



voluntary aflatoxin sampling plan (VASP) program

Voluntary Aflatoxin Sampling Plan (VASP) Program Manual

Purpose

The VASP 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 is intended to reduce the number of consignments rejected in the EU by sampling and controlling each lot for aflatoxin to the same stringent accept or reject levels adopted by the European Commission prior to shipping.

Background

From 2004 through 2006 there were increased rejections of almond consignments in the EU due to detections of aflatoxin in the product at higher levels than that allowed by the EU. As a result, the EU Food and Veterinary Office (FVO) conducted an audit mission in September of 2006 to assess the aflatoxin control systems in place within the California Almond industry for consignments destined for shipment to the EU. Subsequently, the European Commission adopted Special Measures for all almond consignments shipped to the EU. The VASP program was created by the ABC to allow the industry the opportunity to control and test for aflatoxin prior to shipping, thereby demonstrating the industry's commitment and avoiding excessive mandatory controls on imports. The EU agreed that those consignments shipped with a VASP certificate would be subject to less stringent controls, for example, 5% controls vs. the 100% for consignments shipped without a VASP certificate. In January of 2009, the FVO conducted a follow-up mission to reassess the control systems in place, including a thorough review of the USDA-approved laboratory program for aflatoxin test-

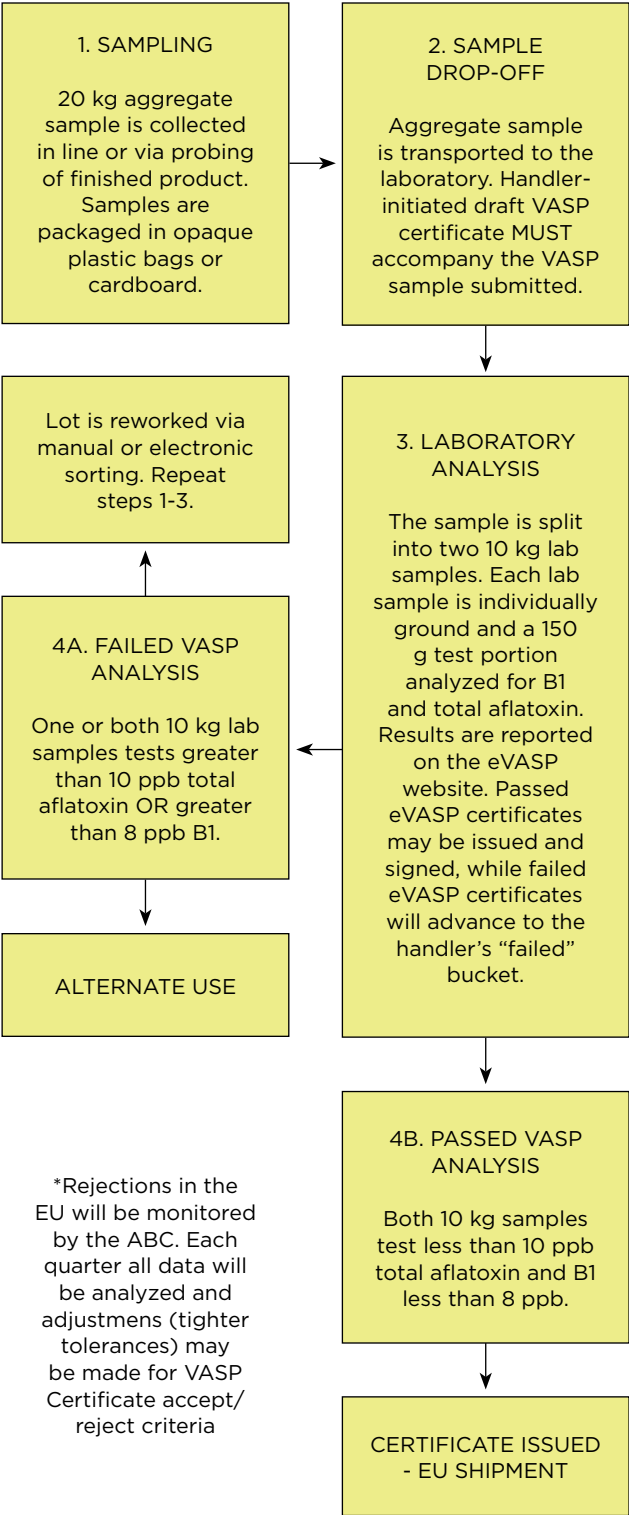
ing. Based on confidence in the VASP program, EU commission regulation (EC No 1152/2009) directed that consignments shipped with a VASP certificate be subject to random controls and those without a VASP certificate be subject to 100% controls.

Program description

There are numerous parties involved in the VASP program, each with specific roles and responsibilities as shown under "VASP Participants and Responsibilities" later in this manual. The VASP program revolves around industrywide uniform sampling practices, USDA approved laboratory aflatoxin analyses, specified accept or reject criteria, and standard reporting of results on an eVASP certificate. In addition to following the sampling and analysis protocol, those parties (such as handlers) directly involved in the process should implement Hazard Analysis and Critical Control Point (HACCP) or equivalent-type programs to effectively control and minimize the potential for aflatoxin in the product (see page 12: Voluntary Aflatoxin Sampling Programs). Shown on page 13 is a flow chart describing the basic steps in the process and responsible parties from the time of sampling throughout analysis, reporting of results and shipping of consignments.

