



*the Almond*  
**CONFERENCE**  
2019

# How to Deal with Rejection



california  
**almonds**  
Almond Board of California

# Session Speakers

Geoffrey Bogart, ABC

Nico Blonk, Synergy Food Ingredients and Processing

Tim Birmingham, ABC





# How to Deal with Rejection

Tuesday, December 10, 2019

# Topics to be Covered Today

- Why did we do this session?
- What do we mean by rejection? What are the main options for dealing with a rejected consignment?
  - Reprocessing in the EU. Yes you can do it (Spain and the Netherlands)
  - Return Goods to the U.S. (EU and Japan)
- You can also ship to a Non-EU Market (MRL); or destroy the Consignment (rare)
- Costs of Rejection
- What is ABC Doing?
- Role of the Foreign Agricultural Service/US Embassy
- General Discussion and Q and A

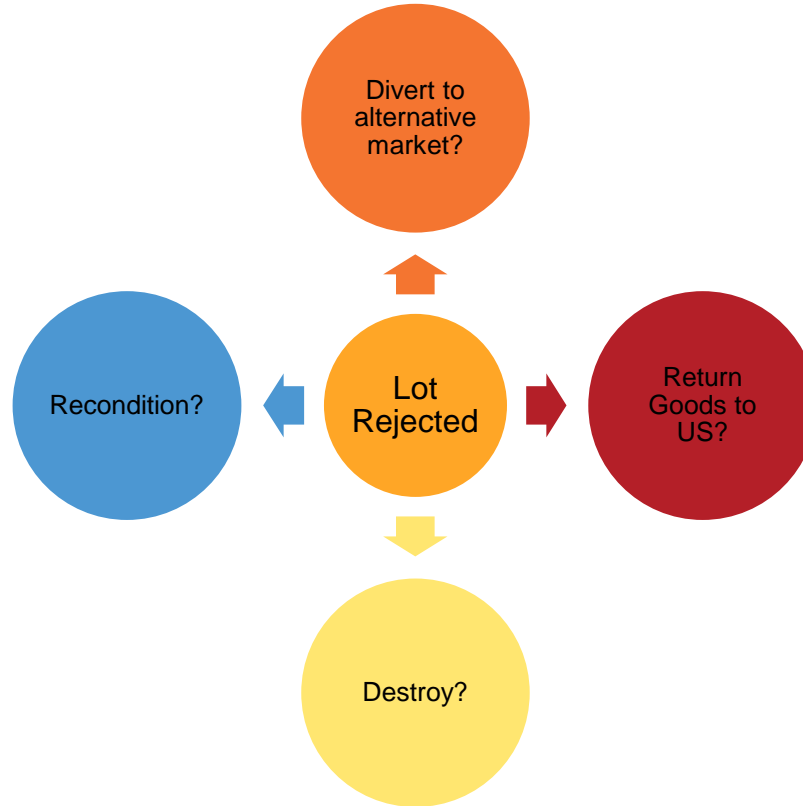
# Rejection Defined for Today's Seminar

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 and salmonella have also been the basis for rejection)

- The focus will be primarily on the European Union for this discussion, however....
- We are very aware that Aflatoxin issues in Japan are a real concern
- 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.

