

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

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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

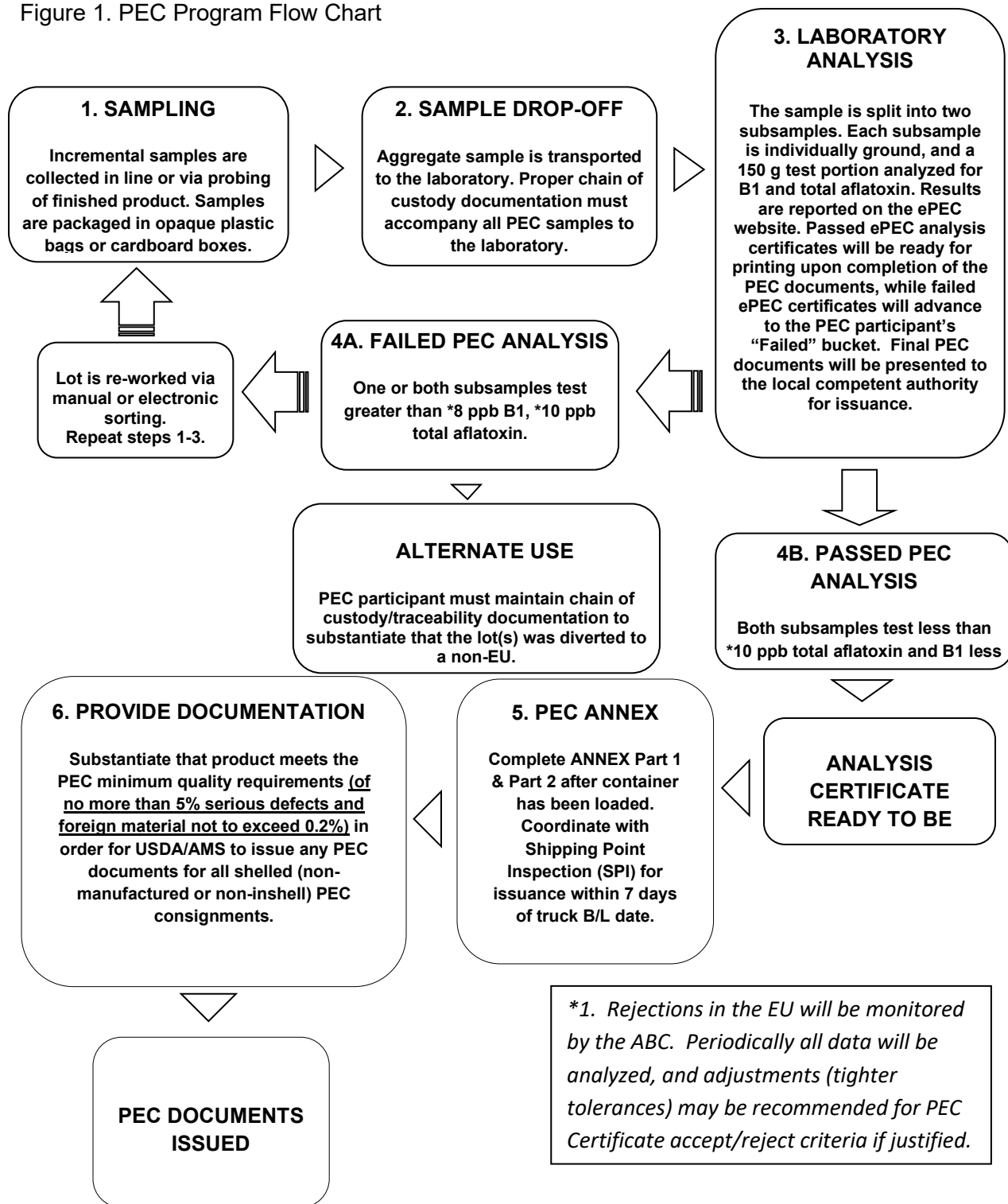
The European Commission adopted Special Measures for all almond consignments shipped to the EU on September 1, 2007, the VASP Program was implemented to allow the California Almond industry the opportunity to control and test for aflatoxin prior to shipping, demonstrating the industry's commitment, and 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 was 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. NOTE: After Brexit, United Kingdom retained the PEC legislation with some minor tweaks. Thus, on January 15, 2024, shipments to Great Britain will follow the GB-PEC protocol and will be issued a GB-PEC certificate.

