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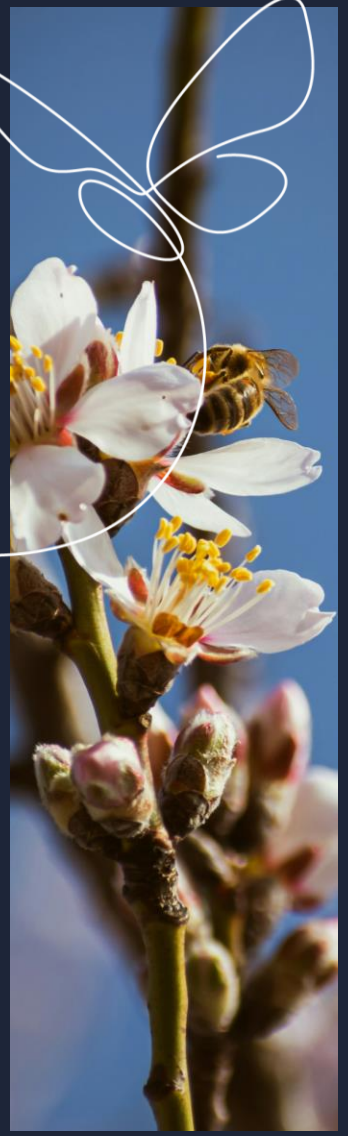

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Dealing with Rejections and Goods Returned

Moderator: Tim Birmingham (ABC)

Speakers: Abhi Kulkarni (ABC), Tim Birmingham (ABC)

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There and Back Again: A Tale of Returned Goods

