United States Export Fumigation of Almonds to India Pilot Accreditation Program

Animal and Plant Health Inspection Service
Plant Protection and Quarantine

USDA APHIS
Plant Protection and Quarantine

STANDARDS
FOR
PHYTOSANITARY MEASURES

REQUIREMENTS FOR PARTICIPANTS IN THE EXPORT FUMIGATION OF ALMONDS TO INDIA PILOT ACCREDITATION PROGRAM

March 31, 2008

United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection and Quarantine
Riverdale, MD

REVIEW

Plant Protection and Quarantine Standards for Phytosanitary Measures are subject to periodic review and amendment. The present document is a working document for use during the pilot stage for the implementation of the US Export Fumigation to India (EFAI) Accreditation Program. It will be finalized at the end of the pilot stage. The finalized Standard will have its first review one year after its completion.

ENDORSEMENT

Approved by:

_____

USDA APHIS PPQ

AMENDMENT RECORD

Amendments to this Standard will be dated and filed with APHIS Headquarters in Riverdale, MD.

INTRODUCTION

This protocol establishes the requirements for accreditation of facilities to conduct export fumigation of almonds to India. It also describes the responsibilities of Animal and Plant Health Inspection Service, State and County Co-Operators, and Industry participants, in addition to describing requirements for approving, auditing and suspending facilities from the Program.

A. SCOPE

This protocol specifies the requirements which must be met by exporting facilities of almonds in order to be accredited in the pilot for Export Fumigation of Almonds to India (EFAI) accreditation program. Parties accredited under EFAI are accredited **only** to perform fumigations for almonds to be exported to India. Other phytosanitary requirements – such as official inspections, applying for and receiving certificates, etc. – are **not** part of this program, and must be achieved by exporters separately. This protocol outlines the requirements of the EFAI which includes:

Application Process;
Approval Process;
Auditing of Approved Facilities;
Quality Assurance Manual Requirements;
Responsibilities for Accredited Facilities and their staff; and
Responsibilities of Federal, State/County and Industry.

B. REFERENCES

U.S. Department of Agriculture, Plant Protection and Quarantine Treatment Manual.

C. DEFINITIONS, ABBREVIATIONS AND ACRONYMS

For the purposes of this program, the specified terms, abbreviations and acronyms are defined as follows:

ACO - Authorized Certification Official (NAPPO RSMP No 5, 2004)

Accreditation Manager (AM) - A member of the accredited facility's management team or ownership who has the authority to implement actions required under the EFAI and Corrective Action Requests.

Accredited Facility (AF) - A facility involved in the export of Almonds to India whose management has signed an application for designation in the EFAI program which is in compliance with the terms and conditions of the EFAI program.

APHIS - The Animal and Plant Health Inspection Service of the United States Department of Agriculture

CDFA - California Department of Food and Agriculture

CDA - County Department of Agriculture

CFR – Code of federal regulations

Certifiable Chamber - Permanent structure with four solid walls that passes a positive pressure test

EFAI -Export Fumigation of Almonds to India

External Audit - An objective appraisal of the EFAI program at a facility that is carried out by an APHIS Audit Team

Facility Evaluation - The initial verification that a facility is capable of competently fulfilling the specifications outlined in their Quality Assurance Manual (QAM), and that those specifications clearly meet the requirements of the EFAI program when used in a practical application OR part of the acceptance process when a facility wishes to be reinstated in the program after a suspension or voluntary withdrawal.

FAO – Food and Agriculture Organization of the United Nations

Internal Audit - An objective appraisal of the EFAI conducted under the direction of the facility's Accreditation Manager.

ISPM – International standard for phytosanitary measures

NAPPO – North American Plant Protection Organization

Non-Conformance - Failure to comply with a requirement of the EFAI standards

PCB (Pest Control Business)- see Pest Control Operator (PCO)

Pest Control Operator (PCO) - An individual who is employed by or contracted by an accredited facility, and who is responsible for conducting and monitoring fumigations/treatments of almonds as described in the QAM. The individual may have a Pest Control Business (PCB) License if contracted and/or a Qualified Applicator Certificate (QAC) and/or a Qualified Applicator License (QAL).

Phytosanitary Certificate - An official document issued by the Plant Protection Organization of the exporting county to the Plant Protection Organization of the importing country. It attests that the plants or plant products covered by the certificate have been inspected according to appropriate procedures, and are considered to be free from regulated pests and practically free from other injurious pests, and that they are considered to conform to the current phytosanitary requirements of the importing country.

PPQ - Plant Protection & Quarantine

Practically Free - A consignment, without pests (or a specific pest) in numbers or quantities in excess of those that can be expected to result from, and be consistent with good culturing and handling practices employed in the production and marketing of the commodity (FAO 2005, ISPM 5).

Procedure - A written description of the steps used to carry out an activity or process. A procedure also indicates the purpose and scope of the activity and identifies who has the authority to perform the activity. Any record or form associated with the activity must be referenced or attached to the procedure. Definitions may be included, if appropriate.

Qualified Applicator Certificate (QAC)/ Qualified Applicator License (QAL) - See Pest Control Operator (PCO)

Quality Assurance Manual (QAM) - Document stating/outlining the specific operations in place in a given facility that meet the requirements of the EFAI standards.

Quarantine Pest - A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled (FAO 2005, ISPM 5).

Record - A piece of evidence or information constituting an account of something which has occurred. For the purpose of this protocol, a record is used to verify continuous compliance with the EFAI program and to demonstrate that procedures have been carried out as specified in the Quality Assurance Manual. Records must include the date that the activity was carried out, the signature of the designated person that carried out the activity, specific information related to the activity, comments and notes describing any deviation from described procedures.