# How to Deal With Rejection – What Are My Options?

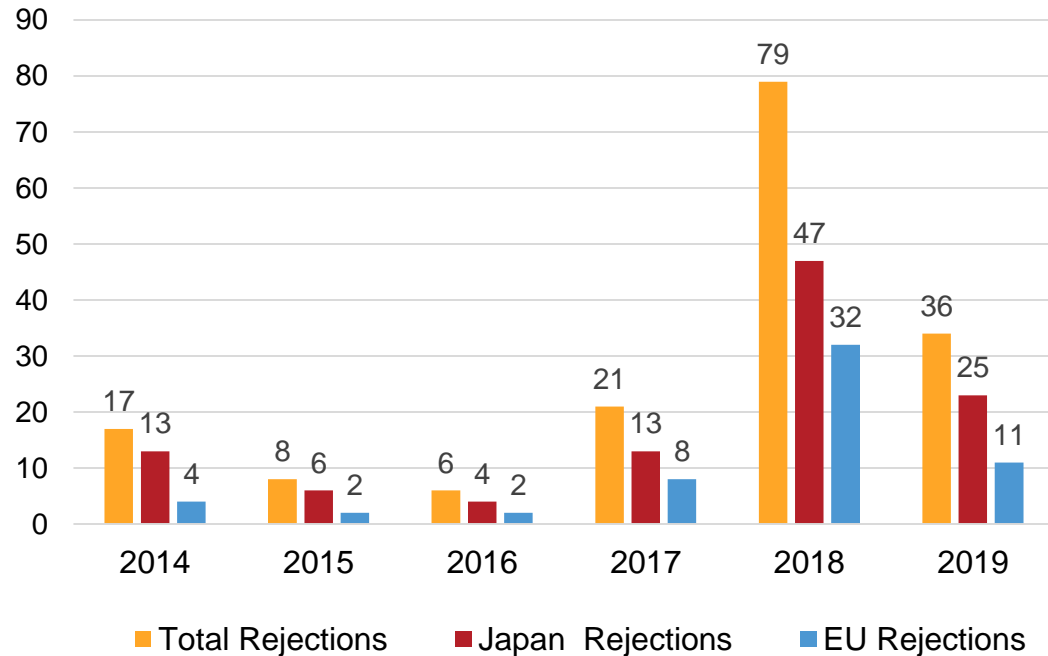
- Ultimately what you do with the product will be depend upon:
  - Specific Country Requirements
  - Practicality
  - Customer Needs
  - Costs



# EU & Japan Aflatoxin Historical Rejections

- # of Rejections is low on a percentage basis.....
- But # of rejections is still significant
  - Particularly if you are one of the “lucky” ones!
- Rejections trending lower this year
- Will continue to have to deal with rejection as crop grows

