

Almond Board of California
Pre-Export Checks (PEC) Program Manual
Version 9.0

Issued by:
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PEC At A Glance

PEC REQUIREMENTS

| General Requirements | Responsibility |
|--|---|
| Signed Memorandum of Understanding | Handler Participants |
| Trained Employees | Handler employees responsible for PEC sampling, sample submission, and certificate issuance |
| Sampling SOP | Handler employees responsible for sampling |
| Use of Opaque or Cardboard Containers for sampling | |
| Proper Storage / Control of Samples | |
| Use of ePEC System | Handler employees responsible for initiating and printing certificates |
| Implementation of Basic Hygiene Principles | Facility where product is produced |
| Failed Lot Control | Handler employees responsible for lot control/processing and issuing PEC certificates |
| Program Documentation | Handler employee(s) responsible for PEC sampling, sample submission, certificate issuance, and program management |

PEC REQUIRED DOCUMENTATION

| Document | Purpose |
|---------------------------------------|---|
| Training Log / List | To ensure those individuals responsible for PEC sampling, sample submission and certificate issuance have been trained and training documented |
| Sampling Standard Operating Procedure | To ensure a standard practice is in place in order to pull a representative sample from the lot |
| Sample Lot/Record | To ensure that individuals responsible for PEC sampling document those samples pulled per sampling SOP; To verify that at least 22 incremental samples are pulled and a total aggregate sample of 20KG is collected |
| PEC Issuance Log (PIL) | To document issuance/signing of PEC certificate by SPI |
| Container Inspection Log (CIL) | To document hygienic conditions of container before loading |
| PEC Certificate Signed Copy | To provide evidence of certificate signing/issuance |
| Shipment Records | To confirm PEC certificates to actual shipments |
| Failed Lot Records | To demonstrate control of failed lots |

PURPOSE

The PEC program was developed by the California Almond industry to provide an aflatoxin sampling plan for the analysis of ready to eat product with equivalency to that being used by the European Union (EU) for official testing of incoming consignments. The program ensures the industry is not vulnerable to inconsistent or arbitrary controls, with frequency of physical checks at the EU port specified at less than 1% for those consignments with a PEC certificate. PEC status was granted under EC Regulation Number (EU) 2015/949, and became effective on August 1, 2015.