Voluntary Aflatoxin Sampling Programs

Figure 1. VASP Program Flow Chart



VASP program applicability

The VASP program is applicable for ready-to-eat (RTE) almonds, as well as manufactured goods containing almonds, destined for shipment to the EU. However, VASP certificates will be issued only if the product meets the "accept" criteria established by the EU for RTE product as shown in Table 1 below.

Table 1. Accept Limits for VASP Analysis and Certificate Issuance

Maximum Aflatoxin Levels Allowed (ppb)	Laboratory Sample 1 Size	Laboratory Sample 2 Size
B1	8	10 kg
Total	10	10 kg

Product sampling

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. One source of uncertainty is due to the non-uniform distribution of aflatoxin contamination in a given lot. In order to select a representative 20 kg aggregate sample from a lot, it is important to collect a large number of incremental subsamples throughout the lot. The European Commission has established sampling protocols for nuts for official mycotoxin control (Commission Regulation EC No 401/206). In order to remain consistent within the industry and reduce variability, participants in the VASP program should implement a similar sampling protocol for product shipped to the EU with a VASP certificate. An example of such a sampling program is shown in Tables 2 and 3, on following pages.

Table 2. Recommended Minimum Number and Size of Incremental Samples per Lot

Sampling Type	Total Aggregate Sample Size	Lot Size (lbs)	# of incremental Samples	Incremental Sample Size	
				Grams	Pounds
In-Line, Packaged Product or Manufactured Goods Sampling	20 kg (44 lbs.)	< 10,000	60	330	.75
		10,000 - 20,000	80	250	.55
		20,001 - 44,000	100	200	.44

- Sample collection—Incremental samples should be collected from the lot to provide a good representation of the entire lot. Once all of the incremental samples are pooled, the total aggregate sample should equal 20 kg (44 lbs.) at a minimum. A lot number or ID should be assigned to this sample and will be required on your VASP certificate and on each carton or bin that is shipped. The 20 kg aggregate sample should be collected and stored in opaque plastic bags, boxes or other suitable opaque container. If a sample is not immediately submitted to a USDA-approved laboratory for analysis, then it should be stored under similar conditions as the lot that it represents. The 20 kg aggregate sample should be delivered to the laboratory along with the handler-initiated VASP draft certificate as indicated in the sample submission section below. After delivery, the laboratory will divide the 20 kg aggregate sample into two 10 kg lab samples.

- Qualified personnel—Those personnel directly responsible for collecting VASP samples should be properly trained on VASP protocols including sampling, recordkeeping and aflatoxin control (HACCP type) principles. A personnel training record should be kept for all employees involved in the VASP program and be made available to the ABC when requested for audit purposes.
- Sampling Standard Operating Procedures (SOPs)—Each VASP participant should develop a standard operating procedure that de-

scribes the following:

- Sampling frequency and incremental sample size control practices
- Sampling record and log
- HACCP-type program for aflatoxin control
- Employee VASP training
- VASP certificate documentation

SOPs must be made available to the ABC when requested for audit purposes.

- Sampling recordkeeping—Written records should be maintained for all sampling activities. Both in-line and packaged product sampling require documentation of the following:
 - Sampling frequency
 - Laboratory sample size
 - Lot code and product description
 - Lot size
 - Aggregate sample size

For packaged-product sampling or manual in-line sampling, an operator log sheet should 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 should be maintained verifying periodically that the sampler is appropriately collecting samples. An example of a manual in-line sampling sheet is shown on page 13 of this section.

Sampling records must be made available to the ABC when requested for audit purposes.

Table 3. 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 defined time intervals throughout the run to ensure representation of entire lot.</p> <p>Sampling can be automatic or manual.</p> <p>Base total # of samples and sample size on total lot size using guidelines shown in Table 2.</p>
		<p>Example 1: 40,000-lb. lot to be processed and packed over a 10-hour period.</p> <p># of samples to pull (based on guideline in Table 2) = 100 Weight per sample (based on guideline in Table 2) = 200 grams Samples to draw = 100 samples ÷ 10 hours = 10 samples per hour 60 min. per hour = 10 samples per hour = 6 minutes per sample</p> <p>In this case, in-line sampling should be set up so that one 200-gram sample is pulled every 6 minutes.</p>
Packaged (Finished) Product Sampling (e.g., 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 representative number of bins, boxes or other containers as appropriate to ensure representation of the entire lot.</p> <p>Base total # of samples per container and sample size on total lot size using guidelines shown in Table 2.</p> <p>If probing sealed bins, boxes, cartons, etc., it is important to seal the probe hole and initial and date it so that the customer knows it was not tampered with.</p>
		<p>Example 2: 15,000-lb. lot packaged in 50-lb. boxes = 40 boxes per pallet.</p> <p># of samples to pull (based on guideline in Table 2) = 80 Weight per sample (based on guideline in Table 2) = 250 grams Total # of boxes = 15,000 lbs. ÷ 50 lbs. per box = 300 Total # of pallets = 300 boxes ÷ 40 boxes per pallet = 7.5 pallets # samples needed per pallet = 80 samples ÷ 7.5 pallets = 10-11 samples per pallet</p> <p>In this case, finished-product sampling should be conducted so that 10 to 11 250-gram samples are pulled from each full pallet (individual boxes) with a total of 80 samples drawn.</p>
		<p>Probe a representative number of bins, boxes or other containers as appropriate to ensure representation of the entire lot.</p> <p>Base total # of samples per container and sample size on total lot size using guidelines shown in Table 2.</p> <p>If probing sealed bins, boxes, cartons, etc., it is important to seal the probe hole and initial and date it so that the customer knows it was not tampered with.</p>
		<p>Example 3: 44,000-lb. lot packaged in 2,200-lb. bins = 20 bins.</p> <p># of Samples to pull (based on guideline in Table 2) = 100 Weight per sample (based on guideline in Table 2) = 200 grams Total # of bins = 20 # samples needed per bin = 100 samples ÷ 20 bins = 5 samples per bin</p> <p>In this case, finished-product sampling should be conducted so that five 200-gram samples are pulled from different locations throughout each bin. (If probing through the bin, the hole should be sealed with a signature and notation that probing was for VASP analysis.)</p>