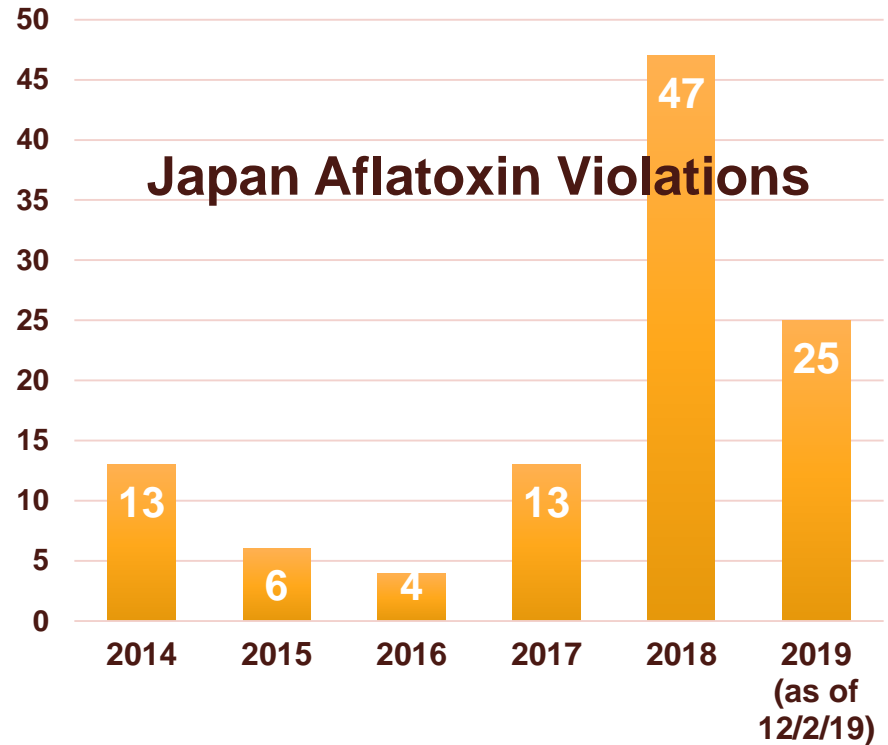
## Aflatoxin Rejections





# Latest on Japan Aflatoxin Inspections

- To date, 25 consignments rejected for aflatoxin; only option, Return to US
- Japan is still inspecting at the 100% level
- MHLW unwilling to engage with industry on “policy” matters
- Trade supportive of ABC initiative
- ABC recent meetings in Tokyo with USDA/FAS agreed to a strategy – workplan now being developed
- ABC working with FAS to engage MHLW
- Hoping to build on success of EU recognition of equivalent systems
- No PEC program for Japan contemplated





# 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 again applicable (meaning, return to < 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:

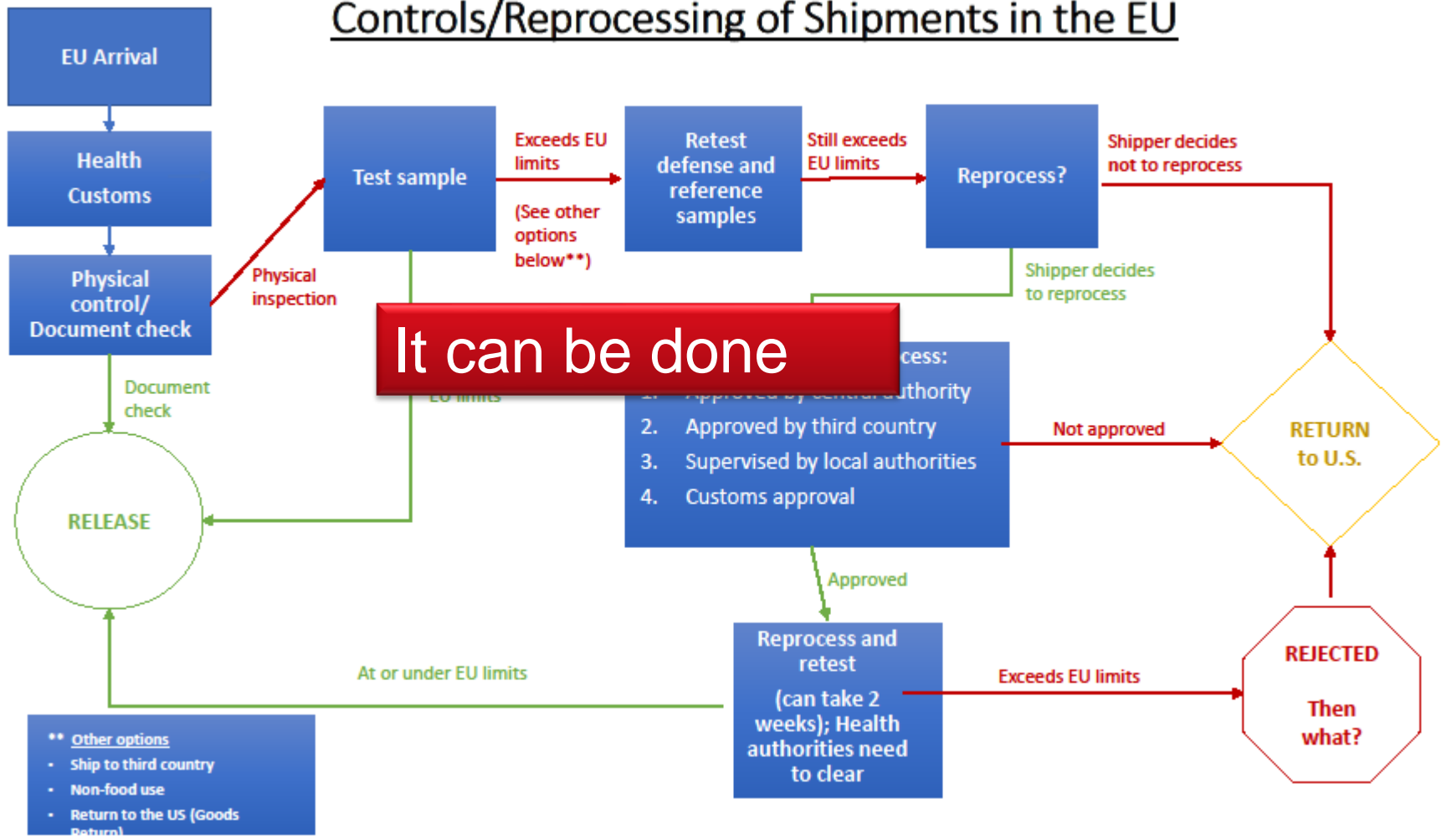
- Your consignment was PEC-certified in California
- It leaves Port of Oakland on-time headed to Spain; your buyer is notified that all is well
- The consignment arrives three weeks later in Valencia, Spain
- Valencia Health Authorities inspect the load; samples are taken
- The Aflatoxin lab results 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 Geoffrey Bogart 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

