

Guidelines for Validation of Blanching Processes

Overview

Blanching is a thermal process that is used by almond processors to remove almond skins. Dr. Linda Harris of University of California at Davis (UCD) studied the efficacy of hot water on the reduction of *Salmonella* on almonds in a hot water bath (*ABC Supporting Document DOC002*). Based upon the information from that study, the ABC Technical Expert Review Panel (TERP) determined that a minimum process of 2.0 minutes or more of exposure to hot water at 190°F or above will provide a 5-log or greater reduction of *Salmonella* on almonds.

Subsequently, the US Food and Drug Administration (FDA) reviewed this information and issued a Letter of Determination to acknowledge this process as a pasteurization process. **Almond products processed utilizing those conditions may be labeled as pasteurized.** (*ABC Supporting Document DOC005*)

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 for process authorities to validate lethality of almond blanching processes in terms of 4-log reduction and 5-log reduction criteria.

Understanding the Blanching Process

A typical blanching process is illustrated in Figure 1. Scalding and drying are the steps in which almonds are exposed to heat, and scalding is the step of interest for validation.

Scalding is a continuous process that is carried out in a circular tube in which hot water or steam-injected water is used to soak almond kernels (Figure 2). Almond kernels are directly exposed to hot water only in the section from point A to point B. The duration of the exposure to hot water is controlled by the scalding speed dial. The water temperature in the scalding is controlled by a control panel with a thermocouple attached to the near-end of the immersion section (point B). Some scalders may be equipped with a temperature recording device to monitor the water temperature. Though the scalded kernels from point B to the exit may be hot and carry residual hot water, this is not considered part of the controlled thermal treatment. The temperature of almond kernels at the input and loading speed (throughput) may make the water temperature fluctuate.

The scalded almond kernels pass through a series of rubber rollers in the blanching chamber in which the loosened skins are removed. The blanched kernels, with some free skins, drop to a shaking table where the free skins are aspirated away while the debris is rinsed off the kernels by spraying water. The blanching chamber and water rinsing table operate in a wet and warm environment. Some thermal stable or thermophilic bacteria that survive the scalding step can populate to increase microbial count for finished blanched products. This also applies to the transference conveyor or elevator buckets between the water rinsing table and dryer. Proper and frequent sanitation is key to the reduction and control of microbial growth in these areas.

The same scalding parameters (time and temperature) can be used for different blanched products (whole, whole and broken, pieces, cutting inputs, etc.) while the same blanched product may utilize different scalding time and temperature parameters if the almonds are different varieties or have different moisture levels. Therefore, there may be many sets of scalding time and temperature parameters utilized by a blanching line. To avoid validating every set of parameters, it's suggested that the worst case scenario (lowest temperature and shortest time) of all sets of parameters be identified. The validation test can then focus on the worst case parameters, and other sets of parameters would be validated if the worst case scenario parameters are proven to be efficient for treatment criteria.

Validation of Blanching Process

Objectives of Validation Testing:

- To verify how long almond kernels are immersed from point A to B under certain operating parameters
- To verify the temperature at the coldest point in the hot water immersion of almond kernels

Blanching Line Description to Include:

- Flow chart to illustrate line configuration
- Scalding and drying mechanism: temperature control and recording device, parameter compliance verification frequency, temperature recording device calibration document
- Scalding speed dial setting and calibration document
- Maximum throughput
- Raw input and blanched product segregation procedure
- Line sanitation procedures

Products Covered Under this Validation:

- List all products made through the line to be validated
- List all products to be validated or covered by the same parameters
- Maximum throughput of each product that has been validated
- Worst case scenario parameters for each product