Sample submission

Once the 20 kg aggregate sample is collected, it should 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 eVASP draft Certificate of Aflatoxin Sampling and Analyses must be filled out by the applicant, as seen on page 14. To fill out a certificate, the applicant must log into the eVASP system. Once logged in, the applicant will select the “New VASP 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
 - Crop Year—Fill in the calendar year in which the crop was harvested.
 - Product Type—It is very important that the description used here match the Ocean Bill of Lading and/or invoice.
 - # Of Cartons, Bins, Etc.—Make sure that the numbers accurately represent the lot and add up to the total pounds of the lot.
 - Lot No./ID Marks—Only one lot number or ID should be assigned to each sample submitted to the lab. Make sure that this number matches the paperwork and what is printed on the containers, bins, etc. The second field is optional and must also appear on each carton or bin.
 - Total Lot Size—This should be the total pounds that the VASP analysis represents. Please note: After analyses is completed, there is an option to issue certificates that represent a partial lot. This can be done multiple times until the total pounds represented by the certificate is reached.
- Sampling agency—Check the appropriate box

to indicate whether the product was sampled by in-house staff or an outside third party. If sampled by a third party, indicate the name and address. Please note: below the Sampling Agency box, there is another empty box. This box is used for any shipping notes. The purpose is to add more description as needed. For instance, if a partial load is shipped you can make reference to that in the Shipping Notes section.

- Lab—Select the lab you wish to use from the drop-down menu.
- Sampling Information:
 - Date Sampled—Enter the date when the sample was collected.
 - Destination (Country)—Enter the European Union. This allows flexibility on delivery to any country within the EU.
 - By—Enter the name of the individual responsible for collecting the sample.

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.

VASP 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 VASP certificate. For each of the two 10 kg laboratory samples, if the results

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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 certificate will be available for issuance at the applicant’s request. 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 have the certificate issued.

- VASP certificate issuance—When VASP applicants are ready to ship a full or partial lot of product to the EU, they can request that the certificate be issued (assuming the sample has been analyzed) only 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 eVASP system and following the prompts to enter a certificate. The applicant will be required to enter the total pounds being shipped. Please note: The total pounds shipped cannot exceed the total pounds previously listed in the Products Description section of the certificate. However if the applicant wishes to ship a partial load, they can enter fewer pounds than indicated in the Products Description section. The applicant should mention this in the Shipping Notes section of the certificate. Once the applicant finalizes the certificate and selects it to be issued, the lab is notified. The lab will then print out the certificate and finalize it by signing an original copy in blue ink and applying an official USDA stamp in red ink. The original signed copy must be returned to the applicant and included with the lot (or partial lot) shipped to the EU.
- 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 VASP 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.
- VASP participants and responsibilities
 - Handlers and manufacturer VASP participants—As signee’s to the Memorandum of Understanding (MOU), VASP participants agree to adhere to the VASP program as described in this manual. Specific provisions of the program require the following:
 - Implementation of a Hazard Analysis and Critical Control Points (HACCP)-type program for addressing aflatoxin control.
 - Proper training of individuals responsible for implementing VASP sampling protocol.
 - Compliance with audit activities associated with verification of sampling procedures, VASP documentation and training.
 - Agreement to allow company name to be included on a published VASP participant list.
 - Utilization of eVASP or equivalent ABC-approved system.
 - Accompaniment of VASP certificate with all EU shipments.
 - Agreement to retest failed lots only after appropriately reprocessing.
 - Agreement to not ship California almonds from another country to the EU unless appropriate testing equivalent to VASP has been conducted and levels are below the limits adopted by the EU.
 - USDA approved laboratories—The VASP program requires utilization of USDA-approved laboratories for conducting aflatoxin analysis.

A list of currently 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. These include, but are not limited to, participation in annual FAPAS international proficiency test, periodic spiked and check sample analyses and reporting, and annual USDA audits. In addition, prior to being accepted as a USDA approved lab, there is a rigorous review process and strict performance criteria that must be demonstrated.

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

- Almond Board of California (ABC)
 - Administration—The ABC administers the program and assists with issuance and reporting of VASP certificates as needed, and it serves as a resource for program questions and modifications. The ABC also assists the USDA in the validation and oversight activities associated with the approved laboratories. In cooperation with USDA in the U.S. Capital, 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.
 - Compliance—The ABC has a responsibility to ensure that VASP participants (handlers and manufacturers) 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 VASP 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 provide 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, the 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.