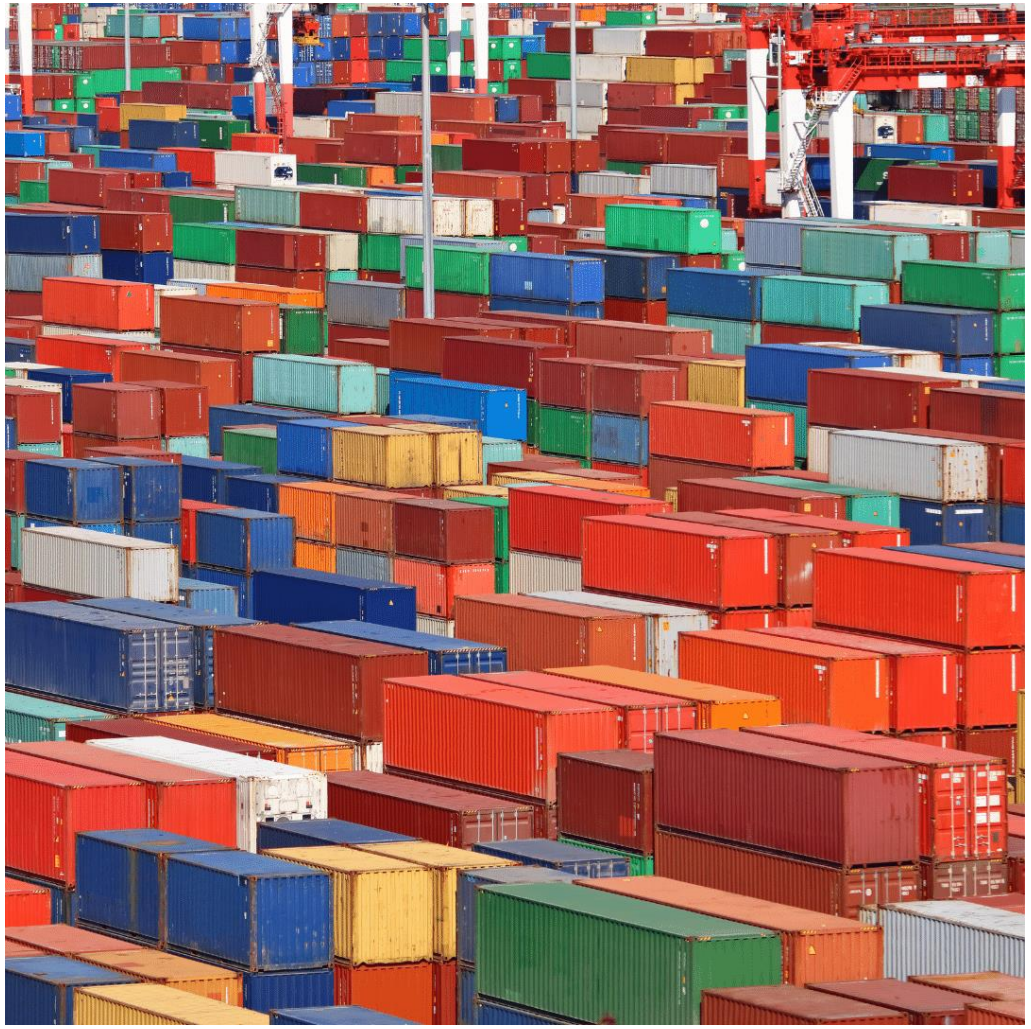
December 11, 2024

From California to the World

Source: Flow Data

Shipping Stats

- 1.964 billion lbs exported (CY 2023-24)
- 45,000 20T containers



What is a Rejection?

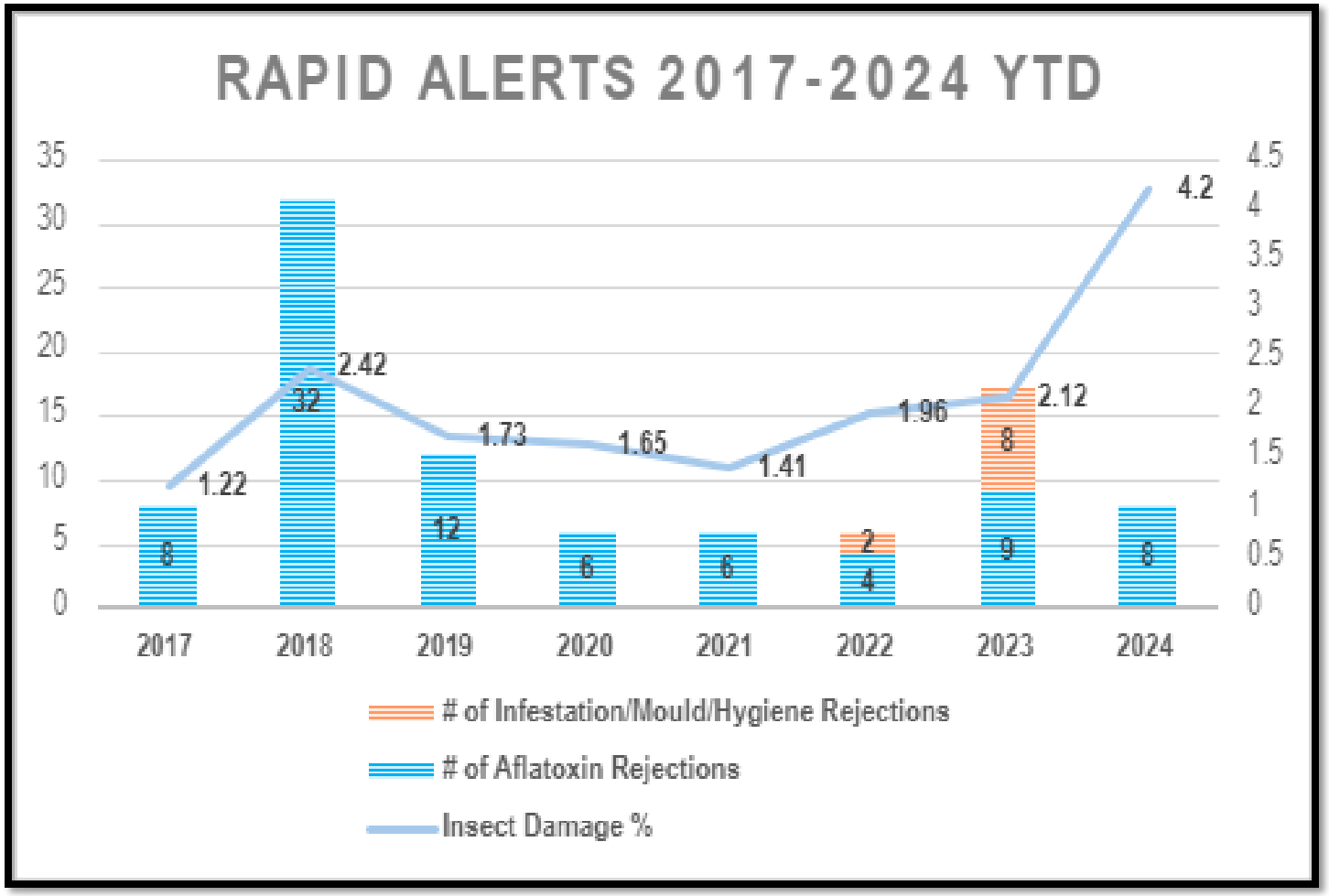
Definition of Rejection: Consignment that is denied entry into the EU or Japan for exceeding approved Aflatoxin Tolerances of 10 ppb. (In a few cases, hygiene/infestation and salmonella have also been the basis for rejection)