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 training, sampling practices, USDA-approved laboratory aflatoxin analyses, specified Accept/Reject Criteria, standard reporting of results on an ePEC Aflatoxin Analysis Certificate, consignment/shipping information and California Department of Food and Agriculture-Shipping Point Inspection attestation on the accompanying PEC documents (ANNEX 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, PEC 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 available to registered almond handlers and applicable for shelled and inshell almonds, as well as manufactured almonds (e.g., sliced, diced, etc.) destined for direct shipment to the EU. Only ship products under the PEC Program which meets PEC minimum quality requirements of (no more than 5% serious defects and foreign material not to exceed 0.2%). Only those products which fall under international harmonized codes HS 0802.11 and 0802.12 are covered under 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 = Aflatoxin Analysis Certificate + ANNEX Part 1 + ANNEX Part 2 will only be issued if the product meets the Accept/Reject Criteria as shown in Table 2 below.

Table 2. Accept/Reject Criteria for PEC Analysis and Certificate Issuance

Maximum Aflatoxin Level 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 lot. Variability is reduced through normal course of sorting which mixes the nuts and distributes aflatoxin spatially throughout the lot. The European Commission has established sampling protocols for nuts for official mycotoxin control (Commission Regulation (EC) No 401/2006). 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 below 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 Size¹

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

¹ “No lab sample division required for Lots Sizes less than or equal to 2,205 lbs. referenced in Table 3 above.”

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.	Pull samples at pre-defined time intervals throughout the run to ensure representation of entire lot. Sampling can be automatic or manual. Automatic sampling procedure (Page 9) 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.
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.	Probe a pre-determined number of bins, boxes, or other containers as appropriate to ensure representation of the entire lot. 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. 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.

Sample Collection:

Samples must be pulled from the lot as described in a sampling “Standard Operating Procedure” (SOP) developed by each PEC participant. Once all the individual samples are pulled, 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 the PEC Certificate of Analysis and on each carton or bin that is shipped. The aggregate sample must be collected and stored in opaque plastic bags, boxes, or another suitable non-transparent container. If a sample is not initially 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 proper chain of custody documentation, which includes the lot number and date(s) sampled on the opaque container. A hard copy of the ePEC Certificate of Analysis may be submitted along with aggregate sample for chain of custody documentation. The aggregate sample size must be equal to or greater than those values shown in Table 3. above for a specific lot size on Page 6.

Qualified Personnel:

Those personnel directly responsible for PEC sampling, sample submission, PEC record-keeping, and certificate issuance must be trained either directly by the Almond Board of California (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 requested. PEC participants are responsible for ensuring that new and existing employees are trained on an as-needed basis. PEC Training Log/Records must be kept for all employees involved in the PEC Program.

PEC participants Training Log/Record must document the following information for verification and accreditation purposes:

1. Employee(s) names are indicated clearly and legible.
2. Areas of the PEC Program trained in per employee are checked in the appropriate areas on the training log:
 - a. PEC Overview & Process Flow
 - b. Employee Training Requirements
 - c. Sampling Requirements
 - d. Required Records & Documents
 - e. ePEC Analysis & Reporting
 - f. Hygiene & HACCP Principles
 - g. Failed Lot Control
 - h. Verification Requirements
3. Indicate date(s) of training(s) performed and ABC trained “Trainer” name(s) clear and legible.
4. The Training Log/Record should be made available upon request from the ABC during verification. Only personnel who have been trained in the appropriate area(s) may perform PEC Program activities.