Handlers are required to take all reasonable measures and precautions to comply with Good Manufacturing Practices (GMPs). GMPs are mandated by the Federal Code of Regulations, Title 21 (CFR 21) part 110. These are general requirements that all handlers must follow. As food manufacturers, almond handlers may be audited by state or federal authorities at any time without prior notice to ensure compliance with GMPs and to verify sanitation programs.

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.

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 the mummies into pieces too small to be accidentally swept up with the next year's harvest and contaminating next year's harvest with aflatoxin.

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 on the new crop.

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 preliminary results from these studies, the following stockpile management guidelines are suggested (for the most current guidelines developed from ongoing research, go to www.almondboard.com):

- To be on the safe side until more is known, don't stockpile in-hull almonds that have a total moisture content exceeding 6.5 to 7%. As a practical guide, kernels, shells and hulls that "snap" when bent between fingers are certainly safe.
- If piles are stacked too wet, there will 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*. Under moist circumstances, it is important to open up the piles in the daytime when relative humidity is lower, and close them at night when relative humidity is high. In the 2007 research, ambient relative humidity ranged from about 90% or more at night, down to 55% or less during daylight hours.

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 ABC. 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

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aflatoxin. Licensed fumigators carry out fumigations.

Voluntary Aflatoxin Sampling Plan (VASP)

VASP is 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. It sets the protocol for sampling and analysis with an equivalent sensitivity to the protocol currently being used in the EU.

Since the VASP program has been in place, rejected shipments to EU countries have been substantially reduced, indicating that sampling procedures and laboratory analyses provide adequate controls.

Hazard Analysis and Critical Control Point (HACCP)

HACCP is a systematic approach to identifying and eliminating risks and potential sources of contamination for a food product and the equipment and environment in which it is processed. There are seven basic principles of HACCP, which are focused on identifying potential hazards, establishing appropriate control points, monitoring practices, and verifying effectiveness. HACCP plans should be specific for the type of risk involved. A HACCP plan for aflatoxin control should focus on steps such as sorting and VASP analysis, which will reduce the potential for aflatoxin in the finished product. Examples of a HACCP plan summary and flow chart specific for aflatoxin control are shown on pages 11 and 12. This plan should be customized for each facility to reflect the steps in place that are controlled and monitored to reduce the potential for aflatoxin contamination.

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 VASP procedures and issuing VASP certificates to accompany shipments.

Finished product storage

Because sorting and testing are the final CCPs, the industry must be vigilant in storage of the finished product. It is important to keep the product in controlled conditions to prevent mold growth and potential aflatoxin development.

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 almond industry on many subjects, including GAPs, GMPs, HACCP, pasteurization 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, almondboard.com.

