

Guidelines for Validation of Propylene Oxide Pasteurization

Overview

Propylene oxide (PPO) is a registered fumigant in the US for reduction of bacteria, yeasts, and mold on raw nut meats, etc., and PPO fumigation has been used by the nut industry for insect and microbial control for decades. Recently, ABC funded research projects demonstrated that PPO fumigation is an effective treatment for almond pasteurization. The efficacy study of PPO pasteurization for almond kernels was carried out by Dr. Linda Harris of the University of California, Davis (UCD) and ABC staff in collaboration with Blue Diamond Growers, Inc. (Sacramento, CA) and Industrial Sterilization (Sparks, NV) (*ABC Supporting Document DOC001*).

After reviewing all research findings obtained from the studies sponsored by ABC on the efficacy of PPO in reducing *Salmonella* in almonds, the U.S. Food and Drug Administration (FDA) issued a Letter of Determination confirming the validity of PPO as a pasteurization treatment for raw almond kernels in September 2004 (*ABC Supporting Document DOC004*). Accordingly, **almonds which are treated in accordance with the PPO treatment parameters described in the study can be labeled as “pasteurized.”**

To facilitate application of PPO fumigation as an almond pasteurization process, ABC has issued two documents: Almond Pasteurization Using Propylene Oxide--Standard Operating Procedure (the SOP) (*ABC Supporting Document DOC006*) and Guidelines for Almond Pasteurization Using Propylene Oxide (the Guideline) (*ABC Supporting Document DOC007*). The two documents provide a full description of the PPO pasteurization process and outline critical control factors for delivering pasteurization process.

Since the mandatory treatment criterion is a minimum 4-log reduction of *Salmonella* on almonds (*Federal Register/Vol. 72, No. 61/Friday, March 30, 2007/Rules and Regulations, Pages 15021-15036*), a handler or Direct Verifiable (DV) user may choose to have their process validated to achieve a minimum 4-log reduction. Please note that while this will satisfy the mandatory treatment criterion, the products processed under such conditions may not be labeled as “pasteurized”. The purpose of this document is to provide guidance to process authorities for validating PPO almond pasteurization processes.

PPO Almond Pasteurization Process

The ABC SOP and the Guideline documents specifically emphasize that handlers and third parties who have PPO treatment facilities must follow the parameters specified in the SOP in order to ensure they are achieving the 5-log pathogen reduction. Individual treatment facilities must be validated and their

equipment calibrated to demonstrate that the facilities are operating within the established parameters. If a pasteurization process does not meet the requirements in the SOP, then independent studies must be conducted to validate that the procedures will provide at least a 4-log reduction or 5-log reduction of *Salmonella*.

The operating parameters for PPO pasteurization of almond kernels are presented in the following table. It is important to note that the PPO treatment described in the SOP is currently only accepted for use on bulk-packed almonds (2000- or 2200- totes or 50-lb cartons on pallets). Pallets may be single or double stacked.

PPO Pasteurization Operating Parameters

Parameters	Operational Level
Initial product temperature	Not less than 86°F (30°C)
Temperature inside chamber at start and during sterilization	117-125°F(47-51°C)
Chamber vacuum before PPO injection	At least 27”Hg vacuum
PPO vaporizer temperature at point of PPO injection	140 -160°F (60-71°C)
Initial PPO concentration in Chamber	Not less than 0.5oz PPO/ft ³
Chamber vacuum at completion of inert gas injection	5-6 inch Hg vacuum
Duration of pasteurization	4 hours
Aeration cycles	Not <4 and not >14
Post ventilation	100-110°F (38-43°C) for 2 days or above 59°F (15°C) for 5 days.

Validation of PPO Treatment Chambers and Operations

A process authority should carefully study all of the supporting documents mentioned above before proceeding to validate any chambers or processes. The following outlines some aspects for PPO treatment validation.