- The focus will be primarily on the European Union and Japan, however….
- Tim's talk on Goods Return will apply to EU and Japan or anywhere else a rejection must be shipped back to the U.S.

NOTE Lack of PEC documents is not grounds for rejection

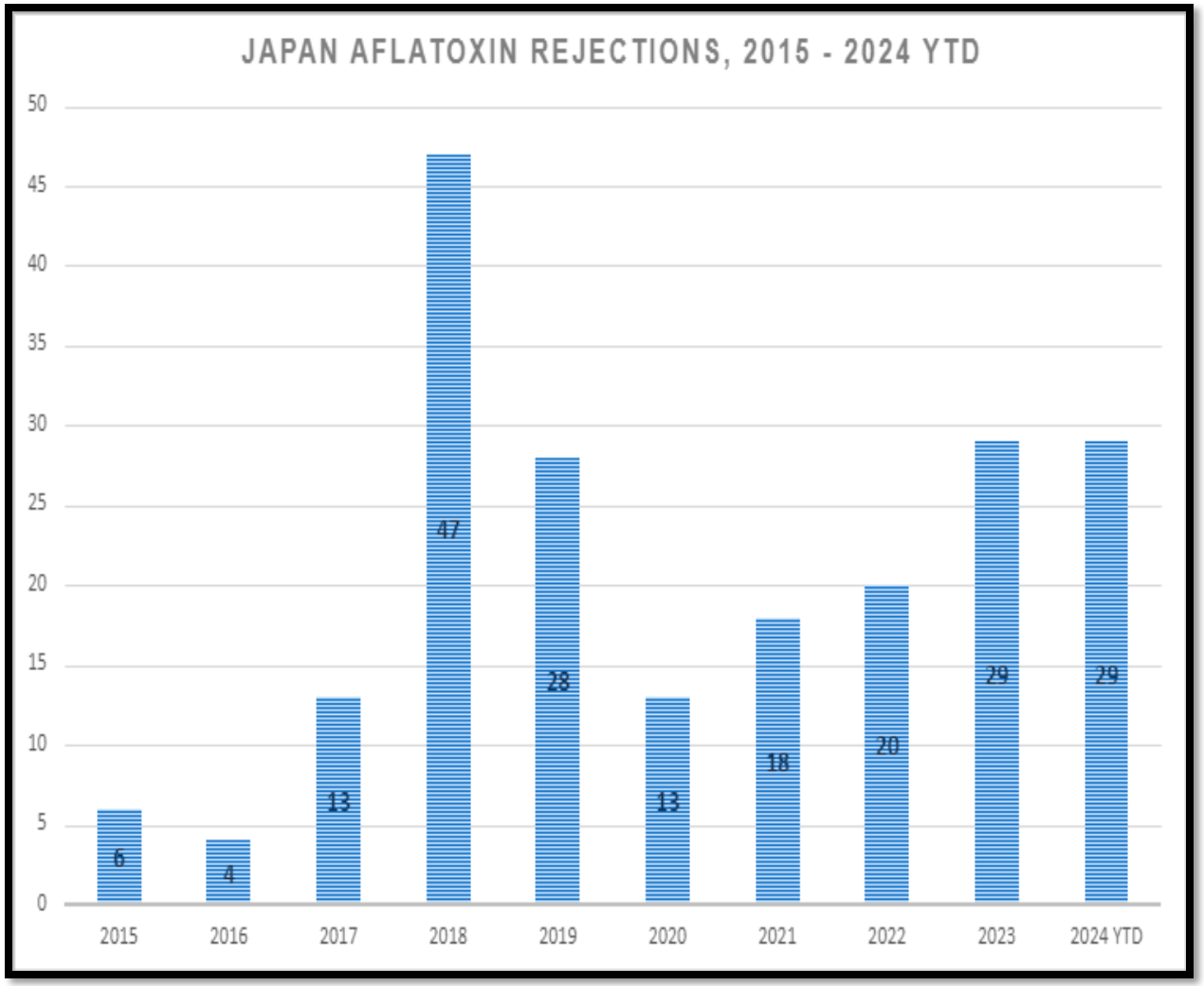
Rejections in the EU

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



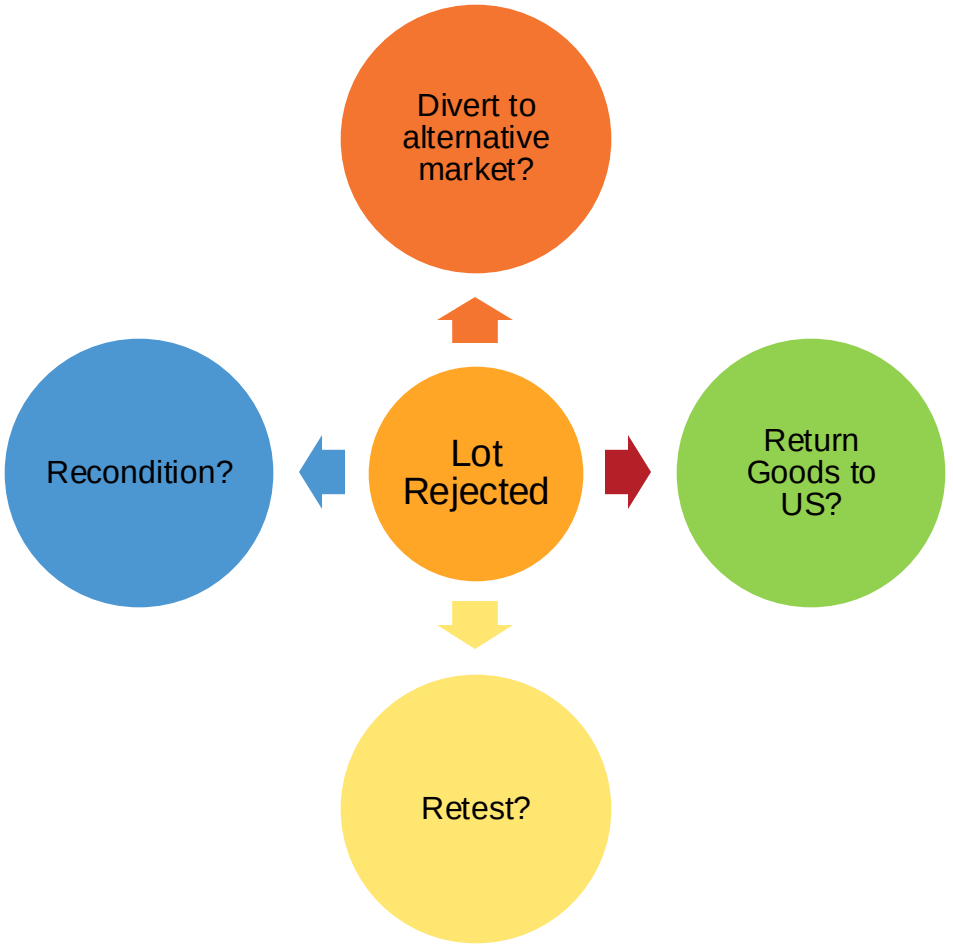
Rejections in Japan

- Japan is inspecting at the 100% level
- Currently, the only option is return
- ABC recent meetings with MHLW to discuss an inspection protocol…stay tuned
- Trade supportive of ABC initiative



What Are My Options?

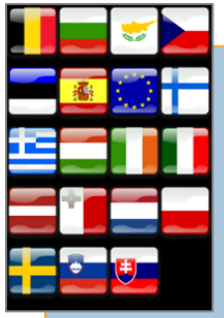
- Ultimately what you do with the product will be depend upon:
  - Specific Country Requirements
  - Practicality
  - Customer Needs
  - Costs



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:

- Your consignment was PEC-certified in California
- It leaves Port of Oakland on-time headed to Spain; your buyer is notified that all is well
- The consignment arrives few weeks later in Valencia, Spain
- Valencia Health Authorities inspect the load; samples are taken
- The Aflatoxin lab results come back as **24 ppb.** Valencia health authority rejects the consignment
- You get that dreaded email from your buyer. **You shout an expletive**, and then you call Abhi Kulkarni at the Almond Board
- 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
Transportation: Send load to Re-processor. (Cost will depend on distance, etc.). $2000-3000	Transportation: Estimated $4000-5000 per container in just shipping costs to port in the U.S.
Demurrage ($100-200 per day). Make sure buyer/importer makes logistics arrangements to avoid excessive delays.	Demurrage: ($100-200 per day). Number of days will vary.
Reconditioning: $1,200 (40,000 lbs. @$0.03-0.04 cents)	Reconditioning: If required upon return. Cost will depend on reconditioning plan approved by FDA
Retesting: $250-500, depending on how samples are taken, third-party involvement, etc. TOTAL: $3000-5000 * ***Based on estimates from industry***	Retesting: $250-500, depending on how samples are taken, third-party involvement, etc. TOTAL: $8000-9000

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 authorities in Spain (Madrid and Valencia), Italy (Rome), and The Netherlands (Utrecht)
- Visit from Japanese MHLW delegation along with FAS staff
- Ongoing efforts to educate port officials and inspectors on the PEC program and quality controls

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Bringing the Goods Back

December 11, 2024

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

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

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

U.S. Goods Returned: 3 Part Process

1. Get the product back onto US soil
2. Prepare & Submit a reconditioning plan
   – Only required if Detention Notice is received by FDA
3. Reconditioning – Carrying out the Plan

Note: If aflatoxin rejection >20PPB in foreign port <u>expect and prepare</u> 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 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"

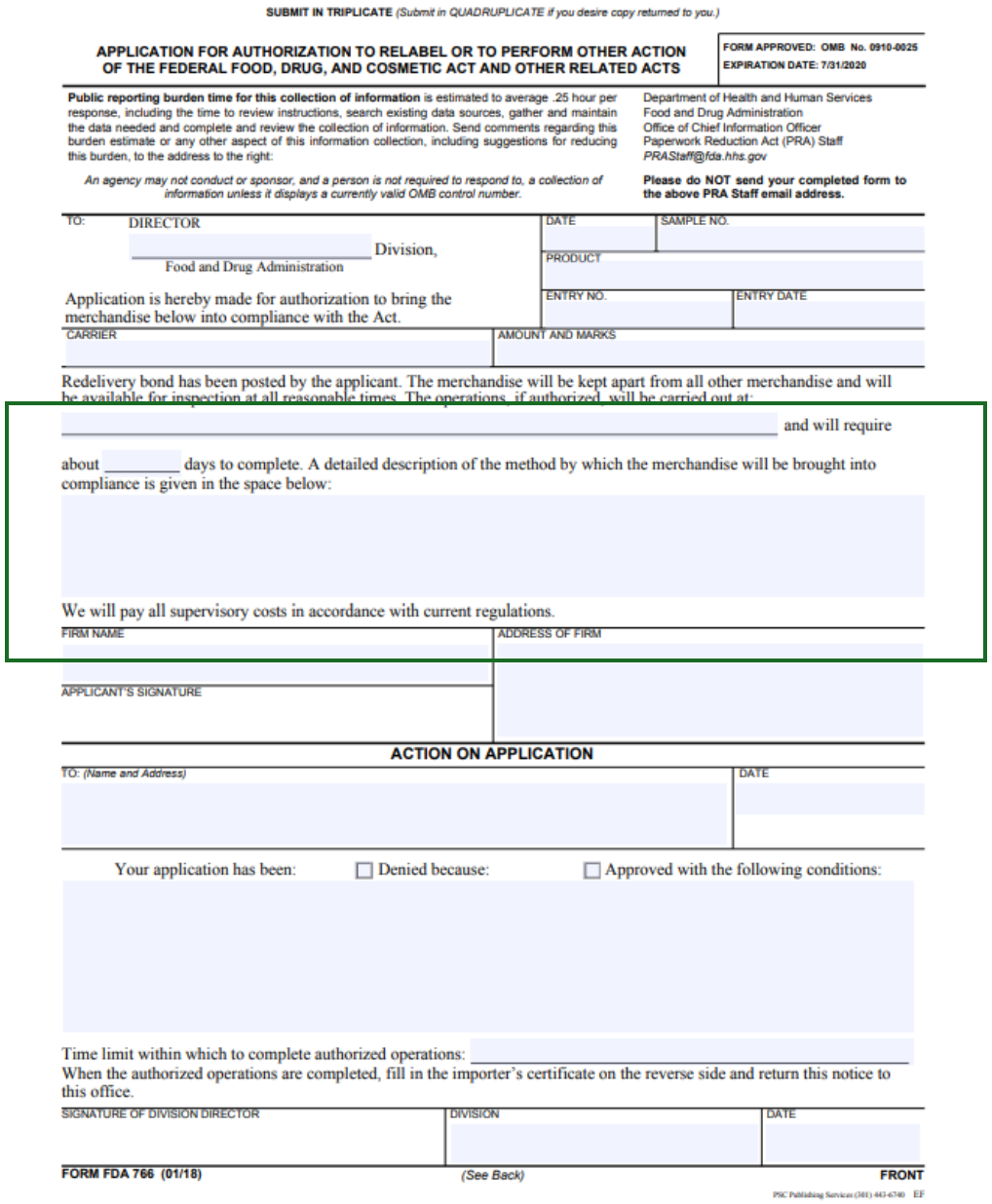
- Handler will have a limited amount of time to submit a plan to bring the product into compliance after notice issued