Hazard Analysis Critical Control Point Summary for Aflatoxin Control

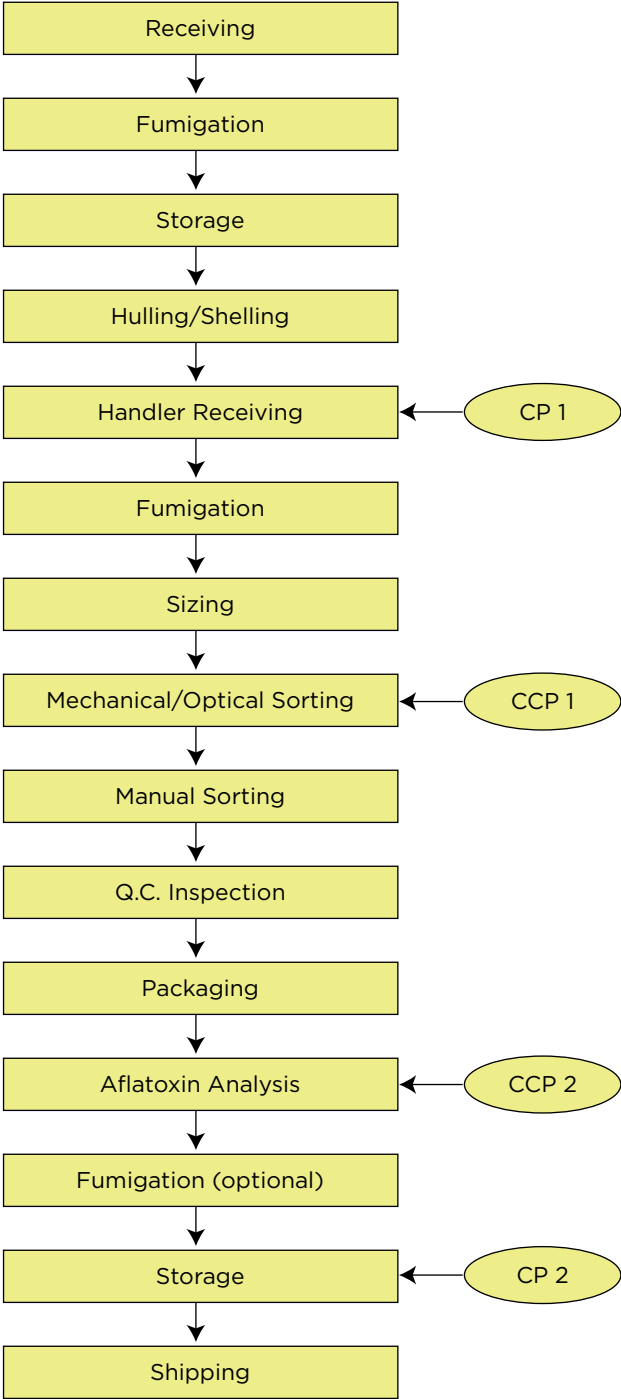
Products: Almonds

Process: Almond Harvest and Processing

CP or CCP	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 #1	Handler Receiving Chemical: Aflatoxin	For each delivery: Identify and isolate high rejects. Opportunity to test for aflatoxin. Test for moisture.	USDA incoming inspection: .5/50% inedible disposition rule Internal specs: < 7.0% internal spec <5% USDA	Isolate product based on handler's internal spec Isolate product Dry product to <6.0%	USDA inspector Handler employee (Receiving or QA) Testing records	Periodic management review ABC Quality Control Report
CCP #1	Mechanical/Optical/Manual Sorting Chemical: Aflatoxin	Internal specifications to control serious damage. Opportunity to monitor for aflatoxin per internal specs.	Per USDA grades or internal standards EU is <2 ppbB1, 4 ppb total	Downgrade to lower quality Isolate and reprocess	Third party inspection Production/Quality personnel QA records	Periodic management review
CCP #2	Finished-Product Testing Chemical: Aflatoxin	For each EU shipment: If >2% serious damage, sample 15 kg of product including at least 50 to 300 gram incremental samples. Mix all incremental samples together and split into 3 X 5 kg individual samples. Analyze each sample separately for aflatoxin. Refer to VASP for details.	Domestic is < 20 ppb total EU is < 2 ppb B1, 4 ppb total VASP limits are 3 X 5 kg with all samples < 2 ppb total Testing accomplished by USDA-approved laboratories	If one test exceeds 2 ppb, then the shipment is rejected Shipment may be reprocessed and retested to the same standards or diverted to other markets if standards are met	USDA-approved laboratory chemist USDA-approved COA Laboratory test documentation Management records	Ten check samples per year from USDA USDA annual audit Laboratory Proficiency Program AOCS-optional Customer test results
CP #2	Finished-Product Storage Chemical: Potential Aflatoxin Increase	Monitor per internal specs 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

This form is only a sample and should be modified to meet the needs of your particular operation.

Industry HACCP Flow Chart



Voluntary Aflatoxin Sampling Programs

CERTIFICATE OF AFLATOXIN
SAMPLING AND ANALYSIS FOR CALIFORNIA ALMONDS
VOLUNTARY AFLATOXIN SAMPLING PLAN
USDA/AMS APPROVED LABORATORY

CERTIFICATE NO.: e14489
SAMPLE NO.: _____

APPLICANT:		PRODUCT DESCRIPTION:	
Company Name:	ABC - Handler TEST	Crop Year:	2009
Contact:	Sue Olson	Product Type:	Should Match OBL or Invoice
Address:	1150 9th Street Modesto CA 95354	# of Cartons, Bins, etc.:	Example 880 cartons, 20 bins
Telephone:	847-875-5253	Lot No./ID Marks:	VIPXXX ONLY IF CUSTOMER INSISTS!
Fax:	252-795-9972	Total Lot Size (lbs):	44000
SAMPLING AGENCY:		SAMPLING INFORMATION:	
In House <input checked="" type="checkbox"/> Third Party <input type="checkbox"/> Third Party Name and Address:		As a VASP participant, the memorandum of understanding (MOU) with the Almond Board of California has been signed, declaring that the almonds have been produced, handled, processed, packaged, and transported in line with good hygiene practices. From this consignment, representative incremental samples have been collected from throughout the lot to equal the aggregate weight of 20 kg., in accordance with the Commission Regulation (EC) No. 401/2006. The collected samples were submitted to the USDA/AMS-Approved Laboratory noted below.	
Shipping Notes: Place for additional notes - for example: Only shipped 19x2200 lb bins net weight = 41,800 pounds		Date/Time Sampled:	02-04-2010
		Destination (Country):	European Union
		By:	Sue Olson Sampling Agency Representative

To Be Filled Out By Laboratory
USDA/AMS-APPROVED LABORATORY

Lab Location	Third Party Name and Address:
	Test Lab
	123 test street
	Sacramento CA 95812

The representative incremental samples collected from the lot must all be mixed together to be sure that each sub-sample contains portions of the whole lot. Grinding should be accomplished by a method which not only reduces the particle size but also is effective in thoroughly mixing the particles to a homogenous grind and conforms to the USDA/AMS Laboratory Approval Program procedures.

Sample has been divided into 2x10kg subsamples. Each of the sub-samples has been individually ground and presented for analytical analysis. This sampling and analytical protocol are comparable to the parameters of Regulation (EC) 401/2006.

Sample has been analyzed using HPLC with a limit of quantification (LOQ) of _____ ppb for total Aflatoxin.

Sample has been analyzed using the _____ methodology with a detection limit of _____ ppb.