BACKGROUND

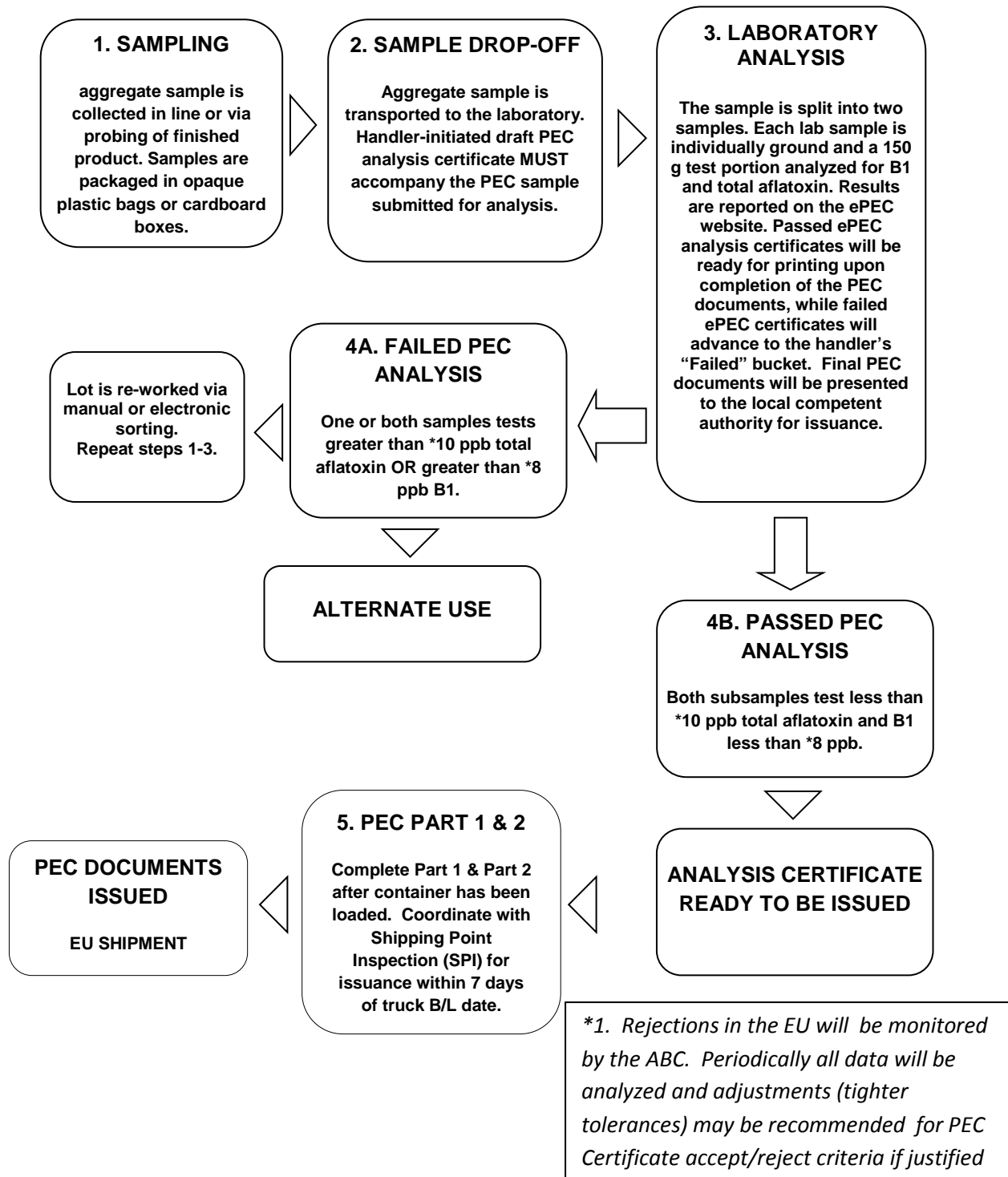
The European Commission adopted Special Measures for all almond consignments shipped to the EU and on September 1, 2007 the VASP program was implemented to allow the California Almond industry the opportunity to control and test for aflatoxin prior to shipping, demonstrating the industry's commitment, and thus avoiding excessive mandatory controls on import. Based on confidence in the VASP program, the EU Commission set mandatory controls at "random" (<5%). In September 2014, California Almonds were removed from Special Measures requirements, allowing the industry to be recognized instead under the Pre-Export Checks (PEC) Program. PEC is a voluntary program. However, consignments without a PEC certificate will be randomly controlled at the discretion of the import authorities.

PROGRAM DESCRIPTION

There are numerous parties involved in the PEC program, each with specific roles and responsibilities as shown in the PEC Participants & Responsibilities section. The PEC program requires documented sampling practices, USDA-approved laboratory aflatoxin analyses, specified accept/reject criteria, standard reporting of results on an E-PEC aflatoxin analysis certificate, consignment/shipping information and California Department of Food and Agriculture- Shipping Point Inspection attestation on the accompanying PEC documents (Part 1 & 2 specified below). In addition, participation in the PEC program requires that almonds subject to PEC have been produced, sorted, handled, processed, packaged, and transported in line with good hygiene practices. Also, as appropriate, program participants should employ HACCP type principles to address potential hazards in their operations.

Shown on the following page is a flow chart describing the basic steps in the PEC process and the responsible parties from the time of sampling throughout analysis, reporting of results and shipping of consignments.

Figure 1. PEC Program Flow Chart



PEC PROGRAM APPLICABILITY

The PEC program is applicable for bulk ready to eat (RTE), as well as manufactured almonds (e.g. sliced, diced, etc.) destined for shipment to the EU. Only those products which fall under international harmonized codes HS 0802.11 and 0802.12 are covered by PEC as seen in Table 1 below. **If you have any questions regarding how your export shipments are classified, contact your customs broker/agent.**

Table 1. Almonds Covered Under PEC

| Covered under PEC | <u>NOT</u> Covered under PEC |
|---|----------------------------------|
| In-shell Bulk | Roasted/Toasted Almonds |
| Shelled Bulk | Almond Butter, Paste, Puree, Oil |
| Sliced, Diced & Blanched | Almond Beverages |
| “Raw” or “Whole Natural” Consumer Packaged Products | Almond Flour, Meal |

PEC certificates will only be issued if the product meets the accept criteria established by the EU for RTE product as shown in Table 2 below.