RSPM – Regional standard for phytosanitary measures

State Plant Health Director (SPHD) - Individual who directs all work within the State of California for USDA, APHIS, PPQ activities.

Surveillance Audit - Continual monitoring and verification of the status of an entity/facility and analysis of records to ensure that specified requirements are being fulfilled. For the purposes of this document this definition is taken to mean: a verification that the status of the EFAI program and records conform to the QAM.

Suspended Status - Facilities in suspended status are not allowed to ship material under the EFAI program. The facility will be removed from the registry of approved facilities until corrective actions are completed to the satisfaction of APHIS.

Systems Audit - A systematic examination of the organizational structure, procedures, processes and resources used in implementing the EFAI Program within the accredited facility. The objective of a systems audit inspection is to review the system and determine whether all the required procedures have been identified in the QAM and that those continue to be sufficient to meet the requirements of the EFAI program.

USDA - United States Department of Agriculture

1.0 GENERAL REQUIREMENTS

1.1 LEGISLATIVE AUTHORITY

Plant Protection Act of 2000
7 CFR 353 and 354

1.2 FEES

2.0 SPECIFIC REQUIREMENTS

2.1 APPLYING FOR ACCREDITATION

Eligible applicants are packing facilities/sheds in the State of California.
To apply for accreditation under EFAI, the facility (or facility management) must:

1. Be located in United States;

2. Have completed, signed and forwarded to the APHIS Riverdale Office an application for designation in the EFAI Accreditation Program indicating that they are willing and able to comply with the terms and conditions of the Program;

3. Submit a Quality Assurance Manual (QAM) clearly stating how they will meet EFAI program requirements;

4. Designate qualified individuals to be the Accreditation Manager and the Pest Control Operator; and,

5. Allow APHIS, State, and county representatives to undertake an initial Facility Evaluation of the treatment system, and perform audits and reviews as necessary during the export shipping season.

2.2 APPROVAL PROCESS

The approval process consists of review of the application submitted by the facility, review of the QAM and the final facility evaluation. If these are all found to be satisfactory, the facility is approved.

2.2.1 DOCUMENT REVIEW

APHIS will review the Application for Designation form to ensure that the facility is eligible for approval under the EFAI Pilot Program and that the application is complete and signed. APHIS will also review the EFAI Pilot QAM to ensure that it contains all the required elements and that it is sufficient to meet the requirements of this protocol. APHIS may require the facility to revise or rewrite their EFAI Pilot QAM prior to approval. Once APHIS considers that the EFAI Pilot QAM satisfies the requirements of the EFAI program, APHIS will recommend the facility for consideration. The EFAI Pilot QAM must be approved before the facility undergoes the next stage of the approval process, the Facility Evaluation.

2.2.2 QUALITY ASSURANCE MANUAL

Each facility will develop and submit a QAM for approval by USDA-APHIS-PPQ, State and County Departments of Agriculture. The manual will address the standards as identified by this agreement. A template will be provided for developing the QAM. Each facility will have to develop, submit, and have their QAM approved in order to be eligible for full accreditation.

USDA-APHIS and State/County cooperators will evaluate the QAM to ensure the Program requirements are being met and can be implemented by the facility. The QAM may need to be updated to meet the requirements identified in these reviews. Once the manual has been approved, a facility evaluation will be arranged and conducted by APHIS and the State/County cooperators.

2.2.3 FACILITY EVALUATION

Once the Application is received and the EFAI QAM is approved by APHIS, an APHIS audit team will carry out a Facility Evaluation. The purpose of the evaluation is to determine whether the facility has the infrastructure and staff in place that would permit it to successfully implement the fumigation operation and safeguarding as described in the QAM, and meet all the requirements outlined in its EFAI QAM. The facility must meet all requirements as described in their QAM. During the Facility Evaluation, there will also be a comprehensive review of the workflow schematic in relation to the facility layout to ensure adequate safeguarding. A written

audit report summarizing the findings of the Facility Evaluation will be prepared and submitted within three weeks (21 days) of the evaluation.

2.2.4 APPROVAL

Once APHIS is satisfied that the facility's QAM meets the requirements of this protocol, and that the facility has the capacity to effectively implement all the procedures described in their QAM, the facility can be considered to be an AF. Each AF approved under the EFAI Program will be assigned a unique facility number by the Almond Board of California (ABC), who will provide a master list to the USDA-APHIS-PPQ State Plant Health Director (SPHD).

Parties accredited under EFAI are accredited only to perform Phosphine fumigations for almonds to be exported to India. Other phytosanitary requirements such as official inspections, applying for and receiving certificates, etc., are independent of this program and must be achieved by exporters separately.

2.3 AUDITING OF APPROVED FACILITIES

The facility must undergo a yearly systems audit, periodic surveillance audits by the County, and must conduct their own internal audits to assure conformity with program requirements.

The initial treatment of each facility needs to be monitored by County and/or APHIS officials at the time of gas introduction and at the time of treatment completion.

2.3.1 SYSTEMS AUDIT

A systems audit is a complete review of the facility's fumigation operation. A systems audit is conducted each year by a joint Federal/County audit team.

2.3.2 SURVEILLANCE AUDITS

- The County Department of Agriculture must conduct up to four surveillance audits during the shipping year for the first year as deemed necessary. These audits may be reduced the second year based on prior performance. Surveillance audits will identify any non-conformances and make recommendations for corrections and provide the facility with a specified time period in which to make corrections. The audit team will return after the specified time period to ensure all corrections have been made. In the event of a critical non-conformance the county will notify the SPHD of California, with a copy of the notification sent to the designated APHIS representative in Riverdale, Maryland. A report of the audit results will be provided to the facility and APHIS within three weeks of completing the audit; and
- APHIS may elect to participate in surveillance audits.