Sampling Standard Operating Procedures (SOP's):

Each PEC participant must develop a sampling “Standard Operating Procedure” (SOP). The purpose of the sampling SOP is to describe the process to ensure that the appropriate aggregate 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. Material used
 - a. labels, markers to label container
 - b. probes, sample pails or collection utensils
3. Sampling Record/Log procedures
4. Sample container requirements (opaque like containers)
5. Sample storage and lab delivery procedures
6. 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. All sampling techniques in-line, automatic and packaged product sampling require documentation of the following:

1. Sampling frequency: The time interval between collection of samples from the production lot.
2. Number of incremental samples: this is according to the lot size. Reference Table 3 on Page 6.
3. Times associated with each incremental sample collection drawn.
 - a. Note: for packaged-product sampling (probing) start, and finish times must be recorded.
4. Lot No./ID/Product Description
5. Lot size
6. Aggregate Sample Weight: The total combined weight of all incremental samples.
7. Sampling Operator: The trained operator must initial or indicate name clear and legible per incremental sample drawn.
8. Date(s) of Sampling Indicated on Sample Log/Record

For packaged product sampling or manual in-line sampling, an operator log sheet must be filled out as the sample is drawn. It should include the time the sample was taken, the size of the sample and the operator initials or name clear and legible. For automatic in-line sampling, a minimum of 2 checks per hour should be documented to verify that the sampler is appropriately collecting samples according to PEC participants SOP sampling protocol. Electronic Sample Log/Records requests must be submitted to the Almond Board of California (ABC) prior to use for review. ABC will coordinate with USDA for further review of the electronic Sample Log/Record request. If approved by USDA, the PEC participant must explain in their SOP how these electronic records will be maintained. Sampling records will be reviewed by ABC during onsite verifications.

PEC Program requirements outlined in the MOU and this PEC Program Manual will be subjected to an on-site PEC verification. Repeated minor non-conformities may result in suspension or increased oversight frequency. Written corrective action responses must be submitted to address any non-conformities and observations within 20 days.

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 total aggregate sample to a USDA approved laboratory, an ePEC System draft Certificate of Aflatoxin must be filled out. To initiate a certificate, the applicant must log into the ePEC System. Once logged in, the applicant will select the “Add Certificate” tab and then complete the appropriate sections of the form as follows:

Applicant Section:

This section is auto populated based on the PEC participant’s ePEC 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 are being shipped by using drop down function.
3. **Lot No./ID Marks:** For each PEC sample submitted to the lab a unique Lot No./ID must be assigned. Make sure that this number matches the paperwork 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 pounds (lbs.).**

Select the lab you wish to use from the drop-down menu:

After the draft certificate is completed, 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 Draft Certificate” button. The aggregate sample must be delivered to the laboratory along with proper chain of custody documentation, which includes the lot number and date(s) sampled on the opaque container. A hard copy of the ePEC System Certificate of Analysis may be submitted along with aggregate sample for chain of custody documentation. When the PEC participant is ready to submit the sample for analysis, the “Send to Lab” button must be clicked. Doing so will place the analysis request in the lab’s inbox.

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 subsamples, if the results exceed the aflatoxin limit of 10ppb total or 8ppb B1, then the certificate will automatically be placed into a “Failed” tab and will not be available for issuance. If the results are within the PEC accept/reject criteria of 10ppb total or 8ppb 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 “Reported” tab. The certificate will stay in this tab until the PEC participant is ready to print all three PEC pages for SPI signature and issuance.

PEC ANNEX Part 1 & Part 2:

In addition to the PEC Aflatoxin Certificate of Analysis that is generated by the lab analysis, the PEC Program has an ANNEX Part 1 to be completed by the PEC participant before final endorsement by Shipping Point Inspection (SPI). ANNEX Part 1 contains information about the consignment and the parties responsible for the shipment. ANNEX Part 2 consists of the attestation for the PEC documents and is where the local competent authority, Shipping Point Inspection, will sign the document thereby providing for its official issuance; **this may be completed no more than 7 calendar days from when the consignment has left the PEC participant’s facility (truck bill of lading date)**. ANNEX Part 2 is automated by the ePEC System and will be attached to Certificate of Analysis and ANNEX Part 1 when applicants press “Finalize and Print All.” **A detailed list of each item and a description is listed below.**

ANNEX PART 1

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

I.2 Certificate Reference Number: Unique identifier, determined by the PEC participant (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. Note: by selecting "United Kingdom" you will be assigned a Great Britain (GB) Certificate for the destinations (England, Scotland and Wales) This certificate will not work for EU destinations.