Table 2. Accept Limits for PEC Analysis and Certificate Issuance

| Maximum Aflatoxin Levels Allowed (ppb) | |
|--|----|
| B1 | 8 |
| Total | 10 |

PRODUCT SAMPLE SELECTION AND ANALYSIS

There is a certain amount of variability attributed to sampling, sample preparation, and analysis, which can make it difficult to obtain an accurate estimate of the true aflatoxin concentration in a lot. Variability is reduced through normal course of sorting which mix the nuts and distribute aflatoxin spatially throughout the lot. The European Commission has established sampling protocols for nuts for official mycotoxin control (Commission Regulation EC No 401/206). Per the Pre Export Checks granted by the EU, sampling and analysis should be in accordance with the provisions of the Commission Regulation (EC) No 401/2006 or with equivalent requirements. Given that the lot has been thoroughly mixed at time of sampling, the high number of incremental samples specified in (EC) No 401/2006 is not as important as the total aggregate sample size. However, incremental samples must still be drawn from throughout the

lot. The PEC protocol for sampling requires 22 incremental samples for a lot size of 44,000 pounds, which exceeds FDA requirements (10 samples), and is statistically equivalent to the EU protocol for a well mixed lot. Shown on the following page in Table 3 is the PEC sampling protocol. It is important to note that smaller lots can also be sampled under PEC, if they fall within the specified HS codes. Sampling type and description are shown in Table 4 on page 7.

Table 3. Required Incremental and Total Aggregate Sample Size

| Sampling Type | Required Total Aggregate Sample Size | | Lot Size (lbs) | Required # Incremental Samples |
|--|--------------------------------------|------|--------------------|--------------------------------|
| | Kg | Lbs | | |
| In-Line, Packaged Product or Manufactured Goods Sampling | 2 | 4.4 | ≤220 | 10 |
| | 3 | 6.6 | >220 - ≤ 441 | 10 |
| | 4 | 8.8 | > 441 - ≤ 1,102 | 10 |
| | 6 | 13.2 | >1,102 - ≤ 2,205 | 10 |
| | 8 | 18 | >2,205 - ≤2,409 | 10 |
| | 12 | 26.4 | >2,409 – 11,023 | 10 |
| | 16 | 35.2 | >11,023 - ≤ 22,046 | 22 |
| | 20 | 44 | >22,046 | 22 |

Table 4. Sampling Type and Description

| Sampling Type | When To Use | Sampling Description |
|---|--|--|
| In-Line Sampling | In-line sampling is preferred when it is known that a given production lot will be shipped to the EU, and a mechanism exists to collect samples during the run. | <p>Pull samples at pre-defined time intervals throughout the run to ensure representation of entire lot.</p> <p>Sampling can be automatic or manual.</p> <p>Sampling frequency and sample size should be determined before run in order to collect a minimum of 22 incremental samples (for lots > 11,023 Lbs.) and a total aggregate sample size as shown in Table 3 for a given lot size.</p> |
| Packaged (Finished) Product Sampling (i.e. bins, boxes, etc.) | Packaged or finished product sampling is to be used when unsampled/tested product has been packaged and then chosen for shipment to the EU, and/or when in-line sampling is not available. | <p>Probe a pre-determined number of bins, boxes, or other containers as appropriate to ensure representation of the entire lot.</p> <p>Sampling frequency and sample size should be determined before run in order to collect a minimum of 22 incremental samples (for lots > 11,023 Lbs.) and a total aggregate sample size as shown in Table 3 for a given lot size.</p> <p>If probing sealed bins, boxes, cartons, etc., it is important to seal the probe hole and initial/date it so that the customer knows it was not tampered with.</p> |

Sample Collection:

Samples must be pulled from the lot as described in a sampling standard operating procedure. Once all of the individual samples are pooled, the total aggregate sample weight should equal or exceed the amount shown in Table 3 for a specific lot size. A Lot No/ID must be assigned to this sample and will be required on your PEC analysis certificate and on each carton or bin that is shipped. The aggregate sample must be collected and stored in opaque plastic bags, boxes or other suitable non-transparent container. If a sample is not immediately submitted to a USDA approved laboratory for analysis, then it must be stored under similar conditions as the lot that it represents. The aggregate sample must be delivered to the laboratory along with the handler-initiated PEC draft certificate as indicate in the sample submission section below. The aggregate sample size must be equal to or greater than those values shown in Table 3 above for a specific lot size.