RESULTS:(ppb)	SUBSAMPLE 1	SUBSAMPLE 2	Date Sample Received: (mm-dd-yyyy):	00-00-0000
	B1 _____	B1 _____		
	B2 _____	B2 _____		
	G1 _____	G1 _____	Date Sample Analyzed: (mm-dd-yyyy):	00-00-0000
	G2 _____	G2 _____		
	Total _____	Total _____		

Draft Not Issued

This is a USDA/AMS-Approved Laboratory for Aflatoxin Analysis in almonds. Official methods of the AOAC as approved by the USDA/AMS are used in all analyses unless previous in-laboratory validation studies shows minor modifications can be made to the analytical procedures as approved by the USDA/AMS to provide consistent equivalent aflatoxin results. Reported results are not corrected for recovery or expanded measurement of uncertainty. Reports are for the exclusive use of the applicant. We certify to the truth and accuracy of this report as applying to the samples tested only.

BY: _____
Signature, Authorized Lab Representative

_____ Printed Name

CERTIFICATE DATE: 00-00-0000
(Certificate valid four months from issue)

This form is only a sample and should be modified to meet the needs of your particular operation.

U.S. Goods Return Procedures

Consignments of almonds rejected in Europe for exceeding EU aflatoxin limits have several alternatives:

- Request a retest
- Reprocessing in Europe
- Ship to another non-EU country/returned to U.S.
 - European authorities may require confirmation from the non-EU country's authorities that the goods will be accepted upon arrival
 - Almonds rejected in Japan must be returned to the U.S.
- Destroyed or diverted to non-food use

The following procedures outline the goods return process and can be applied to all almond shipments returned to the U.S. including those rejected for aflatoxin in the export market.

While the Consignment is in the Foreign Port

Before the Goods Can Be Returned to the U.S.

If the consignment will be returned to the U.S., some European authorities require confirmation that the goods will be accepted on arrival in the U.S. USDA and FDA have expressed a preference to work through the Almond Board of California rather than responding to individual requests. FDA has confirmed that ABC can respond to specific inquiries, and has provided a letter to ABC which outlines the U.S. regulations related to aflatoxin. Handlers who are requested to provide the letter to European authorities need to provide ABC with the information below. ABC

will prepare a letter incorporating the details provided, attaching the letter provided by FDA.

- Container number
- Shipping date/date of arrival
- Product description
- eVASP certificate number
- European aflatoxin results (a copy of the official lab results – Japanese authorities do not always provide this)
- Packer name
- Port of Return
- Contact details for European port authority (name, organization, fax number/email address)

Please send this information to Caroline Stringer at cstringer@almondboard.com or call 209.343.3256.

IMPORTANT: ABC will send the letter directly to the European import authorities, with a copy of the letter to the FDA/CFSSAN office in Washington, DC and the FDA District office (Alameda). A copy is also provided to the handler. Handlers can forward copies to interested parties (for example, their brokers in Europe).

FDA Inspection Process

Before Arrival in the U.S.

- The representative¹ responsible for filing for entry to the U.S. should provide the European aflatoxin analysis results and the Goods Return letter ABC provided to European authorities when submitting entry documents to FDA. At

¹ The representative responsible for filing for entry to the U.S. is referred to by several different names depending on the organization. FDA, for example, calls this individual the “filer” while other organizations call this individual the “broker.” In this document, the individual will be referred to as the representative.

Voluntary Aflatoxin Sampling Programs

the time the representative files these documents, an Entry Number is created by the representative.

Before the consignment arrives, FDA screens the documents using a computer program known as OASIS (Operational and Administrative System for Import Support). Once the consignment arrives, it may be inspected and detained by FDA's Compliance division even if the consignment was not flagged by OASIS.

- Prior to arrival at the U.S. port, handlers should provide ABC with the Entry Number for the consignment; this will be relayed to the FDA District office. This will facilitate FDA's ability to tie the returning consignment with the Goods Return letter – and, may help expedite FDA clearance.
- Even if the returned consignment tested below the U.S. aflatoxin limit, FDA may detain the consignment for further screening. Providing the aflatoxin analysis from the foreign laboratory prior to arrival of the goods may help keep it from being detained.

Upon Arrival in the U.S.

- If the returning consignment tested above the U.S. aflatoxin limit (20 ppb total) at the foreign port, the handler may be required to provide a reconditioning plan* to bring the consignment into compliance with U.S. standards without FDA performing sampling or analysis.
 - Do not provide this documentation until it is requested by FDA; ABC suggests preparing the reconditioning plan beforehand and keeping it on file until it is requested.
 - Once approved by FDA, the consignment is reconditioned under FDA supervision and released for circulation once it is demonstrated that the consignment conforms to U.S. aflatoxin limits.

- If the consignment is detained, FDA will send out a "Notice of FDA Action."** FDA may request the foreign laboratory results and/or analysis from a private laboratory*** to prove that the consignment complies with FDA standards.
- The consignment can be stored at the handler's warehouse with FDA approval while awaiting release.
- The FDA may also sample the consignment using its own lab for analysis
- Should the consignment be found noncompliant, FDA will send a "Notice of Detention and Hearing."

If no notice is received from OASIS, the goods are still subject to further scrutiny by FDA's compliance division. Importers should not assume that since the consignment was not detained after inspection of the entry documents that it will be released for circulation once it arrives.