2.3.3 INTERNAL AUDITS

The EFAI manager or their backup will conduct a minimum of four internal audits each year of operation under the EFAI. APHIS, State and County Agriculture officials may elect to

participate in internal audits as needed. These audits will identify any deficiencies or non-conformances and implement corrective actions. Records of the audits will be documented and maintained at the facility to support surveillance audits. In addition, a detailed report must be prepared within three weeks of conducting each audit.

3.0 NON-CONFORMANCES

Non-Conformances are violations of the standards and are classified as Critical, Major, or Minor Classification of Non-Conformances.

3.1 CRITICAL NON-CONFORMANCE

A critical non-conformance is any single finding that reveals that the integrity of the EFAI Program is jeopardized. Phytosanitary certificates cannot be issued because this non-conformance violates the integrity of the certificate. In the event of a critical non-conformance, the facility will be immediately suspended from the EFAI Program in the event of a critical non-conformance.

The following list provides examples of critical non-conformances, but is not comprehensive:

- ☐ Detection of live pests of quarantine significance by the importing country;
- ☐ Failure to keep treated almonds separate from non-treated almonds; commingling is not allowed;
- ☐ Failure to safeguard treated almonds while placed in storage or after processing awaiting shipment to India;
- ☐ Failure to perform internal audits as required;
- ☐ Facility is operating without an AM or Pest Control Operator;
- ☐ Failure to keep consistent accurate pest management records of post harvest treatment, storage, and shipment;
- ☐ Failure to undertake ordered corrective action(s) as directed by Audit team in the specified time frame;
- ☐ Failure to have sufficient, adequately trained staff in place to meet the requirements of the EFAI;
- ☐ Facility modifies their QAM and/or implements changes without prior approval from APHIS;
- ☐ Pest Control Operators or Contract Fumigators operating with an expired license; and
- ☐ More than two major non-conformances are detected at an AF during a single audit.

3.2 MAJOR NON-CONFORMANCE

A major non-conformance is any single isolated incident of non-conformance that has no direct impact on the integrity of the product provided that corrective actions are completed within the time frame specified by a lead auditor. Should the facility fail to complete the corrective action in the specified time frame, the non-conformance becomes a critical non-conformance and the facility is suspended from the Program. If more than two major non-conformances are detected during a single audit, the non-conformance is considered a critical non-conformance and the facility will be suspended from the EFAI Program.

The following list provides examples of major non-conformances:

- ☐ Failure to notify APHIS when the Program AM changes;
- ☐ Failure to have a designated backup for the AM;
- ☐ Failure to provide records/reports as requested;
- ☐ Failure to maintain records of calibration and servicing of fumigation equipment;
- ☐ Failure to undertake corrective actions ordered by the AM (from an internal audit) in a timely manner;
- ☐ Improper safeguarding of treated commodities;
- ☐ Use of unauthorized/non-certified chambers (if so being used);
- ☐ Failure to satisfactorily meet phytosanitary requirements;
- ☐ Failure to consistently sign and date reports or records; and
- ☐ More than three minor non-conformances are detected at an AF during a single audit.

3.3 MINOR NON-CONFORMANCE

Minor non-conformances are those that do not immediately or significantly affect the status of the product or the integrity of the fumigations performed, but could lead to a major non-conformance if not addressed. The designated facility must take remedial action before the next audit or within the time frame provided by a lead auditor. If more than three minor non-conformances are detected during the inspection, the classification of the non-conformance is changed to a major non-conformance. (For example, five minor non-conformances are equal to one major non-conformance and one minor non-conformance; whereas, eight minor non-conformances are equal to two major non-conformances and results in suspension of the facility).

The following list provides examples of minor non-conformances:

- ☐ Failure to observe good facility management practices and safety with respect to treatment;
- ☐ Failure to maintain written training records for staff involved in treatments;
- ☐ Failure to maintain training records for staff involved in implementing the EFAI Quality Assurance Pilot Program;
- ☐ Failure to maintain an up-to-date list of all employees involved in implementing the EFAI Quality Assurance Pilot Program;
- ☐ Failure to provide complete treatment data in the APHIS specified format within 48 hours of the request by APHIS; and
- ☐ Documents not signed.

3.4 REINSTATEMENT OF SUSPENDED FACILITY

If a facility is suspended due to non-conformance, it must petition USDA-APHIS for reinstatement. It must demonstrate to the satisfaction of USDA-APHIS that all corrective actions have been made. In the case of live quarantine pests being intercepted upon export inspection or at destination, an investigation and full systems audit will be conducted prior to reinstatement.

4.0 RESPONSIBILITIES

4.1 FACILITY MANAGEMENT AND STAFF RESPONSIBILITIES

- Appoint an Accreditation Manager and backup for the EFAI Accreditation Program. This individual will ensure that the standards and requirements of the Program are adhered to. The contact EFAI manager will conduct the internal audits and record the findings as required under the Program.

- Provide a list of all personnel involved in the export fumigation program at the accredited facility. This information must include each person's name and responsibilities. This can be provided in an Appendix, so that any future changes to personnel can be readily updated.

- Have the necessary equipment to conduct and monitor the fumigations as identified in the USDA-APHIS Treatment Manual.

- Conduct the export fumigation using approved labeled schedules for phosphine. Use treatment procedures as identified in the USDA-APHIS Treatment Manual.

- Monitor the fumigations as prescribed and take the necessary reading as required by the USDA-APHIS treatment schedule.

- Ensure all treatment equipment is calibrated by an authorized entity and maintain calibration records.

- Record all treatments and sign the treatment records. Provide electronic or hard paper copies of all treatment data to APHIS on demand in the format specified by APHIS. See Appendix B, Fumigation Record Worksheet, for the data format.

