Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

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Chapter 6

Use of Heat Treatments as a Process Control

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[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

Appendix 6-E: Summary Process Control Table for Heat Treatment; Salsa Processor A

6.1 Purpose of this Chapter

The purpose of this chapter is to explain how to establish and implement a heat treatment (e.g., baking or cooking) as a process control for bacterial pathogens. See Chapter 4 – Preventive Controls for additional detail on heat and other lethal treatments.

This chapter does not address controlling bacterial pathogens by those heat treatments, such as retort processes, that are subject to 21 CFR part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers; commonly called "Low-Acid Canned Foods" (LACF)) because the microbial hazards in LACF are not subject to the requirements for hazard analysis and risk-based preventive controls.

6.2 Considerations to Keep in Mind If You Use a Heat Treatment as a Process Control

Heating is only one of the process controls that you may choose to use to produce a safe product. Based on your hazard analysis, there may be other process controls to consider. In addition, the heat treatments discussed in this chapter are designed to kill/destroy vegetative cells of bacterial pathogens (e.g., *Salmonella*), but are not adequate to inactivate spores of sporeforming bacteria (e.g., all strains of *C. botulinum*). Therefore, if you use one of the heat treatments described in this chapter, you may need to establish and implement additional preventive controls to control spores. See Chapter 4 for further information regarding additional process controls for pathogenic sporeformers. See Table 6-1 for additional strategies for controlling bacterial pathogens.

Table 6-1 Strategies Other than Heat Treatment for Controlling Bacterial Pathogens

Preventive Control	Chapter
Time/Temperature Control	7
Formulation Control (e.g., water activity, pH, and chemical preservatives)	8
Dehydration/Drying	9
Sanitation Controls	10

6.3 Examples Used in this Chapter

Sections 6.12 through 6.16 of this chapter provide examples to illustrate how to properly apply heat treatments as a process control and to establish and implement preventive control management components (i.e., monitoring, corrective actions and corrections, and verification) for those heat treatments. These examples are:

- Cookie Processor A: Cookies baked using a batch process (in batches on trays in convection ovens), wrapped by twos in plastic (Section 6.12)

- Cookie Processor B: Cookies baked using a continuous process (in a continuous band oven), packaged in boxes of 24 cookies (Section 6.13)

- Soup Processor A: Ready-to-Eat (RTE) soups containing vegetable particles, cooked using a batch process (in a kettle), packaged in 8 ounce plastic bowls, and frozen (Section 6.14)

- Soup Processor B: RTE soups (clear broths and creamed vegetable soups, without vegetable particles) cooked using a continuous process (in a continuous flow heat exchanger), packaged in 5 gallon bags, and refrigerated (Section 6.15)

- Salsa Processor A: Chopped mixed vegetable salsa (an acidified food) that is directly acidified, cooked in a kettle, and hot-filled into glass jars (Section 6.16)[2]

Each of these examples describes certain activities that must be either performed, or overseen by, a preventive controls qualified individual (PCQI). When a PCQI oversees (rather than performs) these activities, the activity could be performed by a designee of the PCQI. For simplicity, we describe the activity as performed by a PCQI, without specifying each time that the activity could be performed by a designee of a PCQI.

6.4 Understand the Potential Hazard

Heat is known to be effective against bacterial pathogens and is a common process control for these hazards. However, if heat treatments are not properly designed and implemented, the pathogens of concern may survive the process and cause illness. See Chapter 3 for more information on bacterial pathogens.

6.5 Terms Used in This Chapter

Part 117 specifies that process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system: (1) Parameters associated with the control of the hazard; and (2) the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control. (See 21 CFR 117.135(c)(1).)

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[2] In forthcoming chapters, we will provide an example of formulation control for this acidified food (Chapter 8 – Use of Formulation as a Process Control) and an example of control of glass hazards (Chapter 13 – Preventive Controls for Physical Hazards).

The examples in this chapter describe:

- Process parameters such as baking/cooking time, baking/cooking temperature, dough weight, particle size, belt speed, and pump speed;

- Maximum values for some of these process parameters (e.g., 28 g portion of dough); and

- Minimum values for some of these process parameters (e.g., 350°F (177°C) minimum baking temperature, 13 minutes minimum baking time).