Qualified Personnel:

Those personnel directly responsible for PEC sampling, sample submission, PEC record keeping and certificate issuance must be trained either directly by ABC or by an ABC trained "Trainer," on PEC procedures and requirements. Training conducted by the ABC is only required upon entry into the program, or if new "Trainers" are needed by a Handler participant. Handler participants are responsible for ensuring that new and existing employees are trained on an as-needed basis. A personnel training record must be kept for all employees involved in the PEC program and be made available to the ABC when requested for audit purposes. Only personnel who have been properly trained may pull samples for the PEC program.

Sampling Standard Operating Procedures (SOP's):

Each PEC participant must develop a sampling standard operating procedure. The purpose of the sampling SOP is to describe the process to ensure that the appropriate sample has been collected, labeled, packed and logged for a given lot intended to be submitted for aflatoxin analysis under the PEC program. A sampling SOP must describe the following:

1. Sample collection practices
2. Sampling record and log procedures
3. Sample container requirements
4. Sample storage and lab delivery procedures
5. Employee PEC training

ABC will review the sampling SOP during the verification to ensure that it is being followed.

Sampling Recordkeeping:

Written records must be maintained for all sampling activities. Both in-line and packaged product sampling require documentation of the following:

1. Sampling frequency
2. Number of incremental samples
3. Laboratory sample size
4. Lot Code/Product Description
5. Lot size
6. Aggregate sample size
7. Sampling Operator
8. Date of Sampling

For packaged product sampling or manual in-line sampling, an operator log sheet must be filled out as the sample is taken. It should include the time the sample was taken, the size of the sample and the operator initials. For automatic in-line sampling, a log sheet must be maintained

verifying periodically that the sampler is appropriately collecting samples. An example of a manual in-line sampling sheet is shown in Appendix 2.

Sampling records will be reviewed by ABC during onsite verifications.

SAMPLE SUBMISSION

Once the aggregate sample is collected, it must be stored in an opaque plastic or cardboard container under the same conditions in which the lot it represents is stored. Prior to submitting the aggregate sample to a USDA approved laboratory, an ePEC draft Certificate of Aflatoxin Sampling and Analyses must be filled out by the applicant, as seen in Appendix 3. To fill out a certificate, the applicant must log into the ePEC system. Once logged in, the applicant will select the “New PEC Form” tab and then fill out the appropriate sections of the form as follows:

Applicant Section:

This section is auto populated based on the log in credentials.

Product Description:

1. **Crop Year:** Fill in the calendar year in which the crop was harvested.
2. **Product Type:** Distinguish whether almonds are inshell almonds or shelled almonds that is being shipped by using drop down function.
3. **Lot No./ID Marks:** Only One Lot No./ID can be assigned to each sample submitted to the lab. Make sure that this number matches the paper work and what is printed on the containers, bins, etc.
4. **Total Lot Size:** This should be the total pounds that the PEC analysis represents.
5. **Depending on total lot size entered the aggregate sample size required will be displayed in kgs.**

Select the lab you wish to use from the drop down menu.

After the draft certificate is filled out, the applicant is ready to click the “Save Draft” button. The draft certificate can then be reviewed and a hard copy printed out by using the “Print to PDF” button. The hard copy of the draft certificate must be provided to the lab for each sample submitted. Labs will not conduct an analysis without the draft certificate. When the applicant is ready to submit the sample for analysis, the “Submit to Lab” button must be clicked. Doing so will place the analysis request in the lab’s in-box.

PEC ANALYSIS AND REPORTING

Analysis:

Once the aggregate sample is delivered to the USDA approved lab, the analysis will be conducted according to specific program protocols. Once the results are obtained, they are entered by the lab in the reporting section of the PEC aflatoxin analysis certificate. For each of the two 10 kg laboratory samples, if the results exceed the total aflatoxin limit of 10 ppb or 8 B1, then the certificate will automatically be placed into a "Failed" bucket, and will not be available for issuance. If the results are within the EU limits of 10 ppb total and 8 B1 then the aflatoxin certificate will be available for issuance once final pages of PEC documentation are printed out for signing by Shipping Point Inspection (SPI). Analysis certificates that pass are automatically moved into the "Submitted to Issue/Sign" bucket. The certificate will stay in this bucket until the applicant is ready to print all three PEC pages for signature and issuance.