- Inspect almonds to ensure efficacy of treatment prior to export certification.

- Provide a system of safeguarding of all treated product against re-infestation. Submit current facility layout diagrams with corresponding work processes that demonstrate a standard operating procedure for safeguarding is in place.

- Provide a system of traceability for treated commodities and maintaining product identity.

- Maintain treatment, equipment certification/calibration and internal audit records for a minimum of three years.

- Conduct internal audits of the program as prescribed and maintain records of these audits for a minimum of three years.

- Notify APHIS and the CDFA/CDA of changes in the program or of personnel changes within 10 working days.

- Provide all requested records and access of the facility for systems and surveillance audits to APHIS, state, and county officials.

- Make corrective actions as identified by APHIS and or State/County in the time period identified.

Treatment Operations and Schedules

The facility will conduct fumigation operations as prescribed by the USDA-APHIS Treatment Manual and use appropriate safety equipment. The facility will retain a copy of the USDA-APHIS Treatment Manual segment on phosphine as part of the QAM. This segment of the treatment manual can be presented as an appendix to the QAM.

Treatment Schedules

The facility will adhere to the treatment schedule as provided in Appendix A to this Standard. The facility will use the temperature, duration and dosage as prescribed.

Certified Chambers

No concentration readings are required for certified chambers. The PCO will take temperature readings at least every 24 hours and the record the temperature readings on the Appendix B, Fumigation Record Worksheet. **Certified/Certifiable chambers are permanent structures with four solid walls that pass positive pressure tests. Chambers must be certified by Federal, State, or County personnel.**

Non-Certified Structures

The PCO will take concentration and temperature readings at least every 24 hours and will record treatment concentration levels (ppm) and temperature readings on the Fumigation Record Worksheet form. The format of Appendix B, Fumigation Record Worksheet, should be followed for treatment data collection and submission.

Record Keeping

The participating facility will maintain records of all treatments for a minimum of three years and provide this data in the format specified by APHIS upon request.

The facility will keep on file copies of the pesticide applicator certificate/license(s). The facility will maintain training records of all applicators and of all staff involved in the treatment operation.

The facility will maintain records on internal audits and make them available upon the request of the audit team.

The facility will maintain service records of fumigation equipment.

The facility will maintain a current QAM.

4.2 STATE/COUNTY RESPONSIBILITIES

The CDFA and/or the County Department of Agriculture are responsible for the following:

- Identify those packing facilities interested in participating in the Program.
- Each county will approve the Application for Designation in the EFAI Accreditation Program (Appendix I) and provide a copy to CDFA.
- Re-certify chambers for fumigation as applicable for the upcoming export shipping season.
- Conduct physical commodity inspections before issuance of Federal Phytosanitary Certificates.
- Assist USDA-APHIS as part of the evaluation team in reviewing each of the QAM.
- Assist USDA-APHIS in a systems review of each facility to authorize their participation in the Program.
- Conduct Surveillance Audits on a prescribed schedule to ensure compliance with the protocol.
- Provide the facility with a final report on the surveillance audit three weeks after the review is concluded. Supply the APHIS-SPHD office with a copy of the report.
- Identify any non conformance, and if critical, advise USDA-APHIS immediately.

4.3 USDA/APHIS/PPQ RESPONSIBILITIES

USDA-APHIS is responsible for the following:

- Provide oversight of the EFAI Program.
- Review and approve the QAM.
- Lead the initial Systems Audit of facilities in collaboration with the County. APHIS may elect to participate in surveillance audits.
- Perform quality assurance audits of the program including facilities and treatments performed.

- Maintain a list of registered facilities.
- Provide formal notification of accreditation to the facilities once approved.
- Make final decision on suspension and reinstatement of facilities.
- Perform initial certification of all chambers including all certifications during the pilot program and new chambers for use at accredited facilities.

4.4 ALMOND BOARD OF CALIFORNIA RESPONSIBILITES

The Almond Board of California is responsible for the following:

- Assign a unique facility number to each participant.
- Provide list of participants to the APHIS-SPHD office and the APHIS Riverdale office.

APPENDIX A

FUMIGATION DOSAGE REQUIREMENTS

When conducting any phosphine treatment to India, the commodity temperature must always be at or above 5 degrees Celsius (41 degrees Fahrenheit). There are no exceptions.

Commodity temperature	Exposure in days
5-9.9 C (41-49.9 F)	10
10-14.9 C (50-58.9 F)	8
15-19.9 C (59-67.9 F)	4
20-24.9 C (68-76.9 F)	3
25.0 C and above (77 F and above)	2

The use of a phosphine/carbon dioxide mixture, such as $ECO_2FUME^{®}$, is allowed but it must meet the same temperature and time durations as stated above for phosphine pellets, tablets, bags or trays.

- For pellets, tablets, bags, trays and $ECO_2FUME^{®}$ the application rate of phosphine is $40gm/1000ft^3$.
- $ECO_2FUME^{®}$ application rate: $40gm/1000ft^3 = 4.41\ lbs/1000ft^3$

APPENDIX B

FUMIGATION RECORD WORKSHEET

Commodity Tracking #: **Accreditation Manager Name:**

Facility ID #: **PCO Name:**

TREATMENT INFO									READINGS					
Fumigation Date/Time	*Fumigant*	*Fumigant Form*	*Treatment Schedule*	*Treatment Duration*	*Mass of Fumigant*	*Enclosure Volume*	*Commodity*	*Lbs. of Commodity*	*Date/ Time*	*Concentration*	*Temp Min*	*Temp Max*	*Aeration Time*	*Initials*
Comments:														

