WRRC, USDA-ARS, Albany, CA; 2011</p> <p>** Research has shown a correlation between insect damage and aflatoxin concentration. Furthermore, it has been demonstrated that sorting techniques to remove insect damage including hand sorting, electronic sorting, laser sorting, or other means are effective at reducing aflatoxin contaminated kernels from a lot, thereby lowering the levels of aflatoxin to acceptable levels." "Correlation Between Aflatoxin Contamination and Various USDA Grade Categories of Shelled Almonds," Whitaker Et Al.: Journal of AOAC International Vol 93, No. 3, 2010 943</p>		
C3. Equipment Used for Reconditioning (List All and Describe; Attach Flow Chart):		

C 4. Reconditioning Records (Check All that apply; Provide Examples):			
<input type="checkbox"/> Pre and Post Sorting Weight <input type="checkbox"/> QC Line Sheets (% Insect Damage) <input type="checkbox"/> Aflatoxin Sampling Record <input type="checkbox"/> Aflatoxin Analysis <input type="checkbox"/> Reject Records (Lbs. Removed) <input type="checkbox"/> USDA Outgoing Inspection Certificate <input type="checkbox"/> Other (Describe):			
C5. Staff Qualifications (Describe for staff used in reconditioning process and records review):			
C6. Estimated Reconditioning Start Date/Timeframe:		C7. Post Reconditioning Lot Control:	
C8. Estimated Reconditioning Completion Date/Timeframe:		C9. Reject Product Control:	
D. POST RECONDITIONING: AFLATOXIN TESTING			
D1. Sample Collection:		D2. Sample Size:	D3. Collection Date:
<input type="checkbox"/> In House USDA Designated Inspector		D4. Analysis Date	D5. Analysis Result (Attach COA)
Additional Notes:			

Reconditioning Method – Describe in Detail!

- Reconditioning location and method
- Process description describing the product flow, staff and equipment Include a process flow chart
- For equipment used to sort/remove insect damage, provide a brief description of how the equipment works
 - Provide photos and flow charts as appropriate to assist in visualization of sorting mechanism
- For hand and electronic sorting, describe how the removal of insect damage will be monitored
 - Describe records that will be maintained to demonstrate insect removal



Post Reconditioning Compliance Verification (Sampling for Aflatoxin Testing)

- Identify where sampling will occur
- Identify who will conduct the sampling
- Identify how product will be sampled / labeled / stored / delivered
- Identify records used to document sample collection

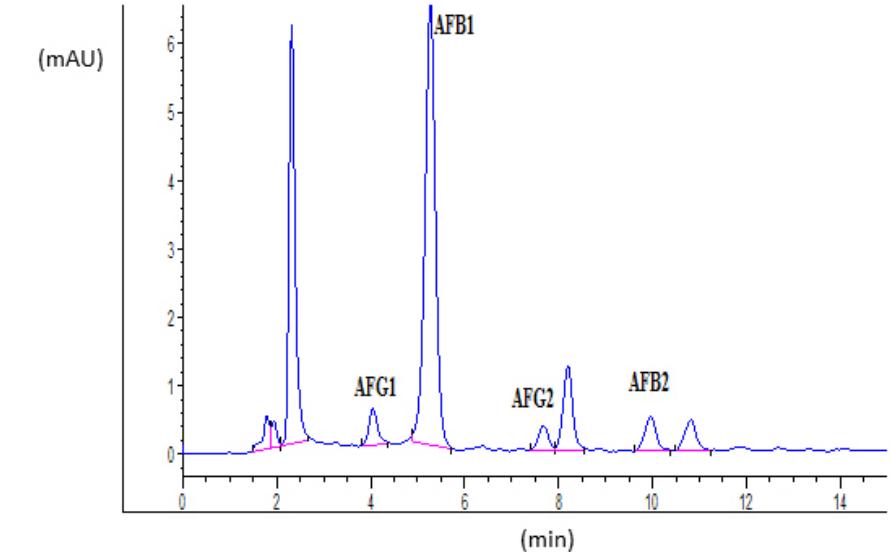


Tip: Reference PEC Sampling SOP

Post Reconditioning Compliance Verification (Aflatoxin Laboratory Testing)