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

I.13 Place of Loading: This will default to "California, USA."

I.14 Date of Departure: Truck Bill of Lading date (when consignment leaves PEC participant'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 Waybill 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 be transferred 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 Tons (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.

ANNEX PART 2:

The PEC participant 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 PEC Aflatoxin Certificate of Analysis from the lab and the ANNEX 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. PEC participants are to maintain a copy of the signed set of PEC documents for their own records and for verification purposes. The original must be provided at the port of entry into the European Union.

PEC Certificate Issuance:

The PEC participant has up to 7 calendar days from when the consignment has shipped (truck bill of lading date) to complete all necessary PEC paperwork for issuance. Upon receiving a passing PEC Aflatoxin Certificate of Analysis from an approved USDA Laboratory the PEC participant may ship a full or partial lot of products to the EU. PEC participants can now print out the PEC Aflatoxin Certificate of Analysis and begin implementing PEC ANNEX Part 1 & Part 2 in the ePEC System. The PEC participant initiates this process by logging into the ePEC System and following the prompts and making sure that you have previewed the PEC Aflatoxin Certificate of Analysis and ANNEX Part 1 before administering the "Finalize and Print All" tab for downloading a pdf of the PEC documents. Please save a copy of the SPI signed/issued PEC certificate for your records. Note: The PEC Aflatoxin Analysis Certificate can only be printed if the aflatoxin limits are within the acceptable limits as described above and shown in Table 2 Page 5.

Failed Lots:

If a tested lot exceeds the Accept/Reject Criteria for PEC Analysis and Certificate Issuance as shown in Table 2 the certificate will be placed into the "Failed" tab automatically. The certificate will be locked and unable to be signed/issued. As part of the PEC Program, participants agree that prior to retesting, any failed lot must be re-processed with electronic, hand, and/or other sorting means to remove insect-damaged kernels and lower the levels of aflatoxin in the lot. PEC participants must record quality of pre-sorting and post-sorting and maintain

documentation showing the amount of inedible product removed. [Only shelled almonds which meet the PEC minimum quality requirements (no more than 5% serious defects and foreign material not to exceed .2%) for any shelled almond shipments (excluding inshell and manufactured.) PEC participant approved documentation (Quality (QC) Line Sheet, USDA Outgoing Certificate, etc.) to USDA/SPI prior to PEC issuance to substantiate product quality.

Additionally, prior to re-processing any failed lot, the PEC participant must assign a new/unique Lot No./ID and re-generate a new Sample Log/Record for the re-processed failed lot prior to sampling for PEC purposes.

If further processing is not conducted, the PEC participant may decide to divert the lot(s) to a non-EU outlet or an alternative use. If this option is chosen, the PEC participant must maintain chain of custody/traceability documentation to substantiate that the lot(s) were diverted to a non-EU outlet or transferred to an alternative use. This documentation may be requested for verification purposes, during an on-site visit.

PEC PARTICIPANTS AND RESPONSIBILITIES

Handlers PEC Participants:

As signatories to the Memorandum of Understanding (MOU), PEC participants agree to comply with the conditions as outlined in the PEC Program Manual and with any provisions included in 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 inline, automatic, or probing sampling.
 - PEC documents including ANNEX Part 1 and Part 2 (signed by SPI), Certificate of Analysis, PEC Issuance Log (PIL), and appropriate documentation to substantiate that PEC minimum quality requirements are met.
 - One or more failed analysis lot(s) to determine the outcome of the actual lot, specifically to ascertain whether it was re-processed and re-tested or diverted to a non-EU destination.