- The Notice will provide a date by which the importer must present testimony or evidence that the consignment is compliant (usually, private lab analysis results****).
- If, upon review by FDA, the testimony or evidence is acceptable, FDA sends a "Notice of Release."**

Note: If, upon review by FDA, the consignment is not allowed for import into the U.S., the importer has the option to destroy or re-export the consignment. FDA sends a "Notice of Refusal of Admission" and must witness destruction of the consignment; or Customs Border Patrol will oversee the re-export of the consignment. Exporters should work with their brokers or filers to complete the necessary steps for either process.

Important Notes and Links

The FDA's Import Program Overview Web site is currently under revision but can be found at <http://www.fda.gov/ForIndustry/ImportProgram/ImportProgramOverview/default.htm>.

If using a private lab, ask if the staff has experience with FDA-detained goods. If they already know the protocols, this can save a considerable amount of time and money.

- * According to the FDA Regulatory Procedures Manual March 2009, Chapter 9, reconditioning plans must be submitted on a Form FD-766 Reconditioning Plan Proposal. These must be submitted in triplicate at a minimum and in quadruplicate if the handler wants a copy returned for records.
- ** According to the FDA Regulatory Procedures Manual March 2009, Chapter 9, all notices sent by the FDA are to be addressed to the representative, the importer of record, and the consignee designated on the entry documents. ABC understands that in most cases, FDA only notifies the representative. Handlers should expect either method of communication.
- *** FDA may detain consignments to test for any number of food quality or safety issues in addition to aflatoxin. The general experience with almonds returned for aflatoxin rejections is that they are detained for aflatoxin analysis but that does not mean that goods cannot be detained for inspection for other reasons.
- **** FDA does not defer to USDA-approved laboratories for VASP or VASP Protocols – the most significant difference is that FDA re-

quires a 50 lb sample. FDA's accepted sampling and analysis for aflatoxin in almonds differs from that of VASP. If private lab analysis results are provided to FDA, VASP protocols will not be recognized by FDA as sufficient for screening for aflatoxin. Handlers are encouraged to ask private lab managers if they have experience with testing FDA-detained goods before sampling.

For complete guidelines, please instruct private labs to use the following guidance documents:

- FDA Office of Regulatory Affairs (ORA) Laboratory Manual: Section 2 Chain of Custody – Sample Handling
- FDA Office of Regulatory Affairs (ORA) Laboratory Manual: Section 7 Private Laboratory Guidance
- FDA Office of Regulatory Affairs (ORA) Laboratory Manual Section 7 Mycotoxin Analysis
- FDA Inspections, Compliance, Enforcement, and Criminal Investigations Subchapter 4.5 – Sampling: Preparation, Handling, Shipping
- FDA Inspections, Compliance, Enforcement, and Criminal Investigations Chapter 6 – Mycotoxin Sample Sizes

FDA requires that private labs submit analytical worksheets or analytical packets with every submission no matter how many submissions to FDA they have made in the past. Should lab managers have any questions regarding what FDA will need in order to evaluate the results submitted, they should contact the FDA's Compliance Officer listed in the "Notice of Detention and Hearing." Anecdotal evidence suggests that emails are answered the fastest in most cases. If an email is sent to an FDA Compliance Officer, a copy should be sent to SanImportsCompliance@fda.hhs.gov as well.

This document has been reviewed by FDA's Import Operations Branch, San Francisco Office. For further information, please contact Caroline Stringer at 209.343.3256 or cstringer@almondboard.com.

Memorandum of Understanding (MOU)

Between

(Handler or Manufacturer)

and The Almond Board Of California

This MOU is hereby made and entered into by and between

(Handler or Manufacturer)

and the Almond Board of California (ABC).

Background

Aflatoxin is a probable human carcinogen, and as such, maximum tolerance levels for aflatoxin in food have been established worldwide. Some export markets, specifically the European Union (EU), have stringent tolerances for aflatoxin, resulting in a number of rejected almond shipments per year. If rejections continue, it is possible that even more stringent surveillance will be implemented, potentially causing additional disruption to trade. Along with the disruption to trade, there is a direct economic loss that results from rejected shipments.

In an effort to reduce the potential levels of aflatoxin in almonds and to provide customers with the highest-quality product possible, the industry has adopted a Voluntary Aflatoxin Sampling Plan (VASP) program as part of a comprehensive approach to address the aflatoxin issue.

MOU purpose

The purpose of this MOU is to acknowledge the partnership between the ABC and those handlers or manufacturers who have agreed to follow the testing and sampling protocols of the VASP program as outlined in this MOU and described in the VASP Program Manual. The VASP includes procedures for finished product sampling in-line sampling and sampling of manufactured items. Accurate recordkeeping is essential to the success of this program; participants in the program agree to allow ABC staff to periodically review records to ensure participants are performing in accordance with the VASP.

Participating in this program will ensure confidence in the quality of California Almonds and will demonstrate the industry's commitment to providing a safe and healthy food product worldwide.



General provisions

As a participant, I agree to comply with the following conditions as currently outlined in the VASP Program Manual, and I understand that a new MOU must be signed each crop year:

1. Implementation of Hazard Analysis and Critical Control Points (HACCP) principles for addressing aflatoxin control at the handler level for EU destined shipments.
2. ABC verification of handler compliance with the VASP via periodic review of relevant information, sampling programs and records, and documentation pertaining to HACCP principles. I understand that participation in VASP is conditional on compliance with VASP protocol. Either party may terminate the MOU at any time.
3. Agreement to allow company name to be included on a VASP participant list, which may be posted to the ABC website. Furthermore, I understand that removal of our name from the list indicates noncompliance with the program.
4. Each handler will utilize the eVASP or approved equivalent electronic system for reporting results unless ABC agrees to and exemption.
5. VASP certificate will accompany all EU shipments. If product is diverted from another country to the EU, an aflatoxin testing equivalent to the VASP program must be conducted prior to shipping. Please note: All shipments without a VASP certificate will be tested in the EU.