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

1. Fill out FDA Form 766 (Application for authorization to relabel or to perform other action of the FD&C Act)
2. Prepare a detailed Reconditioning Plan in Addition to Form 766
3. 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 TRIPLICATE *(Submit in QUADRUPLICATE 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.

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.

TO: DIRECTOR
_____ Division,
Food and Drug Administration

DATE | SAMPLE NO.
PRODUCT
ENTRY NO. | ENTRY DATE

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.

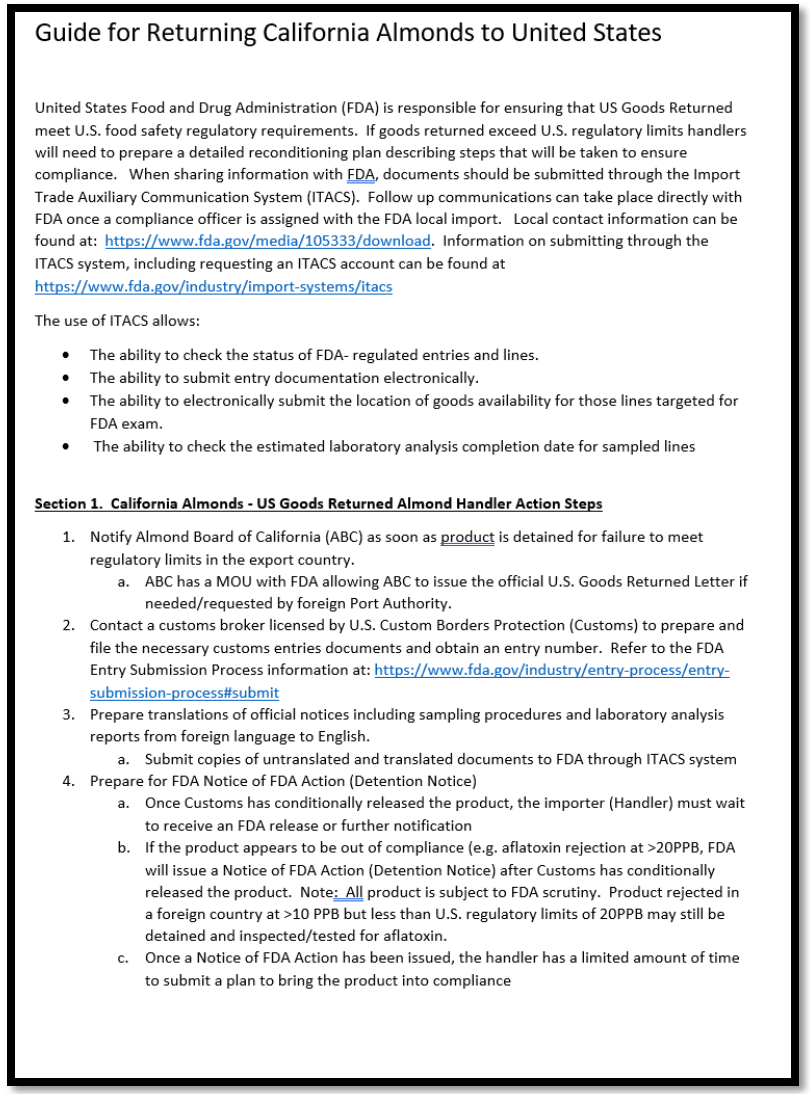
SIGNATURE OF DIVISION DIRECTOR | DIVISION | DATE