PEC Part 1 & Part 2:

In addition to the PEC aflatoxin analysis certificate that is generated by the lab analysis, the PEC program has a Part 1 & Part 2 to be completed by the handler before final sign-off by Shipping Point Inspection. Part 1 will have information about the consignment and responsible parties for the shipment. Part 2 consists of the attestation for the PEC documents and is where the local competent authority, Shipping Point Inspection (SPI), will sign the document thereby providing for its official issuance; **this may be done 7 calendar days after the consignment has left the handler facility**. A detailed list of each item and a description is listed below:

PART 1

I.1 Consignor: Defaults to handler information from analysis certificate, but can be changed by handler before issuance.

I.2 Certificate Reference Number: Unique identifier, determined by the handler (e.g. customer order number).

I.3 Central Competent Authority: Defaults to USDA/AMS

I.4 Local Competent Authority: Defaults to FSIS/CDFA SPI

I.5 Consignee: Enter buyer information here. Companies/addresses can be saved for future consignments in ePEC system.

I.6 Person Responsible for the Consignment in EU: This may be a freight forwarder, trader, etc. who will be responsible for clearing the almonds in the EU. The contact if port has issues with the shipment.

I.7 Country of Origin / ISO Code: This will always default to United States. ISO Code = US

I.9 Country of Destination: Select the name of the country the consignment is shipped to from the drop down list provided.

I.11 Place of Origin: Defaults to handler name and address from the analysis certificate but can be edited. **Approval Number:** Number assigned by ABC to handler for current MOU

I.13 Place of Loading: This will default to City & State of the handler (facility that loaded the container)

I.14 Date of Departure: Truck Bill of Lading date (when consignment leaves handler's control).

I.15 Means of Transport: Defaults with 'Ship' selected.

Identification: Name of ship of air carrier (with specific flight number)

Documentary references: Enter either Ocean Bill of Lading or Air Way Bill depending on transportation mode

I.16 Point of Import in EU: Enter Name of port where almonds will arrive in the EU; if unknown, use EUROPE

I.18 Description of Commodity Enter description of almonds on grade certificate

I.19 Commodity Code (HS Code): Information will transfer from analysis certificate. Either Almonds (Inshell) or Almonds (Shelled).

I.20 Quantity: Enter net weight of consignment in pounds that will be converted to Metric Tonnes (MT)

I.21 Temperature of Product: 'Ambient' will be pre-selected.

I.22 Number of Packages: Enter the number of packages (bins, cartons, etc.)

I.23 Identification of Container/Seal Number: Enter container number. Enter seal number (should be the last seal put on prior to loading on ship).

I.24 Type of Packaging: Enter type: cartons, boxes, bins, totes, bags, super sacks etc.

I.25 Commodities Certified For: 'Human Consumption' is selected. PEC program is for human consumption almonds only

I.27 For Import Into EU: This box will be pre-selected. Can be unchecked if final destination is outside the EU and the load is only transiting through the EU

I.28 Identification of the Commodities: Both the lot number (batch number) and treatment type will automatically transfer over from analysis certificate.

PART 2:

The handler is to have two (2) sets of PEC documents printed out for Shipping Point Inspection personnel to sign and thereby issue. Each set of documents will consist of the analysis certificate from the lab, Part 1 and Part 2. Shipping Point Inspection will take one set of the PEC documents for their records and the other is to be considered the issued set to provide for shipment of the consignment. Handlers are encouraged to make a copy for their own records, but the original must be provided at the port of entry into the European Union.

PEC Certificate Issuance:

The PEC applicant has up to 7 calendar days after the consignment has shipped (truck bill of lading date) to complete all necessary PEC paperwork for issuance. Once the PEC applicant ships a full or partial lot of product to the EU, they can print out the analysis certificate (assuming the sample has been analyzed) and the PEC documents. The analysis certificate can only be printed if the aflatoxin limits are within the acceptable limits as described above and shown in Table 1. The applicant initiates this process by logging into the ePEC system and following the prompts to print two (2) sets of PEC documents.

Failed Lots:

If a tested lot exceeds the limits set forth by the EU and shown in Table 1 of this document, the certificate will be placed into a "Failed" bucket automatically. The certificate will be locked and unable to be issued. As part of the PEC program, participants agree that prior to retesting, any failed lots will be further processed with electronic, hand, or other sorting means to remove damaged nuts and lower levels of aflatoxin in the lot. If further processing is not an option, then participants agree to divert the lot to other non-EU outlets.