# Reprocessing in the European Union

# Controls/Reprocessing of Shipments in the EU



**It can be done**

- \*\* Other options**
- Ship to third country
  - Non-food use
  - Return to the US (Goods Return)

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

| Reprocessing in the EU  | Returning Consignment to the US  |
|---|--|
| <p><u>Transportation:</u> Send load to Re-processor.<br/>(Cost will depend on distance, etc.)</p>                         | <p><u>Transportation:</u> Estimated \$4-5,000 per container in just shipping costs to port in the U.S.</p> |
| <p><u>Demurrage</u> (\$100 per day). Make sure buyer/importer makes logistics arrangements to avoid excessive delays.</p> | <p><u>Demurrage:</u> (\$100 per day). Number of days will vary</p>   |
| <p><u>Reconditioning:</u> \$1,200 (40,000 lbs. @ \$0.03 cents)</p>  | <p><u>Reconditioning:</u> If required upon return. Cost will depend on reconditioning plan</p>             |
| <p><u>Retesting:</u> \$250-500, depending on how samples are taken, third-party involvement, etc.</p>                     | <p><u>Retesting:</u> \$250-500, depending on how samples are taken, third-party involvement, etc.</p>      |
| <p>* <b><i>Based on estimates from industry</i></b></p>   |  |

# Reprocessing in the Netherlands: Conversation with Nico Blonk, Synergy Food

- Who ?
- What ?
- When ?
- Where ?
- How ?
- Issues?



Nico Blonk, Synergy Food Ingredients and Processing

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## 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





## What's ABC Doing?

ABC Visits to Port Officials in 2019  
Barcelona, Valencia, and Naples



## GTRA Visit to Spain and Italy, September 2019

- Efforts to address ongoing issues involving inspections, reprocessing snags
- Visits with authorities in Spain (Madrid and Valencia) and Italy (Rome and Napoli)
- Meetings focused on
  - Reviewing improved crop quality,
  - Communications regarding the return to < 1% controls established by Brussels
- Progress made on securing Government of Italy support to allow reprocessing of aflatoxin consignments in Italy
- Ground-work laid for TASC-funded workshops in Italy, Spain next April
  - Geared towards educating port officials and inspectors on the PEC program and quality controls
- EU Port officials will be invited to California next Spring







## How to Deal With Rejection – Goods Returned

Tim Birmingham, Almond Board of  
California

# U.S. Goods Returned – Why Do We Have to Jump 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
  - 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  $>20\text{PPB}$  in foreign port expect and prepare for FDA detention notice “Notice of FDA Action” upon return



# 1. Getting the Product Back

1. Notify ABC
  - ABC will issue official “Goods Returned Letter” to EU authorities for return to U.S. (if required)
2. Contact Licensed Customs Broker
3. 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 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

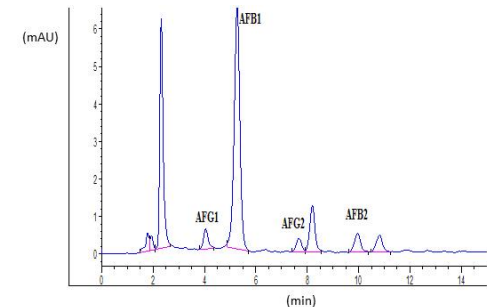
Tip: Provide Detailed Information!!!