Objectives of Validation Testing:

- Verify if the PPO treatment facility equipment and operations meet the parameters specified by the SOP
- Validate the reduction efficacy if the process deviates from the SOP

PPO Treatment Description to Include:

- Flow chart to illustrate configuration of each step of the treatment: pre-warming chamber, PPO chamber (heating, temperature control, PPO injection, vacuum pump capacity, etc), post-ventilation, product movement
- Temperature control and recording device: calibration document, parameter compliance verification frequency.
- Maximum loading capacity and configuration
- Untreated and treated segregation procedure
- Procedures for identifying process deviations

Products Covered Under this Validation:

- List all products and package types that are treated in the facility
- List all products produced when the treatment deviated from the parameters specified by the SOP

Verification of Operating PPO Treatment Operation:

- Verification of the SOP: Does the PPO facility have a SOP in place? If it does, are their parameters the same as the parameters defined by the SOP? If the facility PPO treatment is operating under parameters that are different from the SOP parameters, a supporting document demonstrating efficacy of the treatment for a 4-log reduction or a 5-log reduction of *Salmonella* must be submitted to ABC for review and evaluation
- Calibration of temperature, vacuum and PPO weighing controls and recording devices must be current
- PPO chamber temperature distribution
- Internal quality control policy

Verification of Almond Temperature:

- The almond temperature during PPO treatment must be at or above 86°F
- Product pre-warming procedure (pre-warming mechanism, temperature, duration), handling procedure for the bins that have a product temperature below 86°F.
- Measure almond temperatures from the center of at least 6 bins or pallets per each lot of 22 bins or less, prior to placing goods into the PPO chamber. A digital thermometer equipped with a probe long enough to reach the center of the bin is recommended. The thermometer(s) must be calibrated.

PPO Injection:

- PPO vaporizer temperature must be 140-160°F
- Final concentration of PPO gas in the chamber must be at 0.5 oz PPO/ft³ or above.
- PPO measurement procedure and verification frequency

Chamber Temperature and Inert Gas Pressure:

- Chamber temperature during PPO treatment
- Pressure at PPO injection
- Pressure at completion of inert gas injection

Aeration:

- Aeration procedure
- Number of aeration cycles

Post-ventilation:

- Post-ventilation procedure (temperature and duration)
- Product release procedure

Validation Report:

For each PPO chamber that has been validated, the process authority must submit a written report to ABC for review and evaluation. The validation report, at a minimum, should include detailed information on the following:

- Handler or custom facility information:
 - Contact information
 - Background information
 - General information about almond and other product treatment
- PPO chamber(s) validated:
 - General description of the chamber:
 - Temperature mapping
 - Procedure or device for identifying process deviation
- Product(s) validated:
 - Type of products and packages
- Validation methodology
- Results summary
- Handling procedures for products produced during process deviation
- Date validation conducted
- Conclusions and recommendations
- Process authority: contact information; ABC approval # and date

Almond Pasteurization Using Propylene Oxide (PPO)- Standard Operation Procedures (SOP)

Background:

On September 23, 2004, the U.S. Food and Drug Administration (FDA) issued a letter of determination confirming the validity of propylene oxide (PPO) as a pasteurization treatment for almonds. This letter was a result of reviewing all research findings obtained from a 3-year study on the efficacy of PPO in reducing *Salmonella* on almonds. Accordingly, almonds which are treated in accordance with the Standard Operating Procedure (SOP) can be labeled as “pasteurized.”

The efficacy study of PPO pasteurization, sponsored by the Almond Board of California, was carried out by Dr. Linda Harris of the University of California and Almond Board staff in collaboration with Blue Diamond Growers, Inc. (Sacramento, CA) and Industrial Sterilization of Nevada (Sparks, NV). The study, using *Bacillus stearothermophilus* spore test strips as a bio-indicator as well as almonds inoculated with *Salmonella* Enteritidis Phage Type 30 (SE PT30), demonstrated that the recommended PPO SOP is effective in reducing SE PT30 by more than 100,000-fold (5 logs). The use of *B. stearothermophilus* spore strips could be one option for validating PPO treatments.

The study was conducted under specified operating parameters and found that a dose of 0.5 oz PPO/ft³ in vapor is sufficient for almond pasteurization. Initial product temperature is critical in achieving a 5-log reduction in SE PT30. The initial product temperature must be at least 86°F (30°C); a lower temperature may reduce the efficacy of the process. The post-ventilation is an integral part of 5-log reduction efficacy. The following SOP is the protocol that has been reviewed by FDA.