Process controls typically are established at "critical control points" (CCPs). "CCP" is a term commonly used in HACCP systems. In HACCP systems, the maximum or minimum values for a process parameter established at a CCP are called "critical limits." Our HACCP regulation for juice (21 CFR part 120) defines "critical limit" as the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.

Part 117 does not preclude the use of terms (such as "critical limits" and "critical factors") that are associated with HACCP systems. Because the maximum or minimum values for the process parameters described in the examples in this chapter are established at CCPs, we see no meaningful difference between the terms "maximum value" and "minimum value" used in part 117 for a process control and the term "critical limit" used in HACCP systems for controls established at CCPs. Therefore, in this chapter we use the term "critical limit" when referring to a maximum or minimum value established for a process control parameter. Because part 117 specifies that preventive controls include controls, other than those at CCPs, that are also appropriate for food safety (21 CFR 117.135(a)(2)(ii)), in this chapter we use the more general term "process parameter" (rather than "critical factor") when referring to parameters other than those specified in the examples with critical limits.

Part 117 does not define the term "operating limit." In this guidance, we use the term "operating limit" to mean criteria that may be more stringent than critical limits and are established for reasons other than food safety. For example, if you bake cookies and establish 13 minutes as the critical limit for the minimum baking time to control bacterial pathogens, you could establish 15 minutes as an operating limit for the baking time and assess the cookies for quality if the baking time is less than 15 minutes, but still exceeds the critical limit of 13 minutes (e.g., if the baking time was 14 minutes).

Part 117 does not define the term "adjustment." In this guidance, we use the term "adjustment" when referring to an intervention that you take if you determine that there is a deviation from an operating limit, without a deviation from a critical limit. For example, if you bake cookies, establish 28 g as the maximum value (critical limit) for the weight of cookie dough deposited by an automatic dough depositor, and establish 27 g as the operating limit for the weight of cookie dough, you could make an adjustment to the dough depositor if you observe that the amount of dough deposited exceeds the operating limit of 27 g, but does not exceed the critical limit of 28 g.

6.6 Design and Validation of the Heat Treatment

The heat treatments discussed in this chapter are designed to significantly minimize (eliminate or reduce to an acceptable level) vegetative cells of bacterial pathogens that may have been introduced into the food by raw materials or during processing steps that occur before the heat

step. With few exceptions, the PCHF requirements specify that you must validate that the preventive controls are adequate to control the hazard as appropriate to the nature of the preventive control and its role in your food safety system. The validation of the preventive controls must be performed (or overseen) by a PCQI. (See 21 CFR 117.160.)

To control bacterial pathogens using a heat treatment adequate to ensure that the pathogens do not survive the process, you should:

- Scientifically establish a heat treatment that will significantly minimize the target bacterial pathogens (eliminate them or reduce their numbers to acceptable levels);

- Design and operate the heat treatment equipment so that every unit of product receives at least the established minimum heat treatment; and

- Monitor the established process parameters to verify achievement of the scientifically established heat treatment (e.g., time and temperature).

You could establish process parameters and the critical limits for the process parameters based on scientific information, usually obtained by a scientific study (often from studies in the literature). You also could obtain this information from a process authority that has knowledge about process parameters and minimum/maximum values (e.g., critical limits) for the product being produced. A process authority could also conduct the studies that would establish a valid heat treatment.

For heat treatments, examples of process parameters include:

- Amount of time for the heat treatment (e.g., the amount of time exposed to heat as determined by the speed of the belt through a continuous oven, or observed number of minutes at a boil for some cooking processes)[3];

- Temperature of the heating medium (e.g., temperature of oven or steam or water used for cooking);

- Internal Temperature (IT) of the product;

- Final temperature of the product;

- Particle size (e.g., when heat must penetrate particles such as chopped vegetables so that the interior of the particles receives a complete heat treatment);

- Depth of product on a conveyor belt;

- Container size (e.g., can dimensions when products are heated in containers); and

- Product formulation.

When a study is conducted to establish a valid heat treatment, that study could identify other process parameters that affect the rate of heating of the product.

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[3] When an End-Point Internal Product Temperature (EPIPT) has been determined by a study, there is no time associated with the heat treatment.