🥜 Use an accredited laboratory familiar with U.S. Goods Return process

- USDA approved labs for almonds/aflatoxin are a good choice
- Describe the sample preparation and analysis methodology
- Describe data packet which will be shared with FDA



Tip: Work with a lab that is familiar with the data/analytical packet needed for FDA

3. Reconditioning – Carrying out the Plan

- Almond icon: FDA will provide notification that Reconditioning Plan is approved or denied on Form 766
- Almond icon: Once approved you will have to complete reconditioning within allotted time
- Almond icon: Recondition product EXACTLY as described in plan
- Almond icon: Segregate reconditioned product from reject material
 - Rejects to be destroyed – not for inedible!
- Almond icon: Conduct sampling / Submit for aflatoxin analysis
- Almond icon: Complete Form 766 backside certifying reconditioning
 - Submit to FDA along with supporting documentation



ACTION ON APPLICATION		
TO: (Name and Address)	DATE	
Your application has been: <input type="checkbox"/> Denied because: <input type="checkbox"/> Approved with the following conditions:		
Time limit within which to complete authorized operations: _____ When the authorized operations are completed, fill in the importer's certificate on the reverse side and return this notice to this office.		
SIGNATURE OF DIVISION DIRECTOR	DIVISION	DATE
FORM FDA 766 (01/18) (See Back) FRONT PSC Publishing Services (800) 443-6740 EF		

Tip: Make sure to include detailed data/analytical packet from the lab!

Goods Returned – What's Next

- Almond icon MOU between FDA and USDA to streamline Goods Returned for Aflatoxin
 - Intent is to better leverage systems already in place
 - Awaiting final Approval

- Almond icon Reconditioning Plan – Template
 - Still need to submit FDA 766!
 - Goods Returned Guide

Standardized Template for Aflatoxin Reconditioning for California Almonds Returned to United States (Used in addition to FDA Form 766)

A. COMPANY INFORMATION

A1. Company Name: A2. Company Contact: A3. Company Address: A4. Contact Telephone #: A5. Contact Email: A6. Company Description:

B. PRODUCT INFORMATION

B1. Lot Code: B2. Entry Number: B3. Product Description: B4. Packaging Description: B5. Entry Date: B6. Packaging Labeling: B7. Other ID: B8. Product Current Location:

C. RECONDITIONING PLAN / METHOD

C2. Reconditioning Method (Check all that apply):
 *Blanching
 *Sorting for Insect Damage Removal
 Other (Describe)

*1 Research conducted by United States Department of Agriculture on aflatoxin contamination in kernels.
"Effect of Blanching on Aflatoxin Contamination in Almonds" - Journal of Food Protection, Vol. 63, No. 3, 2000 943

*2 Research has shown a correlation between sorting for insect damage and hand sorting to remove insect damage including hand sorting, thereby lowering the levels of aflatoxin in the lot.
"Correlation Between Aflatoxin Contamination and Insect Damage in Almonds" - Journal of Food Protection, Vol. 63, No. 3, 2000 943

C3. Equipment Used for Reconditioning:

C. RECONDITIONING RECORDS

C4. Reconditioning Records (Check All that apply; Provide Examples):
 Pre and Post Sorting Weight
 CO Line Sheets (% Insect Damage)
 Aflatoxin Sampling Record
 Aflatoxin Analysis
 Reject Records (Lbs. Removed)
 USDA Outgoing Inspection Certificate
 Other (Describe):

C5. Staff Qualifications (Describe for staff used in reconditioning process and records review):

C6. Estimated Reconditioning Start Date/Timeframe: C7. Post Reconditioning Lot Control:

C8. Estimated Reconditioning Completion Date/Timeframe: C9. Reject Product Control:

D. POST RECONDITIONING: AFLATOXIN TESTING

D1. Sample Collection:
 In House USDA Designated Inspector D2. Sample Size: D3. Collection Date: D4. USDA Approved Lab:

D4. Analysis Date D5. Analysis Result (Attach COA)

Additional Notes:

- 🥜 Avoiding shipment rejection by familiarizing import country requirement is key.
- 🥜 Employee training to build familiarity and know how.
- 🥜 If rejection does occur, follow ABC Guideline for Goods Returned process.





THANK YOU

ALMOND BOARD OF CALIFORNIA



CULTIVATING A HEALTHIER
FUTURE