FUMIGATION RECORD WORKSHEET

Commodity Tracking #: **Accreditation Manager Name:**

Facility ID #: **PCO Name:**

TREATMENT INFO									READINGS					
Fumigation Date/Time	*Fumigant*	*Fumigant Form*	*Treatment Schedule*	*Treatment Duration*	*Mass of Fumigant*	*Enclosure Volume*	*Commodity*	*Lbs. of Commodity*	*Date/ Time*	*Concentration*	*Temp Min*	*Temp Max*	*Aeration Time*	*Initials*
Comments:														

APPENDIX C
EXTERNAL AUDIT CHECKLIST

	Audit Criteria	Yes	No	Comments and/or Corrective Actions	Corrective Action Due Date
1	A valid application for participation in the EFAI is signed and maintained.				
2	A designated Facility EFAI Accreditation Manager (AM) has been assigned and has a thorough understanding of the program, and can demonstrate the capability to fulfill requirements.				
3	A backup to the EFAI AM is assigned.				
4	Facility has an assigned applicator. (QAC or QAL with Category "A" indicated on certificate or license) or facility indicates a licensed and registered PCB it has contracted with to perform fumigations.				
5	Facility has the necessary equipment to conduct and monitor fumigations. This may include certified chambers.				
6	Conducts export fumigations using approved label schedule and USDA-APHIS procedures as per the Treatment Manual. A copy of the label is available for review.				
7	Monitors the fumigations, takes the necessary readings, and records them. Records are available and complete.				
8	Records of all treatments are documented and signed.				
9	The facility provides electronic treatment data or hard copy upon request.				
10	Records of any required periodic equipment calibration are maintained and are available upon request.				
11	The facility conducts post treatment inspection of commodity to ensure efficacy of treatment.				
12	A system is in place to ensure safeguarding of treated commodity and no commingling with untreated product.				
13	A facility diagram documenting work processes and standard operating procedures is current and available upon request.				
14	A system of traceability for treated commodities is maintained for product identity. Provide explanation of box and label markings and/or barcodes.				
15	A system of records for treatments, equipment calibration, and internal audits is maintained for the time specified in the EFAI Accreditation Program standards.				
16	Facility conducts internal audits and maintains records of the audits.				

17	A list of all other staff involved in the export fumigation program is available and contains each person's name and responsibilities.				
18	Notifies APHIS and State/County of personnel changes as applicable.				
19	Has identified staff or consultant to develop EFAI Quality Assurance Manual.				
20	Has successfully demonstrated the fumigation operation to the satisfaction of the Export Certification Specialist (ECS) and/or Authorized Certification Official (ACO).				

Name and address of Facility: _____

_____
_____
_____
_____

Facility Accreditation Manager (AM): _____

County Inspector: _____

APHIS Inspector: _____

Date of Inspection: _____

APPENDIX D

ACCREDITATION PROGRAM
EXPORT FUMIGATION OF ALMONDS TO INDIA
QUALITY ASSURANCE MANUAL TEMPLATE

Introduction: This template is intended to provide guidance to facilities in the development of their Quality Assurance Manual (QAM). In order to ensure that all requirements of the program are met, this template must be used, in association with the Export Fumigation of Almonds to India (EFAI) Standards, in the development of the facility's QAM. To expedite the review of QAM's, facilities are requested to adhere to the order of components in the template. Failure to do so may result in return of the QAM for resubmission.

CONFIDENTIALITY: QAM's are considered to be confidential and proprietary documents.

GENERAL REQUIREMENTS

The QAM must be in an electronic format, dated and signed by the Accreditation Manager (AM).

The title page must include the name, address, and phone number of the facility, the date, and the name and email of the person who prepared the document.

The facility's QAM must include an amendment sheet which provides space to document any additions, omissions or changes to the document, the date they were made and who authorized the change.

ADMINISTRATION

1. Management Commitment

The facility's management is responsible for the development and maintenance of the export fumigation and safeguarding program. The commitment of the facility's management will ultimately be responsible for the success of the program.

The facility's QAM must include statements in which:

a. Management commits to ensuring that the procedures described in the QAM are effective for maintaining the integrity of certified plant material and that all procedures described therein are fully implemented;
b. Management commits to the allocation of resources necessary to implement changes, procedures, corrective actions and otherwise ensure compliance with the EFAI Standards.

2. Staff Responsibilities

The facility's QAM must include the identification of specific management names and titles, such as:

a. President and/or Owner;
b. General Manager;
c. EFAI Accreditation Manager; or
d. Pest Control Operator or name of the Certified Applicator;

Management must assign the responsibility of implementing the export fumigation to qualified staff members and:

a. Provide a list of the titles, specific duties and responsibilities (as relates to the EFAI Accreditation Program) of all staff involved in implementing the program; and
b. Provide for those positions the names of qualified alternates.

A list of personnel involved in the program should be provided in Appendix 1.

3. Training

Management must ensure that the facility has sufficient capable, trained staff employed to carry out the requirements of the EFAI Accreditation Program and must identify all employees involved in the implementation of the facility's fumigation program.

All employees involved in conducting fumigations under the EFAI program must receive training which will provide a general understanding of the program and the management system. Staff must have specific training related to those components for which they have a responsibility. The facility must describe their training program which covers the operational aspects of the EFAI.

The facility must provide a copy of the PCB/QAL/QAC in Appendix 2.

4. Export Fumigation Process/Operation

The facility's Manual must describe:

a. The physical layout of the facility and the flow of commodity through the facility, which is also illustrated on a labeled map of the facility as referenced in an Appendix 3;
b. The equipment used to conduct and monitor the fumigation, and the type of fumigation that will be applied, i.e., an approved chamber fumigation, tarpaulin;
c. Treatment schedule to be used. Provide a current pesticide label, MSDS, and USDA treatment manuals segment on Phosphine (this can be done in Appendix 4);

d. Procedures for maintaining and calibrating equipment;
e. System for traceability of the commodity including explanation of box and label markings;
f. Procedures for Safeguarding treated commodities; and
g. Procedures for documenting treatment results, including:
    - Type and quantity of material treated;
    - Location of material treated;
    - Date of treatments;
    - Name of person(s) conducting the treatments; and
    - Treatment schedules used, dosage, duration, temperature, and concentration readings at 24 hour intervals for non-certified structures;

    See appendix B, for the form "Fumigation Record Worksheet" that is to be used for documenting treatment results.