6.7 Develop a Strategy for Preventive Control Management Components

With few exceptions, part 117 specifies that preventive controls are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system: (1) Monitoring; (2) corrective actions and corrections; and (3) verification. (See 21 CFR 117.140.) In the remainder of this chapter, we discuss each of these preventive control management components when the process control is a heat treatment. See Sections 6.12 through 6.16 for examples that provide more detail about how to apply each of these preventive control management components to specific types of heat treatments.

6.8 Establish and Implement Monitoring Procedures

Part 117 requires that, as appropriate to the nature of the preventive control and its role in your food safety system, you establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control. You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed. (See 21 CFR 117.145.)

6.8.1 What to Monitor

Heat treatments designed to significantly minimize pathogens play a key role in your food safety system. When a heat treatment is your preventive control and you have established critical factors for the heat treatment (e.g., as identified by a scientific study or provided by an expert in thermal processing, such as a process authority), you would monitor those critical factors. Exceptions to such monitoring include heat treatments that are designed such that a process parameter is automatically controlled, e.g., when a bar is placed at a specified height above a conveyor belt to ensure that the bed depth of product being heat treated cannot exceed the depth determined to be the critical limit for the depth of product.

6.8.2 How to Monitor

6.8.2.1 How to monitor batch heating equipment

For most temperature determinations in batch heating equipment, you should use a continuous temperature-recording device (e.g., a recording thermometer). You should install the device where it measures the coldest temperature of the cooking equipment (the cold spot determined by a study). In some instances (e.g., to determine the IT prior to heating or to determine the EPIPT), you could use a temperature-indicating device (e.g., a thermometer). Where cooking is performed at the boiling point, you could visually observe minutes at a boil.

For the heating time of a batch process, you should record the times of the start and the end of the cooking or baking cycle and calculate the heating time from this information. To help you do so, you could set timers to give an audible or visible indication that the cooking or baking time has been completed.

For most heat treatments, you should monitor both temperature and time. However, when an EPIPT has been scientifically established, you could monitor only the finished product temperature, because there is no time associated with the heat treatment.

For other process parameters, use appropriate equipment to monitor the parameter, e.g., scales when you establish a critical limit for a weight; rulers or calipers when you establish a critical limit for size.

6.8.2.2 How to monitor continuous heating equipment

For monitoring temperature in continuous heating equipment, you should use a continuous temperature-recording device (e.g., a recording thermometer). You should install the device where it measures the coldest temperature of the cooking equipment (the cold spot determined by a study). For larger heating chambers such as continuous baking or roasting ovens, you should install temperature recording devices in multiple locations, e.g., the top, middle, and bottom baking areas of the oven. For continuous monitoring of the temperature of continuous flow heated liquids, you could use a resistance temperature detector (RTD) placed in line.

For monitoring time (e.g., cooking or baking times) in continuous heating equipment, you could use a stopwatch or tachometer to monitor the speed of the belt drive wheel, or use a stopwatch to monitor the time it takes for a test unit or a belt mark to pass through the equipment. In other systems, you could determine time by the flow rate of a fluid product pumped through a continuous heating system. (In simple terms, the heating time is determined by the speed with which a food flows through the heating system. Determining the appropriate flow rate can be complicated – we recommend you use an expert in thermal processing to establish processes for such continuous heating systems.) To achieve a process-specific flow rate, you could calibrate the pump to a set RPM, mark a set point on the pump, and visually observe the pump setting (i.e., speed measured in RPM). Some systems provide a mechanism whereby you could lock the pump to prevent a change in the pump speed that would affect the product flow rate.

For other process parameters, you should use appropriate equipment to monitor the factor, e.g., scales when you establish a critical limit for a weight; rulers or calipers when you establish a critical limit for size.

6.8.3 How Often to Monitor (Frequency of Monitoring)

6.8.3.1 How often to monitor batch heating equipment

If you use a continuous temperature-recording device (e.g., a recording thermometer) for monitoring, you should do a visual check of the recorded data at least once per batch. If you establish an EPIPT, you should monitor the EPIPT for each batch.