PEC PARTICIPANTS AND RESPONSIBILITIES

Handlers PEC Participants:

As signatories to the Memorandum of Understanding, The PEC participant agrees to comply with the following conditions as currently outlined in the PEC Program Manual, with a new MOU to be signed for each Crop Year:

1. Implement a facility hygiene program
2. As appropriate, use procedures based on Hazard Analysis and Critical Control Points (HACCP) type principles to address aflatoxin control at the Handler level;

3. Allow ABC verification of Handler compliance with PEC via a review of relevant information including sampling procedures, sampling records and documentation, training records, and hygiene programs. This review will consist of documentary as well as physical observation by ABC; in addition the USDA Specialty Crops Inspection Division, as the competent authority for the PEC Program, will participate in a percentage of the audits to verify compliance. Consignments for review will be selected at random by ABC, and will include verification of the following:
 - Sampling procedures, including PEC sampling logs whether in line sampling or probing;
 - PEC documents including Part 1, Part 2 (signed by SPI) and the Certificate of Analysis and PEC Issuance Log for SPI.
 - One or more failed analysis lot(s) to determine the outcome of the actual lot, specifically to ascertain whether it was –re-sorted and re-tested, diverted to a non-PEC country, etc.;
 - Documented evidence that a consignment’s transport to the EU conforms to the good hygiene practices required under PEC. This entails any or all of a container’s sanitary inspection documents completed before loading
4. Agree to have Handler name included on a PEC participant list, which may be posted to the ABC website;
5. Understand that non-compliance with the program will result in removal of Handler name from the PEC list and preventing access to the electronic ePEC system.
6. Utilize the ePEC electronic system for generating PEC documents;
7. Ensure valid PEC certificate/documents accompany EU shipments (attached are current European countries accepting a PEC certificate), which includes:
 - a) Part 1: Details of dispatched consignment;
 - b) Part 2: Certification of Health Information (signed and stamped by local CDFA Shipping Point Inspector;
 - c) Aflatoxin Certificate of Analysis;
8. Agree to have CDFA/SPI, as the local competent authority, sign the certificate attesting to the fact that the Handler is a PEC Participant, and that the aflatoxin results are attached and properly reflected in the certificate;
9. Understand that my participation in PEC is contingent on my compliance with all PEC protocols and procedures and that either aforementioned party may terminate this MOU at any time.

USDA Approved Laboratories:

The PEC program requires utilization of USDA approved laboratories for conducting aflatoxin analysis. A list of current approved laboratories can be found on the ABC website. As part of the program, USDA approved labs are required to conform to specific standards and requirements as set forth by the USDA.

As part of the program, USDA approved VASP laboratories must agree to use the ePEC system of reporting.

Almond Board of California (ABC):

1. Administration: The ABC administers the program and assists with issuance and reporting of PEC certificates as needed, and serves as a resource for program questions/modifications. In cooperation with USDA in DC, its overseas offices, and European authorities, ABC monitors issues related to almond import controls in EU ports. As needed, the ABC assists with options to address loads rejected in the EU.
2. Compliance: The ABC has a responsibility to ensure that PEC participants (handlers) are adhering to the principles as detailed in this manual and agreed to by signing the MOU. As such, periodic audits will occur to verify that PEC practices are in place and being followed by signees of the MOU.

ALMOND INDUSTRY PROGRAMS FOR AFLATOXIN CONTROL

Growers and Handlers Share Responsibility

The intention of the almond industry's food safety programs is to provide a healthful, safe food that will meet the intended needs of our customers and represent good value. Our production, harvest, delivery, storage, processing and quality systems are designed to produce a safe and sanitary product for our customers.

Food safety begins in the the orchard with the implementation of Good Agricultural Practices (GAPs). Almond-specific GAPs have been developed by the Almond Board of California (ABC) as an important first step in food safety. In addition to developing GAPs, ABC has funded research to better understand the contributing factors to aflatoxin development in almonds at both the orchard level and during postharvest handling and storage.

Aflatoxin Prevention in Orchards

Aflatoxins are produced by certain molds, mainly of the *Aspergillus* genus. The mold spores are found in the soil and in dust in the air. The spores can be transferred by navel orangeworm (NOW), and will grow on nutmeats that have been damaged from feeding by NOW. Whether in the orchard or in the stockpile, high moisture content and high temperatures favor mold growth.

There are several critical steps that growers should take to minimize navel orangeworm damage and subsequent mold growth, which leads to aflatoxin contamination.