By initiating the VASP certificate, I certify that the almonds covered by the certificate have been processed, packed and stored in line with good hygienic practices and will be transported to the EU in a container that is consistent with good hygienic practices (e.g., food-grade container).

This is a voluntary, nonbinding agreement. The signature signifies willingness to implement VASP procedures and practices as outlined in both this MOU and the Voluntary Aflatoxin Sampling Program (VASP) Program Manual updated Jan. 5, 2010.

Company Name: _____

Signed: _____ Date: _____

Name (print): _____

For ABC use only:

Almond Board of California

Accepted this _____ day of _____, 2010

for the crop year 2009/2010 ending July 31, 2010.

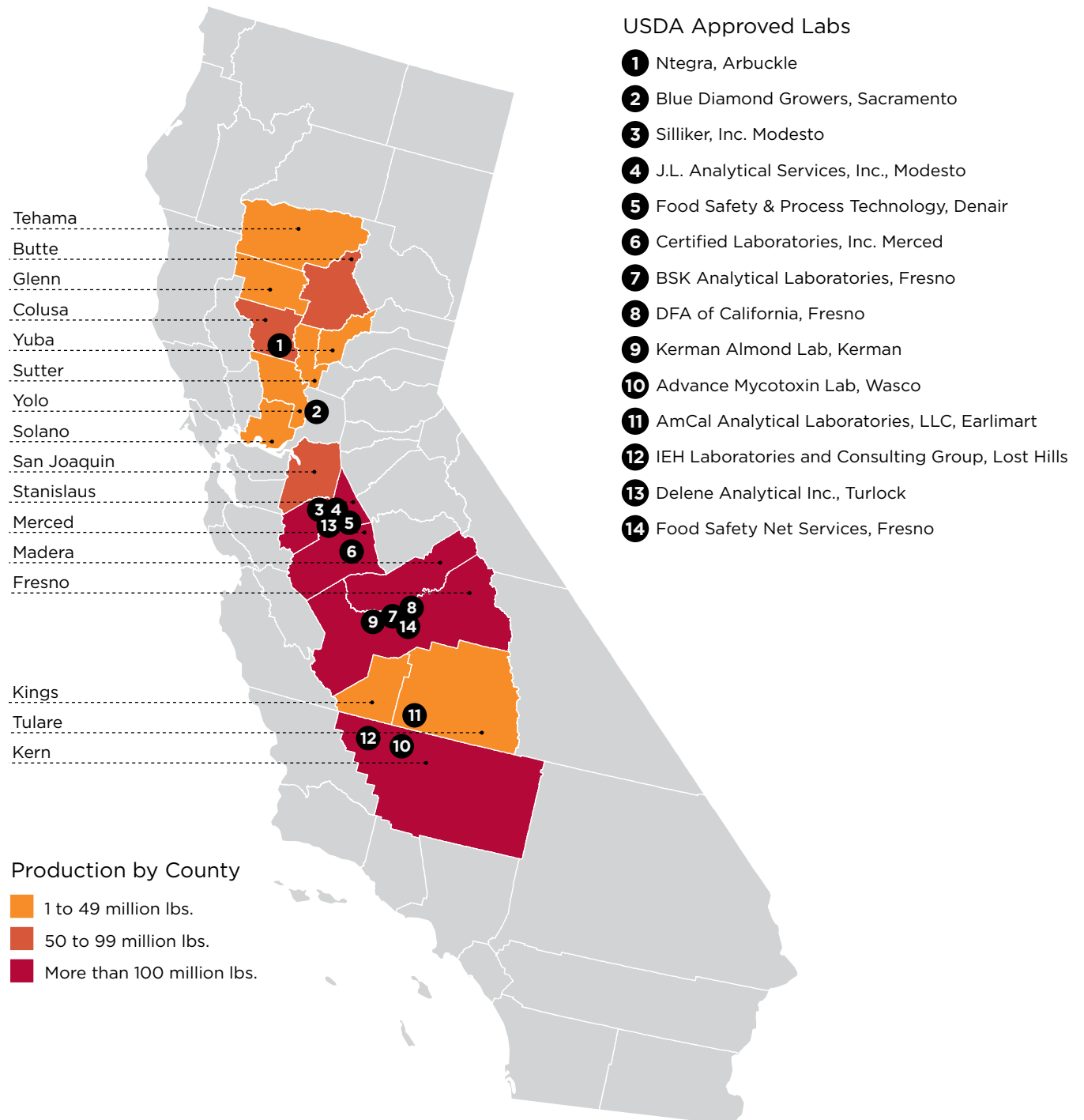
Signed _____ Date: _____

Tim Birmingham
Associate Director, Quality Assurance & Industry Services

Revised: 3/09/10

USDA Approved Labs

Aflatoxin in Almonds Approved Lab Program





Almond Board of California, 1150 Ninth Street, Suite 1500, Modesto, CA 95354 USA