For the heating time of a batch process, you should monitor the recorded start and end times for each batch unless you are using an EPIPT. (When using an EPIPT, the frequency of checking temperature is often designed to minimize exposure to heat once the EPIPT is reached, and it is product quality, rather than product safety, that generally would be negatively impacted.)

You should monitor other process parameters with sufficient frequency to achieve control.

6.8.3.2 How often to monitor continuous heating equipment

If you use a continuous temperature-recording device (e.g., a recording thermometer) for monitoring, you should do a visual check of the recorded data at least once per day.

For the heating time of a continuous process, you should monitor the automated timers at least once per day or pump speed setting at least twice per shift, and whenever you make any changes in the automated timer or pump speed setting.

You should monitor other process parameters with sufficient frequency to achieve control.

6.8.4 Who performs the monitoring

When a person (rather than a machine) is assigned to perform monitoring, that person must have the education, training, or experience (or a combination of these) necessary to perform the individual's assigned duties. (See 21 CFR 117.4(b)(1).)

Examples of who performs the monitoring, or devices that perform monitoring, include:

- A continuous monitoring thermometer measures the product IT or the oven temperature;

- The person who puts ingredients together before they are taken to the line determines the weight of ingredients critical to the formulation of the product or determines that particle size is within specifications;

- The line operator (e.g., kettle cook, bakers), Quality Control (QC) personnel, or any other person who has an understanding of the nature of the preventive controls;

   o Visually checks data generated by a continuous monitoring device to ensure that the critical limits have consistently been met[4];

   o Monitors the temperature for manual (non-automated or non-continuous) devices; and

   o Performs other monitoring activities that occur on the processing line.

6.9 Establish and Implement Corrective Action Procedures

Part 117 requires that, as appropriate to the nature of the hazard and the nature of the preventive control, you must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate: (1) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing; and (2) The presence of an environmental pathogen or appropriate indicator organism detected through environmental monitoring. The corrective action procedures must describe the steps to be taken to ensure that: (1) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control; (2) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur; (3) All affected food is evaluated for safety; and (4) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated or misbranded. (See 21 CFR 117.150(a).)

When your preventive control is a heat treatment, your corrective action procedures would describe the steps you will take when the heat treatment does not achieve the process-specified temperature or time (as well as any other critical limits established for the heat treatment).

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[4] This is sometimes considered a verification activity.

Examples of steps identified in corrective action procedures applicable to a heat treatment include:

- Continue heating a product that has not reached the specified temperature after the specified number of minutes;

- Extend the length of the heat cycle to compensate for a temperature drop (e.g., by continuing to heat the product for a longer time; by slowing the belt speed or flow rate to increase time of exposure to heat), using an alternate process developed by a process authority;

- Process at a higher temperature or longer time to compensate for a low IT, using an alternate process developed by a process authority;

- Reprocess the product (deliver the full process as if no heating had already occurred);

- Chill and hold the product for an evaluation of the adequacy of the heat treatment that has been delivered, and stipulate the disposition of the product if the product has not received an adequate process (e.g., destroy the product, divert it to a non-food use, or reheat it);

- Divert the product to a use in which the critical limits for the parameter are not applicable (e.g., an RTE product may become a not-RTE product or may become an ingredient for further processing by you or another manufacturer/processor);

- Divert the product to animal food (usually for animals other than pets);[5] and

- Destroy the product.

Although part 117 establishes requirements applicable to your corrective action procedures, it neither establishes requirements for other procedures, such as for adjustments, you might establish in your plant nor precludes you from establishing such procedures. Likewise, part 117 neither establishes requirements applicable to any assessment that you do for food quality if a process parameter deviates from an operating limit but does not deviate from a critical limit (e.g., if you have a procedure to assess food quality if the baking temperature for cookies is more than 5-10 degrees above the temperature set as a critical limit).

6.10 Determine Verification Procedures

Part 117 requires that verification activities include, as appropriate to the nature of the preventive control and its role in your food safety system: (1) Validation; (2) Verification that monitoring is being conducted; (3) Verification that appropriate decisions about corrective actions are being made; (4) Verification of implementation and effectiveness; and (5) reanalysis. (See 21 CFR 117.155.) For a discussion of validating a heat treatment, see section 6.6 of this chapter.