FORM FDA 766 (01/18) *(See Back)* **FRONT**

PSC Publishing Services (301) 443-6740 EF

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 Under Development

Standardized Template for Aflatoxin Reconditioning for California Almonds Returned to United Sates (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):

- ☐ *1Blanching
- ☐ *2Sorting for Insect Damage Removal
- ☐ Other (Describe)

*1 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

*2 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

C3. Equipment Used for Reconditioning (List All and Describe; Attach Flow Chart):

C 4. Reconditioning Records (Check All that apply; Provide Examples):

- ☐ Pre and Post Sorting Weight
- ☐ QC 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:

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

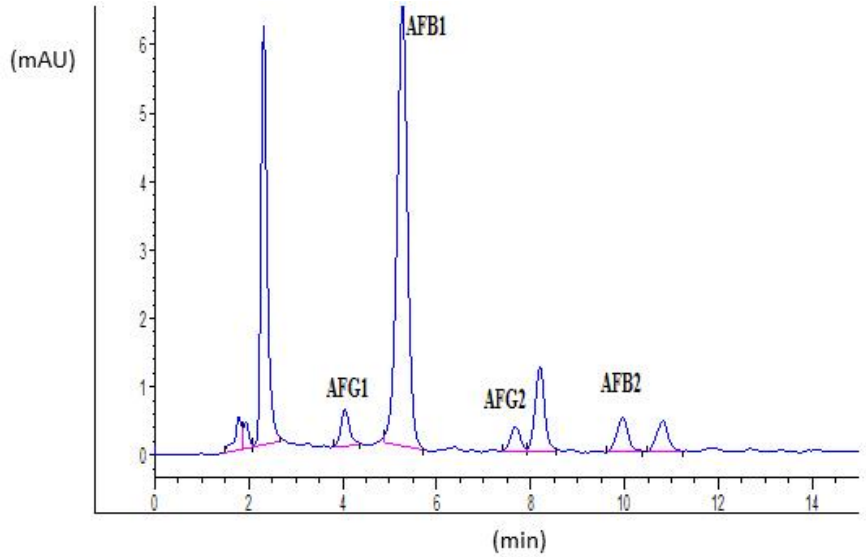
Post Reconditioning Compliance Verification (Sampling for Aflatoxin Testing)

- 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)

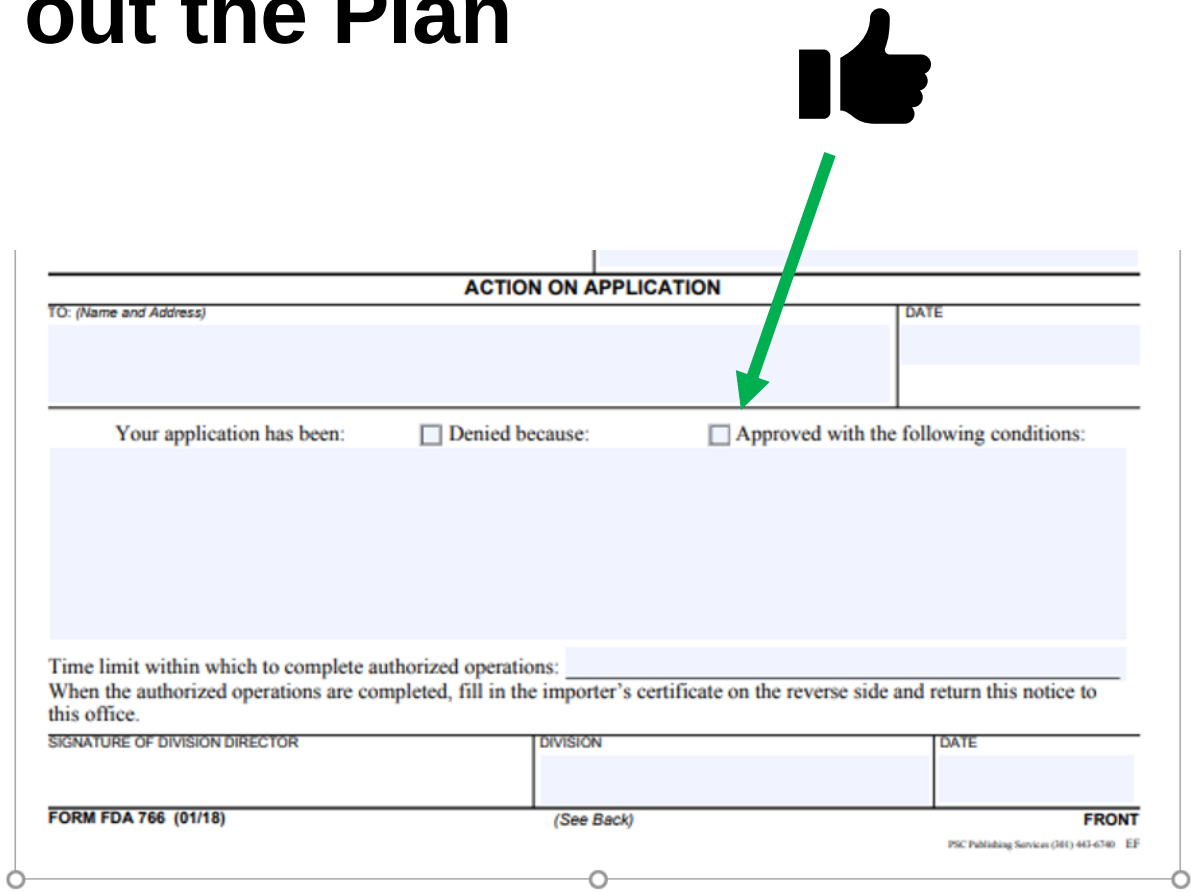
- Use an accredited laboratory familiar with U.S. Goods Return process
  - USDA approved labs for almonds/aflatoxin are a good choice
  - Describe the sample preparation and analysis methodology
  - Describe data packet which will be shared with FDA