5. Internal Audits

The Accreditation Manager must perform, or designate parties to perform, a minimum of four internal audits per shipping year.

The facility's Manual must describe:

a. Procedures which are in place to ensure that internal audits are conducted according to the frequency specified in the EFAI Standard;
b. Procedures which are in place to ensure that an audit report is prepared within three weeks of the audit;
c. Procedures for conducting internal audits and the responsible staff member(s). (An auditor may not audit their own area of responsibility);
d. Procedures for generating corrective action reports for each non-conformance which is identified and classifying the status of each non-conformance (i.e. critical, major or minor);
e. Procedures to ensure that corrective actions are completed in a timely fashion and to prevent reoccurrences of non-conformances; and
f. Procedures to ensure immediate notification of USDA and the State or County Department of Agriculture when any critical non-conformance is present or suspected in the facility or in product purchased or sold by the facility.

6. Records Management

Access to EFAI records should be limited. Records must be maintained for a minimum of three (3) years, regardless of the current status or participation of the facility in the EFAI.

The Manual must include:

a. The names, titles and responsibility of persons who will have access to the records for alteration;

b. Procedures for maintaining all documents, reports and records associated with the program for three years. These records must be maintained regardless of the facility's status or participation in the program; and
c. Procedures to ensure the most up-to-date versions of the reference documents are readily available to all individuals implementing the Program. This includes:
    - Certified Facility's Quality Assurance Manual.
    - EFAI Standard;
    - USDA APHIS Treatment Manual section on Phosphine
    - Pesticide Label
    - MSDS

7. Record of Manual Changes

A record of all changes to the EFAI QAM, such as revisions to the Appendixes, must be maintained, along with a copy of the QAM in its original form. A Record of Manual Changes should follow the title page of the QAM.

APPENDICES

Following are items that may be better addressed in the form of appendices. In cases where forms are supplied, forms must be identified in such a manner that their purpose is clear. Each appendix must be clearly labeled, use of an introduction page may be necessary in some cases for clarity. Suggested titles follow, each title would be a separate appendix (other appendices may be necessary depending on the facility's operations):

Appendix 1

Managerial and staff responsibilities and a list of personnel involved in the program.

Appendix 2

QAL/QAC License(s)/Certificate(s)

Appendix 3

Map of physical layout of the facility and the flow of commodity through the facility.

Appendix 4

Phosphine pesticide label, treatment schedule (Appendix A), MSDS, and USDA Treatment Manual section on Phosphine.

Appendix 5

An example of an Internal Audit Checklist and an example of a Corrective Action Request.

Appendix 6

Any other relevant record keeping documents such as:
Fumigation Record Worksheet (Appendix B), equipment maintenance records, records of fumigation chamber certification, and training records.

Appendix 7

Indication of where the EFAI standards are kept at the facility and who is in charge of ensuring facility has the current version of standards.

APPENDIX E
EFAI QAM CHECKLIST

Facility Name: _____

Date:_____

Reviewer:_____

I.	**General Requirements**
___	The QAM must be in an electronic format, dated and signed by the Accreditation Manager.
___	The title page must include the name and address of the facility, phone number, the date, and the name and email of the person(s) who prepared the document.
___	A record of manual changes or amendment sheet must be included that provides space to document any additions, omissions or changes to the document, the date they were made and who authorized the change(s).
II.	**Administration**
1.	**Management Commitment**
___	A statement of commitment of the EFAI Program by management of the facility.
2.	**Staff Responsibilities**
___	Identification of specific management names and titles such as president and/or owner, general manager, EFAI Accreditation Manager, pest control operator.
___	Provide a list of the titles, specific duties, and responsibilities (as it relates to the EFAI Program) of all staff involved in implementing the program.
___	Provide a list of qualified alternates to item above.
___	List of personnel involved in the program listed in Appendix 1.
3.	**Training**
___	Description of training program which covers operational aspects of EFAI including mention of training documentation record retention (3 years) and who maintains the training records.
___	Program includes training about the EFAI program.
___	Appendix 6 contains an example of a training record.
___	Appendix 2 contains a copy of the QAL/QAC license(s).

4.	**Export Fumigation Process/Operation**
___	Describe the physical layout of the facility and the flow of commodity through the facility which is also illustrated on a labeled map of the facility along with a commodity flow chart as referenced in Appendix 3.
___	Describe equipment used to conduct and monitor fumigations, and type of fumigation that will be applied, i.e., an approved fumigation chamber, tarpaulin, etc.
___	Treatment schedule to be used.
___	Provide current pesticide label, MSDS, and USDA Treatment Manual section on phosphine as referenced in Appendix 4.
___	Program on equipment maintenance and calibrations.
___	System for traceability of the commodity including explanation of box and label markings.
___	Procedures of safeguarding treated commodities, including signage during storage if applicable.
___	Procedures for documenting treatment results.
___	Fumigation Record Worksheet referenced and sample placed in the QAM Appendix.
5.	**Internal Audits**
___	Describe procedures to ensure that internal audits are conducted according to the frequency specified in the EFAI Standard (a minimum of four internal audits required per shipping year).
___	Procedure to ensure that an audit report is prepared within three weeks of audit.
___	Procedure for conducting internal audits and the responsible staff member(s). An auditor may not audit their own area of responsibility.
___	Procedure for generating corrective action reports for each non-conformance which is identified and classifying the status of each non-conformance (i.e., critical, major, or minor non-conformance).
___	Procedures to ensure that corrective actions are completed in a timely fashion and to prevent reoccurrences of non-conformances.
___	Procedures for immediate notification of USDA, State, and/or County when any critical non-conformance is present or suspected in the facility or in product purchased or sold by the facility.