- Documented evidence such as a Container Issuance Log (CIL), that a consignment's transport to the EU conforms to the good hygiene practices based on (HACCP) principles: Sanitation practices, GMPs, GAPs, etc. This includes any or all container's sanitary inspection documents completed before loading.
- 4. Include Handler name on a PEC participant list, which may be posted to the ABC website.
- 5. Utilize and maintain ePEC System for generating PEC documents.
- 6. Ensure valid PEC certificate/documents accompany EU shipments (attached are current European countries accepting a PEC certificate), which includes:
 - a) Aflatoxin Certificate of Analysis
 - b) ANNEX Part 1: Details of dispatched consignment
 - c) ANNEX Part 2: Certification of Health Information (signed and stamped by local USDA/C DFA Shipping Point Inspector)
- 7. Agree to present required documents to CDFA-SPI, as the designated inspection agency under the USDA competent authority for review and signing of the certificate. By signing the certificate, CDFA-SPI confirms that the Handler is a PEC Participant, aflatoxin results presented are within PEC accept limits (Less than 10PPB total and Less than 8PPB B1), and minimum product quality standards are met. **PEC participants must substantiate the PEC minimum quality requirement by providing a USDA Outgoing Certificate, QC line sheet, or other ABC approved documents. CDFA-SPI will confirm if this requirement is met on the PEC issuance log.**
- 8. **Only ship products that meet the Pre-Export Checks (PEC) minimum quality requirement of no more than 5% serious defects and foreign material not to exceed 0.2%. Each individual package/container of the lot must meet minimum quality requirements.**
- 9. **Only ship products under the PEC Program which falls under the HS codes 0802.11 (In-Shell) and 0802.12 (Shelled), including whole kernels, inshell almonds and manufactured almonds such as sliced, diced, and blanched.**
- 10. Comply with the following EU health certificate requirements; By initiating the PEC certificate, I certify that the almonds covered by the certificate have been produced, sorted, handled, processed, packaged, and transported in line with good hygiene practices and have been subject to a pre-export check, as approved by Commission Implementing Regulation EU 2015/949. I further agree that the commodities covered by this certificate will be transported to the European Union in a container, which is in line with good hygiene practices (e.g., food grade container).
- 11. Comply with PEC Program requirements outlined in this MOU and the PEC Program Manual including on-site PEC verification. Repeated minor non-conformities found during subsequent verification may result in suspension or increase oversight frequency. PEC participants must provide written corrective action responses to address any observations or non-conformities within 20 days of report issuance.
- 12. Comply with all PEC requirements outlined in this MOU and the PEC Program Manual, with an understanding that non-compliance may result in suspension from the PEC Program and restrictions from the ePEC System. **Any failure to comply with the PEC minimum quality requirements will result in suspension from the PEC Program for at least one month.**

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 at <https://www.ams.usda.gov/services/lab-testing/aflatoxin>

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 laboratories must agree to use the ePEC System of reporting.

Almond Board of California (ABC):

1. Administration: 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/AM Specialty Crop Inspection Division, 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: ABC has a responsibility to ensure that PEC participants are adhering to the principles as detailed in this manual and agreed to by signing the MOU. As such, periodic onsite verifications 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 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 pulling 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 hull split 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 to 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, preferably 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 products, which are 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 focuses 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 products 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.

Hazard Analysis and Critical Control Point (HACCP) Principles:

Industry wide controls in place since 2007 have reduced aflatoxin as a reasonably likely risk to occur. 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 5 and 6 on the following pages.

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.

PEC AT A GLANCE**PEC REQUIREMENTS**

General Requirements	Responsibility
Signed Memorandum of Understanding	Handler PEC Participants
Trained Employees	PEC participant employees responsible for PEC sampling, sample submission, and certificate issuance.
Sampling SOP	PEC participant employees responsible for sampling.
Use of Opaque or Cardboard Containers for sampling	
Proper Storage / Control of Samples	
Use of ePEC System	PEC participant employees responsible for initiating and printing certificates.
Implementation of Basic Hygiene Principles	Facility where product is produced.
Failed Lot Control	PEC participant employees responsible for lot control/processing and issuing PEC certificates.
Program Documentation	PEC participant 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 substantiate reprocessing via hand/electronic sorting and reduction of insect-damaged kernels. To prove that a new/unique Lot No./ID is used following re-processing. New Sample Log/Record implemented prior to sampling.

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.org.

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 products	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 is listed in Table 2. PEC samples sizes are listed in Table 3 and must meet critical limits above. Testing conducted by USDA-approved laboratories	If test exceeds critical limits, then the lot cannot be shipped to EU. Shipment may be reprocessed and retested or diverted to alternative markets 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