Standard Operating Procedure for Pasteurization of Almonds

This recommended SOP is not intended to supersede any governmental regulation and propylene oxide registration requirements. Please read, understand, and follow all PPO label instructions. To establish an actual PPO operating procedure, consult with equipment and chemical company representatives.

1. Pre-warm product to at least 86°F (30°C) at the coldest point in the container. The product temperature should not exceed 105°F (40°C) during this step due to product quality concerns. The pre-warm temperature area can be in the range of 100 - 120°F to achieve the 86°F (30°C) minimum product temperature.
2. Measure product temperature from the center of every bin or pallet to assure that the product achieves a minimum temperature of 86°F (30°C).
3. Pre-heat the PPO chamber to 117-125°F(47-51°C).
4. Load the conditioned product into the pre-heated PPO chamber and start the cycle.
5. Maintain a chamber temperature of 117°F to a maximum of 125°F (47-51°C).
6. Apply a vacuum until the chamber reaches a minimum of 27” Hg.
7. Turn on PPO vaporizer to achieve a temperature of at least 140°F (60°C), but not in excess of 160°F (71°C).
8. Inject a sufficient amount of PPO through the vaporizer to assure that PPO vapor in the chamber reaches at least 0.5 oz PPO/ ft³. (The absolute amount of PPO will depend upon the chamber size.) The vacuum in the chamber will decrease slightly upon addition of the PPO.
9. Inject an inert gas to decrease chamber vacuum to 5-6” Hg at completion of the injection to assure adequate amount of inert gas added. The pressure may fluctuate a bit during the sterilization process.
10. Treat product for 4 hours. (The pasteurization time begins after completion of inert gas injection.)

11. After 4 hours of exposure, increase the vacuum to 27-28" Hg.
12. Complete the aeration cycle by saturating the chamber with an inert gas or air until atmospheric pressure is reached.
13. Repeat aeration cycles a minimum of 4 times as required by the label, but not more than 14 times, to assure a safe PPO concentration in the chamber for worker access. The number of cycles varies with chamber size and it should allow product right out of the chamber to contain more than 400 ppm of PPO residue.
14. After completion of aeration cycles, transfer the product to a room for post-ventilation treatment. The temperature recommended for post-ventilation is 100-110°F (38-43°C) for at least two days or at ambient temperature above 59°F (15°C) for five days. A higher temperature speeds up dissipation of PPO and shortens the holding time to achieve a PPO residue of 300 ppm or less in the product.
15. Release the product when PPO residue is below 300 ppm.
16. Record all measurements and document all recordings for each PPO pasteurization treatment.
17. Good manufacturing practices must be followed to assure that recontamination of the treated almonds does not occur.

PPO Pasteurization Operating Parameters

Parameters	Operational Level
Initial product temperature	Not less than 86°F (30°C)
Chamber temperature at start and during sterilization	117-125°F(47-51°C)
Chamber vacuum before PPO injection	At least 27"Hg vacuum
PPO vaporizer temperature	140 -160°F (60-71°C)
PPO concentration	Not less than 0.5oz PPO/ft ³
Chamber vacuum at completion of inert gas injection	5- 6 inch Hg vacuum
Duration of pasteurization	4 hours
Aeration cycles	Not <4 and not >14
Post ventilation	100-110°F (38-43°C) for 2 days or above 59°F (15°C) for 5 days.

This procedure is only applicable for pasteurization of bulk-packed almonds on double or single stacked pallets. The procedure is not applicable for retail packed bags.

Handlers and third parties who have PPO treatment facilities must follow the SOP in order to ensure they are achieving the 5-log pathogen reduction required by FDA. Individual treatment facilities must be validated and equipment calibrated to demonstrate they are operating within the established parameters.



For more information, please contact the Almond Board at 209.549.8262 or staff@almondboard.com. The information reported in this document is correct to the best of our knowledge.

The Almond Board of California welcomes the participation of all industry members and does not discriminate on the basis of race, color, national origin, sexual orientation, gender, marital status, religion, age, disability or political beliefs.