6.	**Records Management**
___	Name(s), title(s) and responsibility of person(s) who will have access to the records.
___	Procedures for maintaining all documents, reports, records associated with the program for three years.
___	Procedures to ensure the most up-to-date versions of the reference documents are readily available to all individuals implementing the program. This includes: • EFAI Standard • Quality Assurance Manual (QAM) • USDA APHIS Treatment Manual • Pesticide Label • MSDS
III.	**Appendices**
___	**Appendix 1** - Managerial and staff responsibilities and a list of personnel involved in the EFAI program.
___	**Appendix 2** - Copies of QAL/QAC licenses.
___	**Appendix 3** - Map of physical layout of the facility and the flow of commodity through the facility.
___	**Appendix 4** - Phosphine pesticide label, treatment schedule (Appendix A of EFAI Standard), MSDS, and USDA Treatment Manual section on Phosphine.
___	**Appendix 5** – An example of an Internal Audit checklist and Corrective Action Request.
___	**Appendix 6** – Fumigation Record Worksheet (Appendix B of EFAI Standard), equipment maintenance records, fumigation chamber certification, and training records.
___	**Appendix 7**- Indication of where EFAI standards are kept at the facility and who is in charge of updating and disseminating the standards.
___	**Comments:**

APPENDIX F
INTERNAL AUDIT CHECKLIST

EXPORT FUMIGATION PROCESS/OPERATIONS

Conforms	Corrective Action Needed	Not Applicable	Audit Checklist
			Chamber(s) are currently approved and certified.
			All treatment equipment is calibrated by an authorized entity.
			Facility has the necessary and proper equipment (i.e., temperature recording and gas concentration monitoring devices, etc.) to conduct and monitor the fumigations as identified in the USDA-APHIS Treatment Manual.
			A current copy of the pesticide label and MSDS is available for a review at the facility.
			Treatment procedures used as described in the USDA-APHIS Treatment Manual.
			Export fumigation has been conducted using approved labeled schedules for phosphine.
			Fumigations monitored as prescribed and the necessary concentration readings and results are recorded as required by the USDA-APHIS treatment schedule.

Comments: _____

_____

_____

_____

_____ _____

Signature, Auditor Name

_____

Date

_____ _____

Signature, Facility Accreditation Manager Name

_____

Date

INTERNAL AUDIT CHECKLIST
POST TREATMENT PROCESS/OPERATIONS

Conforms	Corrective Action Needed	Not Applicable	Audit Checklist
			Post treatment inspection of commodity being conducted to ensure efficacy of treatment.
			Treated almonds have been stored separately and not commingled with non-treated almonds.
			Treated almonds have been safeguarded while placed in storage or after processing awaiting shipment to India.
			A system of traceability is in place for treated commodities and for maintaining product identity.

Comments: _____

_____

_____

_____

_____ _____
Signature, Auditor Name

_____
Date

_____ _____
Signature, Facility Accreditation Manager Name

_____
Date

INTERNAL AUDIT CHECKLIST
STAFF RESPONSIBILITIES

Conforms	Corrective Action Needed	Not Applicable	Audit Checklist
			Contact information for the Accreditation Manager for the facility and backup for the Accreditation Program is current.
			County/APHIS has been notified if the Program Accreditation Manager and/or designated backup have changed.
			Facility has an assigned Pest Control Operator (PCO) that is a Contract Fumigator (PCB); and/or QAL/QAC on staff operating with currently valid license(s)/ certificates(s).
			List of all staff, including alternates involved in the export fumigation program at the accredited facility is current, including each person's name, title, duties and responsibilities.
			County/APHIS has been notified of personnel changes as applicable.

Comments: _____

_____

_____

_____

_____ _____
Signature, Auditor Name

_____
Date

_____ _____
Signature, Facility Accreditation Manager Name

_____
Date

INTERNAL AUDIT CHECKLIST
RECORDS MANAGEMENT

Conforms	Corrective Action Needed	Not Applicable	Audit Checklist
			Accurate pest management records of post harvest treatment, storage, and shipment are kept and available for review.
			Facility has notified County/APHIS of any changes or modifications to the QAM and any other facility changes.
			Records of calibration and servicing of fumigation equipment have been maintained.
			Training records for staff involved in implementing the EFAI Accreditation Program standards are current.
			Training records for staff involved in treatments are current.
			Records all treatments and sign treatment records. Electronic copies or hard copies of all treatment data is available on demand, in the format specified by APHIS to certify treatments for phytosanitary certificates.
			A diagram/map showing physical layout of the facility documenting work flow from receiving commodity to processing, storage, fumigation treatment and shipping.
			Corrective actions ordered by the Accreditation Manager (from a previous internal audit) have been implemented.
			All reports or records are signed and dated.
			Maintain treatment, equipment certification/calibration and internal audit records for a minimum of three years.