Figure 1. Blanching Process Flow Chart

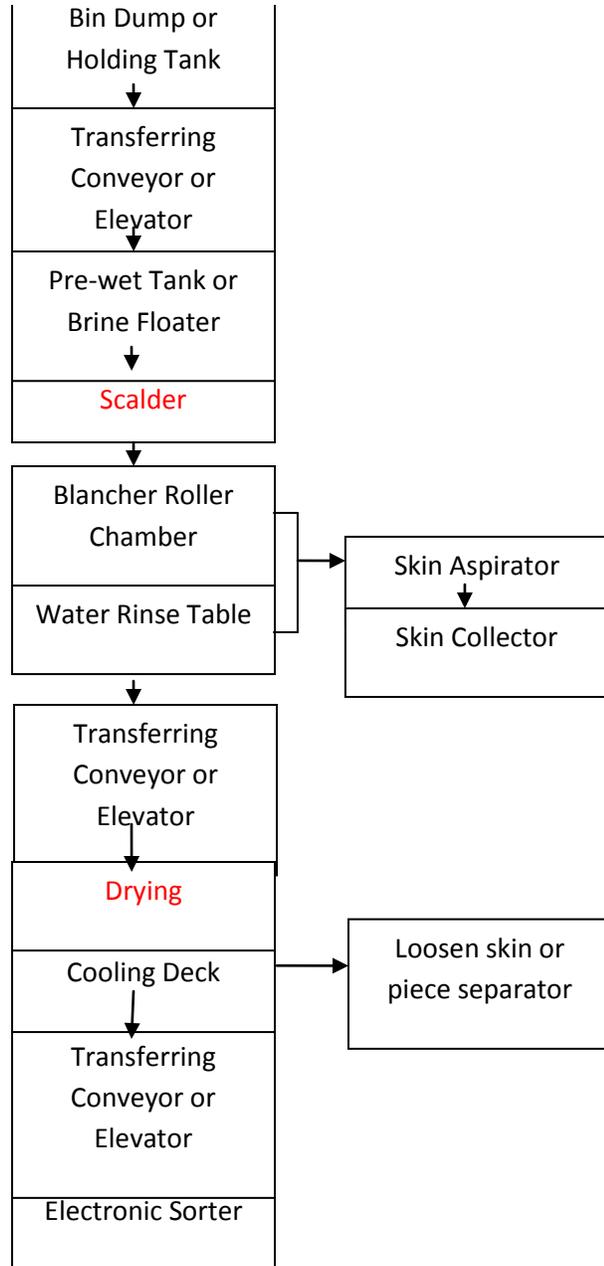
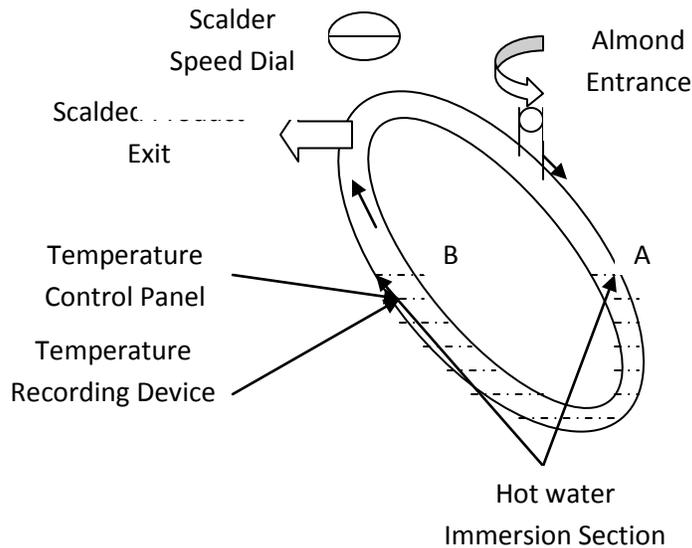


Figure 2. Scalding Illustration



Validation Methodology:

- Temperature measurement of hot water: Temperature of scalding water may be affected by many factors, such as equipment temperature setting, almond temperature at entrance, throughput rate, etc. In addition, under some circumstances, the hot water temperature may not reach the temperature setting of the equipment. In such instances, validation testing is needed to verify the effects of these factors. If a data tracer or thermocouple is used to measure water temperature, it must have a minimum accuracy of $\pm 1.0^\circ$ and calibration of the tracer or thermocouple must be current. Since the minimum time is only 2.0 minutes or less, the recording interval of the tracer or thermocouple should not be more than 2 seconds.
- Duration measurement of hot water immersion: Complete water immersion is only counted from point A to point B, therefore, the temperatures measured prior to point A and after point B should not be included in the calculations.
- Replication of validation runs: For each set of parameters to be validated, a minimum of three (3) validation runs must be conducted. The lowest temperature and shortest time recorded from these runs will be used for determination of product adequacy.
- Minimum input almond temperature: Addition of cold almonds (cold storage product or winter production run) may cause the scalding water temperature to fluctuate widely. A higher equipment temperature setting may be needed to compensate for the drop in hot water temperature caused by the cold almonds. Validation testing is needed to establish a minimum almond temperature for which the temperature of the water will not fall below the minimum lethality temperature. Otherwise, a different set of parameters with a higher water temperature setting may need to be validated.

- Lethality validation: Table 1 lists some calculated time/temperature combinations required for 4-log or 5-log reductions. For a process utilizing hot water between 140 and 190°F, the log reduction can be calculated using D- and z- values. For a process utilizing hot water above 190°F, a minimum of 2.0 minutes exposure time is required for a 5-log reduction, and 1.60 minutes for a 4-log reduction.
- A simple approach is to verify total water immersion time at the lowest temperature. Possible approaches are: 1) measure the lowest temperature of hot water during at least 10 minutes of a production run at the highest throughput rate; 2) calculate the time it takes an individual kernel to travel from point A to point B at a certain scalding speed dial setting; and 3) verify if the total water immersion time at the lowest temperature has reached the required time for that temperature listed in Table 1.

Table 1. Minimum Time/Temperature Requirement for Blanching Processes		
Hot Water Temperature (°F)	Time to Meet Required Lethality (min)**	
	4-Log	5-Log
180	2.47	3.09
181	2.37	2.96
182	2.27	2.83
183	2.17	2.71
184	2.08	2.60
185	1.99	2.49
186	1.90	2.38
187	1.82	2.28
188	1.75	2.18
189	1.67	2.09
190	1.60	2.00

** z = 53 F°

Validation Report:

For each process or product that has been validated, the process authority must submit a written report to ABC for review. The validation report, at a minimum, should include detailed information on the items outlined below:

- Handler or manufacturer information:
 - Contact information
 - Background information
 - General information about almond usage and handling
- Production line(s) validated:

- General description of the production line
 - Lethality control mechanism
 - Procedure for identifying process deviation
- Product(s) validated
- Validation methodology
 - Validation methodology
 - Thermal validation method
 - TDT data used. If not ABC TDT data, a detailed research report should be included that demonstrates the validity of the TDT data used
 - Temperature data acquisition procedure; replication of data collections
 - Cold spot or zone identification
- Results summary
- Handling procedure for the product produced during process deviation
- Date(s) validation conducted
- Product(s) containing almonds not validated or which did not achieve 4-log reduction
- Conclusions and recommendations
- Process authority: contact information; ABC approval # and date