california almonds
Almond Board of California

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Considerations for Proprietary Processes Used for Almond Pasteurization and Treatment

Overview

The purpose of this document is to provide guidance to process authorities for validating the ABC Technical Expert Review Panel's (TERP) accepted proprietary processes for pasteurization (a minimum 5-log reduction) or mandatory treatment (a minimum 4-log reduction) of natural almonds.

There are currently two proprietary processes that have been reviewed and accepted by TERP. These processes include specific sets of parameters for the treatment of almond kernels. The two accepted processes are: FMC JSP-1 pasteurization system installed at Going Nuts (Madera, California) and H_2O Express pasteurization system Chamber 1, installed at the Stewart & Jasper Company, (Newman, California).

Both proprietary processes utilize steam to accomplish the desired log reduction. Each process has undergone extensive validation testing using almonds inoculated with *Salmonella* Enteritidis PT 30 (SE PT 30). Each process has established critical control points for one or two sets of operating parameters that have been accepted by TERP.

For the FMC process TERP has accepted two sets of process parameters: one for a 5-log reduction and another for a 4-log reduction. The US Food and Drug Administration (FDA), after reviewing the 5-log reduction validation results, issued a Letter of Determination to acknowledge that the FMC JSP-1 pasteurization unit, when operated at these defined parameters including belt speed and loading capacity, does deliver a 5-log reduction of SE PT 30 on natural almonds. Accordingly, natural almonds treated using this process under these conditions may be labeled "pasteurized". The process is an inline, continuous conveyor system that treats almonds prior to packaging.

For the H_2O Express pasteurization system, TERP accepted a set of operating parameters for a 4-log reduction of *Salmonella* on almonds for three chambers installed in Newman, California. This process is a batch type system that treats almonds in final packaging. The current acceptance only applies to almonds packed in 50-lb cartons for Chamber 1 and 2,200-lb tri-wall fiber totes for Chambers 1, 2 and 3.

The TERP acceptance process is specific to equipment and operating procedures. The accepted parameters for each process are valid as long as the equipment and procedure are not modified after receiving TERP acceptance. Modification in design, configuration, throughput, etc., would require re-validation for acceptance. Re-validations will require using SE PT 30 or an ABC accepted surrogate.

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 almonds treated under the accepted parameters for a minimum 4-log reduction of *Salmonella,* as opposed to a 5-log reduction. Please note that while this will satisfy the mandatory treatment criterion, the products processed under such conditions may not be labeled "pasteurized". The "pasteurized" labeling can only apply to the almonds that are treated under a process having acquired a Letter of Determination from FDA.

Validation of Pasteurization or Treatment Processes

Please contact the ABC or TERP accepted operation parameters.

Objectives of Validation Testing:

- Verify that the product(s) are treated under TERP accepted processes
- Verify that the process is operating under TERP approved parameters
- Verify whether any modifications have been done to the equipment since TERP acceptance

Pasteurization or Treatment Line Description to Include:

- Flow chart to illustrate configuration of treatment line and facility layout
- Heating and cooling mechanism: temperature control(s) and recording device(s); steam dynamics; parameter compliance verification frequency
- Equipment speed control, speed dial setting, calibration procedures
- Maximum throughput, bed depth, etc…
- Raw and treated product segregation procedures
- Line sanitation procedures

Products Covered Under this Validation:

- List all products treated on the line
- List all parameters that have been used by product type

Verification of Operating Parameters to Include:

- List standard operating procedures for the treatment line to be validated
- Identify critical control points
- Specify operating parameters compliance: observe and record all settings and actual readings for each of the parameters accepted by TERP
- Check recorded data (electronically or manually) for each identified operating parameter from all production days of previous month
- Product temperature measurement: Product temperature (initial, during treatment, at the end of the treatment) must be verified if product temperature is identified as a control point. In this instance, a data tracer, thermocouple or thermometer may be used for measurement. The device must have a minimum accuracy of +/- 1.0° and calibration of the device must be current. The diameter of the thermocouple tip should not be coarser than gauge 30. The recording interval of the temperature measured by the tracer or thermocouple should not be more than 2 seconds.

- Treatment duration verification: At the accepted run speed, measure the time an individual almond kernel is exposed to the treatment (from the entrance to the exit) under normal product throughput. A stop watch or a data tracer can be used for the measurement.
- A minimum of three (3) measurements must be conducted for temperature and duration.

Validation Report:

For each process 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 manufacturer and custom processor information:
  - Contact information
  - Background information
  - General information about almond usage and handling
- Production line(s) validated:
  - General description of the production line
  - Temperature control(s) and monitoring device(s)
  - Procedure(s) or device(s) used for identifying process deviations
  - Findings from process validation and record check
- Validation methodology
  - Verification approach
- Results summary
- Handling procedures for products produced during process deviations
- Date(s) validation conducted
- Product(s) containing almonds not validated or not achieving a 4-log reduction
- Conclusions and recommendations
- Process authority: contact information; ABC approval # and date