Comments: _____

_____ _____
Signature, Auditor Name

_____
Date

_____ _____
Signature, Facility Accreditation Manager Name

_____
Date

APPENDIX G
EXPORT FUMIGATION OF ALMONDS TO INDIA PROGRAM
CORRECTIVE ACTION REQUEST

<table>
<tr><td colspan="5"></td><td>CAR #</td></tr>
<tr><td colspan="2">Facility Name</td><td colspan="4">Address</td></tr>
<tr><td>Facility Location</td><td>Date</td><td colspan="2">Accreditation Manager / Internal Auditor</td><td colspan="2">County/APHIS Auditor</td></tr>
<tr><td>External Audit __</td><td>Internal Audit __</td><td>Critical __</td><td>Major __</td><td colspan="2">Minor __</td></tr>
<tr><td colspan="6">Description of non-conformance:

Signature of Auditor:_____ Date Issued: _____</td></tr>
<tr><td colspan="6">Corrective Action:

Facility Representative:_____ Date for Completion: _____</td></tr>
<tr><td colspan="6">Corrective Action Acceptable: __ yes __ no</td></tr>
<tr><td colspan="6">Follow-up Comments:</td></tr>
<tr><td>CAR Closed</td><td colspan="3">Signature of Auditor:</td><td colspan="2">Date</td></tr>
</table>

NOTE:
Critical **- When an audit reveals that the integrity of the program is in jeopardy the non-conformance will be rated as Critical (Cr). The designated facility will be suspended from the program until remedial action has been taken to the satisfaction of the County/APHIS.**
Major **- When an audit reveals an isolated incident having no direct impact on the integrity of the product, the non-conformance will be rated as Major (Ma). The designated facility must take remedial action within the time frame specified by the lead auditor which shall not exceed a maximum of 2 weeks. Should the facility fail to complete the corrective action in the specified time frame, participation of the facility in the program will be suspended. If more than two Major non-conformances are detected during inspection, the classification is changed to a Critical and the facility will be suspended.**
Minor **- When an audit reveals an incident which does non immediately and/or significantly affect the integrity of the program or product, the non-conformance will be rated as Minor (Mi). The designated facility must take remedial action before the next audit or within the time frame agreed to by the auditor. If more than three Minor non-conformances are detected during the inspection, the classification is changed to a Major.**

Please refer to the standards manual for further information and examples of the different types of non-conformances.

APPENDIX H

EXPORT FUMIGATION OF ALMONDS TO INDIA APPLICATION PROCESS

Step 1: Handlers wanting to participate in the program will complete and forward an application to Almond Board of California (ABC) - Attn: Julie Adams @ fax # 209-549-8267. For a copy of the application, you can contact her directly at 209-343-3238.

Step 2: ABC will assign a facility number (EX: For Acme Nut Company = #01ANC-P; "P" = Preliminary, once approved it will change to "A" = Approved) and maintain a master list of participants.

Step 3: ABC will fax the application to the respective county and to APHIS (Attn: David Black @ fax # 916-930-5518), which will include the preliminary facility number written on the upper right-hand corner.

Step 4: Handlers will submit a Quality Assurance Manual (QAM) to APHIS.

Step 5: APHIS will review the QAM and work with the handler to correct any deficiencies.

Step 6: Once the QAM has been approved, APHIS- Export Certification Specialist (ECS) will work with the county to ensure the program is being implemented properly by conducting an initial facility evaluation and monitoring the first treatment.

Step 7: Once the handler has successfully completed the facility evaluation and treatment monitoring, a final approval letter will be issued to the Handler and a copy provided to ABC and county. APHIS (David Black) will fax the final signed application to ABC. APHIS will also provide the final signed application to the Handler. Once received, ABC will change the Handler's preliminary facility number suffix to "A" for approved.

Step 8: County will advise ABC and APHIS if any handler has been suspended or has discontinued using the program.

APPENDIX I

APPLICATION FOR DESIGNATION IN THE EXPORT FUMIGATION OF ALMONDS TO INDIA (EFAI) ACCREDITATION PROGRAM

Name of Facility: _____

Accreditation Manager: _____

Pest Control Operator: _____

Address: _____

_____

E-mail address: _____

Telephone No.: _____Fax No.: _____

Conditions for participation in the Export Fumigation of Almonds to India Program:

1. Shipments treated under this program will only consist of almonds for exportation to India. Other commodities and/or almonds shipped to countries other than India must be monitored in accordance with APHIS policy.

2. Accredited Facility agrees to adhere to all standards in the EFAI program.

3. Records under the EFAI program must be maintained at the facility for at least three years after shipment treatment, regardless of the status of the facility in the EFAI Program.

4. Appropriate measures must be taken to ensure that the treated commodities to be exported are packaged and stored in a manner to preclude contamination by quarantine pests and remain practically free of other injurious pests; and

5. Facilities must design a Quality Assurance Manual (QAM) explaining how they will meet the standards/requirements of the EFAI program. USDA-APHIS will be responsible for the review and the approval of the QAM.

I, the owner/person in possession, care, or control of the above named facility have read and understand all the conditions and obligations stated herein by which I may export treated almonds to India in accordance with the EFAI program.

Further, I am and shall be responsible for and shall attach no liability to the United States Department of Agriculture or to any officer or representative of the Department, from and against all manners of actions, causes of action, claims, demands, loss, costs, damages, actions or other proceedings by whomsoever made, sustained, brought or prosecuted in any manner based upon, caused by, arising out of, attributable to or with respect to any failure, inadvertent or otherwise, by act or omission, to fully comply with the said conditions and requirements.

Dated _____ at _____ State of _____

Applicant's Signature: _____

-FOR OFFICIAL USE ONLY-

Facility Number (assigned by ABC): _____

Quality Assurance Manual Approved:

_____ _____
Signature, Authorizing Official, USDA Print

_____
DATE

Facility Evaluation Successfully Completed:

_____ _____
Signature, Authorizing Official, USDA Print

_____
DATE

Approved for Participation in the EFAI Program:

_____ _____
Signature, Authorizing Official, USDA Print

_____
DATE

_____ _____
Signature, Authorizing Official, County Print

_____
DATE