1. Winter Sanitation – NOW overwinter in mummy nuts (those that remain on the tree after harvest). The most effective NOW control method is to remove mummy nuts from the tree by shaking or poling until there is an average of fewer than two nuts per tree. Mummies must be removed before budswell, or by Feb. 1. Destroy mummies on the ground by disking or flail mowing by March 15. Removing and destroying mummy nuts

not only reduces the extent of NOW egg-hatches and insect pressure during the next growing season, it also chops mummies into pieces too small to be accidentally swept up with the next year's harvest and contaminating next year's harvest with aflatoxin.

2. Early harvest – The second most effective step to control NOW and prevent aflatoxin is to harvest as soon as possible after the nuts are mature. Maturity is reached when 95% of nuts are at hullsplit at the 6 to 8-foot level of the tree canopy. Harvesting early and removing nuts from the orchard promptly can prevent a third generation of NOW egg-laying and therefore avoid insect damage on the new crop.
3. In-season treatment – If winter sanitation and early-harvest guidelines are followed, an in-season treatment for NOW may not be necessary. A harvest sample can help determine if treatments are required. Treatments are usually required in orchards that have more than two mummies remaining per tree after budswell.

Postharvest Aflatoxin Prevention

Studies supported by the Almond Board of California have shown that certain conditions can lead to the growth of the aflatoxin-producing molds and the resulting aflatoxin production. Based on the results from these studies, the following stockpile management guidelines are suggested:

- Do not stockpile if any of the following moisture content conditions exist:
 - The total fruit (kernel + hulls) moisture content exceeds 9 percent.
 - The hull moisture content exceeds 12 percent.
 - The in-shell kernel moisture content exceeds 6 percent.
- Moisture content described above may result in the relative humidity (rH) exceeding 65%, which is the maximum recommended rH for almond storage.
- If piles are stacked too wet, there may be condensation, pooling of water and mold growth at the outer portions (tops, sides and bottom) of the piles. Of particular concern are the "green molds," including *Aspergillus* (*A. flavus* and *A. parasiticus*). Under moist circumstances, it is recommended that the tarps are opened in the daytime when the relative humidity is lower and closed at night when relative humidity is high.
- The orientation (direction) and shape of the stockpile can play an important role in minimizing the risk of *Aspergillus* mold growth, black molds on hulls, and the appearance of concealed damage in kernels. To reduce chances of mold growth in the stockpile, the Almond Board recommends the following:
 - Place stockpiles on a firm surface, preferable one that is slightly raised to allow moisture to run off rather than puddle around the edges.
 - Orient the long axis of piles from north to south as much as possible. Condensation and mold growth tend to be worse on the north side of piles, where the long axis is oriented from east to west.
 - Smooth the tops of the piles to help minimize the concentration of moisture from condensation that would occur in any low spots.
 - Use a white-on-black tarp which is best at minimizing temperature fluctuations that can lead to condensation and mold growth. Clear tarps allow the greatest

temperature fluctuations, but are fine for dry, in-hull product, which is well below the moisture threshold.

Aflatoxin Prevention and Control in Postharvest Handling and Processing

Electronic sorting technology and quality

The almond industry has invested in advanced sorting technologies to identify damaged almonds and to remove almond “rejects” as well as any foreign material. Foreign material is considered to be anything that is not an almond nutmeat. Removal of these “rejects” is crucial to the control of aflatoxin. Research has shown that through the normal courses of sorting (electronic and hand sorting), levels of aflatoxin in a given lot can be significantly reduced by removal of insect-damaged or mechanically damaged kernels. The industry recognizes this fact and focusses on electronic and manual sorting to remove reject kernels.

Grower deliveries and inedible disposition

Handlers are responsible for receipt and testing of the crop for quality purposes. This can include initial testing for aflatoxin to facilitate isolation of the suspected load for further processing.

Each handler must meet the requirements for the disposition of inedible almonds under the incoming quality control administrative rules and regulations of the federal Marketing Order, which is administered by the Almond Board. The order regulates the handling of almonds grown in California. These regulations help minimize the risk of aflatoxin in almonds by removing inedible kernels from consumer channels. Inedible almonds are poor-quality kernels potentially contaminated with aflatoxin. This action is intended to improve the overall quality of almonds placed into consumer channels by removing product deemed to be inedible.