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

3. Reconditioning – Carrying out the Plan

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

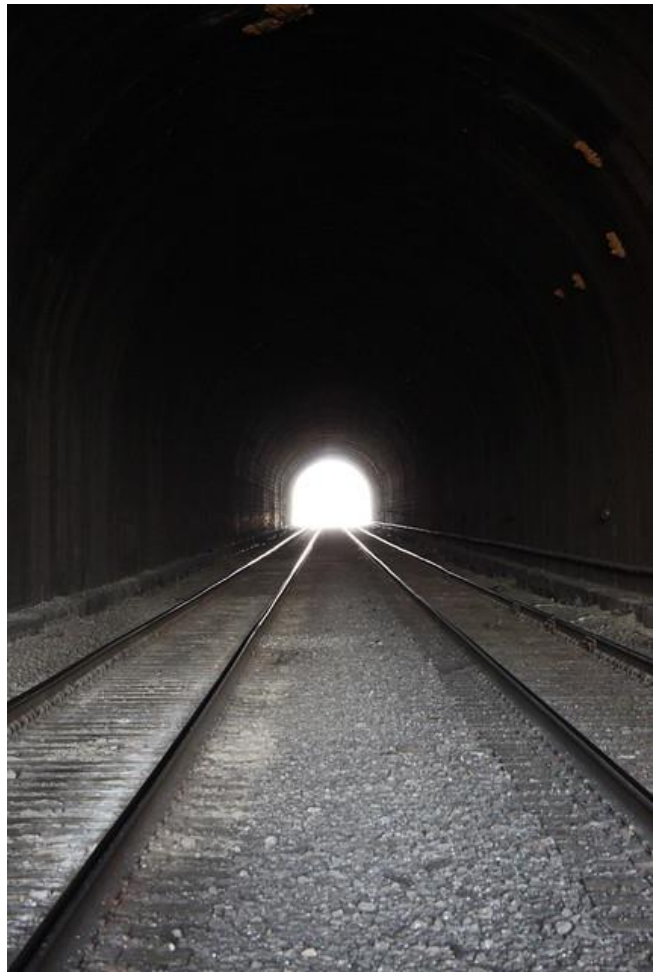
SIGNATURE OF DIVISION DIRECTOR | DIVISION | DATE

FORM FDA 766 (01/18) *(See Back)* FRONT

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

Goods Returned – What's Next

- Existing FDA / USDA AMS MOU for testing of imported peanuts, brazil nuts and pistachios for aflatoxin
  - Draft MOU to include almonds under review by FDA/USDA
    - Intent is to better leverage systems already in place
- ABC Guideline for Goods Returned
  - Updating with companion template

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