SUBMIT IN TRIPPLICATE (Submit in QUADRUPPLICATE 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<br>EXPIRATION DATE: 7/31/2025  |
|---|--|---|
| 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 the review and collection of information, send information to the person to whom the burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the address to the right.                       |  | Department of Health and Human Services<br>Food and Drug Administration<br>Bureau of Food Safety<br>Paperwork Reduction Act (PRA) Staff<br>PRAStaff@FDA.HHS.gov |
| 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.  |  | Please do NOT send your completed form to the above PRA Staff email address.  |
| TO: DIRECTOR _____ Division,<br>Food and Drug Administration  | DATE _____<br>SAMPLE NO. _____<br>PRODUCT _____<br>ENTRY NO. _____<br>ENTRY DATE _____ |   |
| Application is hereby made for authorization to bring the merchandise below into compliance with the Act.<br>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:<br><div style="background-color: #e0e0e0; height: 40px; margin-top: 5px;"></div> |  |   |
| 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: <input type="checkbox"/> Denied because: _____ <input type="checkbox"/> Approved with the following conditions: _____<br><div style="background-color: #e0e0e0; height: 60px; margin-top: 5px;"></div>   |  |   |
| Time limit within which to complete authorized operations: _____<br>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 Service (2011) 468-076-103   |  |   |

# 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



# 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

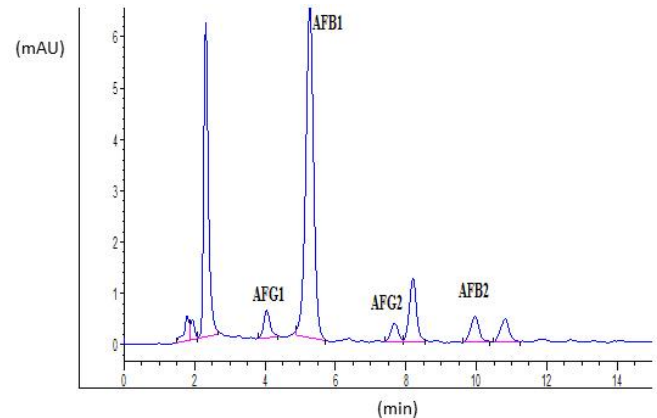
Tip: Reference PEC Sampling SOP



# Post Reconditioning Compliance Verification (Aflatoxin Laboratory Testing)

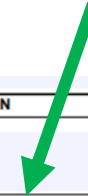
- Use an accredited laboratory familiar with U.S. Goods Return process
  - USDA approved labs for almonds/aflatoxin are a good choice
  - Describe the sample preparation and analysis methodology
  - Describe data packet which will be shared with FDA

Tip: Indicate that the sample will be analyzed by USDA lab following PEC protocol



### 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: <input type="checkbox"/> Denied because: <input type="checkbox"/> Approved with the following conditions:        |            |       |
| <br><br><br><br><br><br>  |            |       |
| 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 |
| <small>PSC Publishing Services (811) 415-6780 EF</small>  |            |       |

# Tips to Avoid Additional Rejection

- Establish rapport with FDA Compliance Officer
  - Harder to reject a plan if FDA Officer understands you want to do the “right thing”
- Ask Questions / Seek input about how you plan to recondition
  - Email communication can work
- Don't assume the FDA Compliance Officer understands aflatoxin in almonds, PEC, or reconditioning options
- Seek advice from ABC – We are happy to help navigate the process





## Goods Returned – What is ABC Doing

- Ongoing work with FDA to streamline process
- FDA recently entered into MOU with USDA AMS for testing of imported peanuts, brazil nuts and pistachios for aflatoxin
  - Exploring options whereby USDA /USDA approved Labs for almond aflatoxin testing could be better leveraged for Almond Goods Returned Process
- ABC Guideline for Goods Returned

Thank-You!

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