Almond fumigation

Each handler or grower is responsible for fumigation of the almond crop to eliminate insect infestations. Insect damage is highly correlated with aflatoxin, so it is imperative to eliminate insects from harvested crops to prevent the spread of aflatoxin. Licensed fumigators carry out fumigations.

Pre-Export Checks (PEC)

The Voluntary Aflatoxin Sampling Plan (VASP) was a voluntary program for the California Almond industry to control aflatoxin in shipments destined for export markets, particularly the European Union (EU) where aflatoxin tolerances are low. Instituted in 2007, the VASP program was quite successful in reducing the level of rejected shipments to EU countries and had widespread participation in the almond industry.

Due to the adequate controls present in sampling procedures and laboratory analysis, Almonds from California were removed from Special Measure in the European Union on September 3rd, 2014. This paved the way for the industry to transition to the Pre-Export Checks program on April 1, 2015 and build upon the legacy of the VASP program.

Hazard Analysis and Critical Control Point (HACCP) Principles

Industry wide controls in place since 2007 have reduced aflatoxin as a reasonably likely to occur risk. As such, aflatoxin specific HACCP plans are not a requirement under the PEC program. However, participants should use a HACCP based approach in decision making as appropriate to control emerging risks or isolated risks associated with aflatoxin contamination. Examples of potential control points for aflatoxin are shown in tables 4 and 5 on the following pages.

USDA-certified laboratories

The USDA developed guidelines and procedures to implement a “USDA Approved Laboratory” program for aflatoxin analysis, which is available to handlers and third-party labs. Approved labs are testing for aflatoxin following the PEC procedures.

Finished product storage

The industry must be vigilant in storage of the finished product to maintain product quality.

Research

The Almond Board funds many research projects from various committees made up of industry members. This research provides critical information to our industry. Research focused on aflatoxin is ongoing and will continue to provide us with a better understanding of how to control it.

Training materials and resources

The ABC has provided training materials and resources for the industry on many subjects, including GAPs, GMPs, HACCP, pasteurization, pathogen environmental monitoring, and aflatoxin control through annual symposiums, conferences and industry communications. These educational resources will continue to provide information on new technologies and procedures as they are developed. Materials and resources can be accessed on the ABC web site, almonds.com

Table 5: Examples of Potential Control Points for Aflatoxin

| CP | Operational Step on Flow Chart and Hazard Control | Monitoring Activity and Frequency (Real Time) | Critical Limits (Specifications) | Specific Action Required if Limits are Exceeded | Employee Responsible and Records Required | Verification Activity and Frequency |
|----------------------------|--|--|--|--|--|---|
| CP | Handler Receiving Incoming Inspection Chemical: Aflatoxin | Inspect each delivery for serious damage and moisture content: Identify and isolate high rejects or high moisture product | Internal specs: <7.0% Moisture <5% Serious damage | Isolate high serious damage product for further sorting Dry product to <7.0% moisture | USDA inspector (Incoming Inspection) Handler employee (Receiving or QA) Testing records | Periodic management review ABC Quality Control Report |
| CP | Mechanical/Optical/Manual Sorting Chemical: Aflatoxin | Electronic and/or hand sorting to control serious damage to internal specifications. | Per USDA grades or internal standards | Downgrade to lower quality; and/or Isolate and reprocess to remove serious damage | Sorting operators; Production & Quality personnel; QA/QC reports | Periodic management review |
| CP | Finished-Product Storage Biological/Chemical: Potential mold growth and Aflatoxin development | Monitor storage environment for temp and % rH | Per internal specs for temp, rH of 60% or less is recommended | Adjust temp and % rH and test product moisture | Production /Quality personnel Temp and % rH records | Periodic management review |
| CP (Verification Activity) | Finished-Product Testing Chemical: Aflatoxin | For each EU shipment: Product sampling and aflatoxin testing per PEC program requirements | Domestic is < 20 ppb total EU is <8 ppb B1, 10 ppb total PEC samples sizes are listed in Table 3 and must meet critical limits above. Testing conducted by USDA-approved laboratories | If one test exceeds 8 ppb, then the lot cannot be shipped to EU. Shipment may be reprocessed and retested or diverted to alternative market if US tolerances are met . | USDA-approved laboratory analysis; PEC program documentation CDFA/SPI signed PEC certificate | Labs subjected to USDA review program; Management review of PEC; ABC verification |

Table 6: Industry Process Flow Chart and Possible Aflatoxin Control Points