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[5] FDA is developing guidance on the use of human food by-products in animal food, including diversion of human food products to animal food use. In 2016, FDA issued for public comment a draft guidance for industry entitled "Human Food By-Products For Use As Animal Food" (FDA, 2016 and 81 FR 58521, August 25, 2016). In determining whether it is appropriate to divert a food product to animal food use, we recommend that you consult the final guidance on this subject when it becomes available.

Part 117 also requires that you verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system:

- Calibration of process monitoring instruments and verification instruments (or checking them for accuracy) (21 CFR 117.165(a)(1));

- Product testing, for a pathogen (or appropriate indicator organism) or other hazard (21 CFR 117.165(a)(2));

- Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples (21 CFR 117.165(a)(3)); and

- Review of certain records by (or under the oversight of) a PCQI, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions (21 CFR 117.165(a)(4)).

Part 117 also requires, as appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, that you establish and implement written procedures for: (1) The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy); (2) Product testing; and (3) Environmental monitoring. (See 21 CFR 117.165(b).)

Examples of verification activities applicable to heat treatments include:

- Calibrating devices used for monitoring (and for verification), such as thermometers, RTDs, timers, and scales, before use (or verifying their accuracy);

- Reviewing monitoring records (e.g., process logs) to confirm that the heat treatment was performed at the proper temperature and for the appropriate amount of time (sometimes also called "batch records review");

- Performing measurements at the monitoring points independent of the routine monitoring activity or observing line operators performing measurements;

- Verifying that appropriate decisions about corrective actions are being made when there are process deviations from critical limits; and

- Conducting, when appropriate, product testing to confirm that the heat treatment has adequately controlled bacterial pathogens that are relevant to the product.

This chapter does not discuss verification activities that are not directly related to heat treatments. For example, this chapter does not discuss environmental monitoring for an environmental pathogen as verification of sanitation controls. Likewise, this chapter does not discuss corrective action procedures that could be associated with such verification activities, such as product testing if the results of environmental monitoring for an environmental pathogen are positive.

6.11 Establish and Maintain Records

Part 117 requires that you document the preventive control management components as follows: (1) The monitoring of preventive controls in records that are subject to verification and records review; (2) all corrective actions (and, when appropriate, corrections) in records that are subject to verification and records review; and (3) all verification activities. (See 21 CFR 117.145(b)-(c), 117.150(d), and 117.155(b).)

Examples of what to document in records applicable to a heat treatment include:

- Monitoring activities of the process parameters that were established by a scientific study or provided by a process authority;

- Corrective actions that you take when a heat treatment does not achieve the process-specified temperature or time or when other critical limits are not met;

- Verification activities for implementation of the heat treatment such as:

  o Calibration records for monitoring/measuring devices, and a review of the calibration records;

  o Review of process records (e.g., logs of IT, process temperatures, process times, temperature charts);

  o Review of any corrective actions taken as a result of a deviation from any of the critical limits for the heat treatment; and

  o Any other verification activities conducted, including any product testing used to verify the adequacy of the heat treatment.

6.11.1 Records of Monitoring Activities

6.11.1.1 Records of monitoring activities for batch heating equipment

Examples of what to document in records of monitoring activities for batch heating equipment include:

- Records of temperature and time, if you monitor both temperature and time;

- Records of the finished product temperature, if you establish an EPIPT (where there is no time associated with the heat treatment);

- Records applicable to a continuous temperature recording device (e.g., a recording thermometer), if you use one, such as:

  o Recorder charts;

  o When applicable, records documenting the visual checks of recorded data (e.g., a hand written note on the recorder charts); and

- o When applicable, records noting the start time and end time of the cooking or baking periods;

- Records of monitoring of critical limits for other process parameters for your heat treatment (e.g., weight or size).

You should keep these records in a "process log" for each production line, with information to identify the plant or facility, dates (and when appropriate, the time) of monitoring, the signature or initials of the person performing the monitoring (e.g., operator initials) and evidence of review (i.e., the initials of the PCQI or designee).

