

Guidelines for Validation of Propylene Oxide Treatment for In-shell Almonds

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. 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*).

After reviewing a recent study by the University of California at Davis (Dr. Linda Harris) on the efficacy of PPO fumigation on the reduction of *Salmonella* on in-shell almonds, the ABC Technical Expert Review Panel (TERP) conditionally accepts treatment of in-shell almonds with PPO as a process that will provide at least a 4-log reduction of *Salmonella*. The PPO treatment conditions must be the same as those that were approved for use in the pasteurization of almond kernels, except that the only acceptable post-treatment ventilation procedure is to hold the treated products at 59-65°F for a minimum of 5 days.

ABC has initiated another project to investigate distribution of inocula on the shell and kernels within the shell under the inoculation procedure used in the study. ABC will also evaluate the efficacy of the PPO treatment on *Salmonella* in the kernels when the inoculated in-shell almonds are treated. The purpose of this document is to provide guidance to process authorities validating the PPO treatment of in-shell almonds.

PPO Treatment of In-shell Almonds

The study by Dr. Harris was carried out with both soft shell and hard shell almond varieties in 50-lb sacks stacked on pallets. The research results show that the treatment of in-shell almonds with PPO can provide greater than a 4-log reduction of *Salmonella* Enteritidis PT 30 (SE PT 30) on soft shell almonds and hard shell almonds under the inoculation procedures and treatment conditions used in the study. The same treatment parameters that were approved for the pasteurization of almond kernels were used in the study for in-shell almonds (*ABC Supporting Document DOC008*).

The ABC issued “Almond Pasteurization Using Propylene Oxide—Standard Operating Procedure (SOP)” (*ABC Supporting Document DOC006*) and “Guidelines for Almond Pasteurization Using Propylene Oxide” (*ABC Supporting Document DOC007*) to assist the industry in operating their PPO chambers to achieve a minimum 5-log pasteurization criteria for almond kernels. The most critical control factors are PPO dosage (a minimum of 0.5 oz PPO/ft³ in vapor) and almond temperature at a minimum of 86 °F prior to PPO treatment. The same parameters will apply to the treatment of in-shell almonds. The SOP for

almond kernels includes two options for post-treatment ventilation: accelerated ventilation at 100-110°F (38-43°C) for 2 days or slow ventilation at 59-65°F (15-18°C) for 5 days. However, to achieve a minimum 4-log reduction on in-shell almonds, the ventilation at 59-65°F (15-18°C) for 5 days is the only acceptable procedure. At the end of such ventilation, PPO residue in almonds may be above 300 ppm--the maximum level for release. Additional ventilation at the same temperature or at a higher temperature may be necessary to lower PPO residue.

Individual treatment facilities must be validated and their equipment calibrated to demonstrate that the facilities are operating within the established parameters. If a 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 of *Salmonella*.

The operating parameters for PPO pasteurization of in-shell almonds are presented in the following table. It is important to note that the PPO treatment described herein is currently only accepted for use on in-shell almonds bulk packed in 50-lb sacks stacked on 2000- or 2200- lb 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	59-65°F (15-18°C) for 5 days.

Validation of PPO Treatment Chambers and Operations

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:

- 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 PPO Treatment Operation:

- Verification of the SOP: Does the PPO facility have a SOP for in-shell almonds 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 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 pallets that have a product temperature below 86°F.
- Measure almond temperatures from the center of at least 6 pallets per each lot of 22 pallets 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 pallet 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