6.11.1.2 Records of monitoring activities for continuous heating equipment

Examples of what to document in records of monitoring activities for batch heating equipment include:

- Records of any continuous temperature-recording device (e.g., a recording thermometer) (When applicable, this would include records of each temperature-recording device installed for each heating area in an oven with multiple temperature recording devices);

- Records of the time interval (in minutes) determined by a stopwatch and automated timer if you use a stopwatch to monitor the time interval of an automated timer;

- Records of the pump speed (RPM) in the line process log every time you do a visual check (if you determine time by the flow rate of a fluid product through a continuous heating system and you visually monitor the pump setting); and

- Records of monitoring of critical limits for other process parameters for your heat treatment (e.g., weights, size, thickness, etc.).

You should keep these records in a "process log" for each production line (or other forms of documentation), with information to identify the plant or facility, dates (and when appropriate, the time) of monitoring, the signature or initials of the person performing the monitoring (e.g., operator initials) and evidence of review (i.e., the initials of the PCQI or designee).

6.11.2 Records of Corrective Actions

Examples of what to document in records of corrective actions that you take when a heat treatment is not properly implemented include records of corrective actions if your heat treatment does not achieve the process-specified temperature or time established for your food product, or any other critical limit you established for a process parameter for your heat treatment.

6.11.3 Record of On-going Verification Activities

Examples of what to document in records of verification activities applicable to your heat treatment include:

- Records (e.g., a log) documenting:

- o The calibration of measuring devices (such as thermometers, RTDs, timers, and scales);

- o   Who conducted the calibration;

- o   The method of calibration (which could be a Standard Operating Procedure);

- o   The date of calibration;

- o   Whether the device was in or out of specification; and

- o   Adjustments needed and performed;

- A record of the process logs review, by whom, and date of review;

- A report of reviewing corrective actions taken when there are process deviations, including initials of the reviewer and the date of review; and

- A report of product testing (when determined appropriate) to verify that the heat treatment has adequately controlled bacterial pathogens that are relevant to the product.

6.12 Example of Cookie Processor A's Heat Treatment

6.12.1 Cookie Processor A's Product, Hazard Analysis, and Batch Heat Treatment

Cookie Processor A bakes cookies in batches on trays in convection ovens and packages them by wrapping the cookies by twos in plastic. Cookie dough is made and deposited on trays in the dough preparation room and racks of trays are moved to the baking room. Trays are removed from the convection oven after baking, placed on clean racks, and moved to the packaging room.

Cookie Processor A's PCQI identified *Salmonella* as the hazard associated with the ingredients (e.g., flour, eggs, peanut butter) used in making the cookies and determined that baking the cookies was the preventive control that would address this hazard. However, to ensure the adequacy of the baking process used as the preventive control in Cookie Processor A's food safety plan, Cookie Processor A's PCQI needed to determine the appropriate processing parameters, including any critical limits, that would provide adequate lethality for *Salmonella* during a batch baking process in a convection oven. To do so, Cookie Processor A's PCQI consulted with a local university's extension specialist in process design and validation of heat treatments. Cookie Processor A's PCQI asked the extension specialist to:

- Identify processing parameters that need critical limits for food safety; and

- Determine critical limits for those processing parameters.

6.12.2 Cookie Processor A's Process Design and Validation

The extension specialist provided Cookie Processor A's PCQI with a published study by Lathrop et al., (2014) on survival of *Salmonella* during baking of peanut butter cookies. The published study showed that peanut butter cookie dough made with peanut butter inoculated with high levels of *Salmonella* (28 g portions of dough, water activity (a_w) of 0.82) and baked at 350°F (177°C) for 15 minutes had no detectable *Salmonella.* Cookies baked for 13 minutes showed at

least a 5.2 log reduction in *Salmonella*. In that published study, the cookie temperature at the end of 15 minutes was 229°F (109°C).

The extension specialist identified the following processing parameters that need critical limits for food safety in Cookie Processor A's heat treatment:

- Convection oven temperature (°F) to achieve specified minimum product temperature;

- Baking time in oven (minutes); and

- Dough delivery process resulting in the specified cookie portion weight (g).

To determine critical limits for those processing parameters when baking cookies in batches in Cookie Processor A's convection oven, and demonstrate that these critical limits can be achieved in Cookie Processor A's convection oven, the extension specialist conducted in-house heat distribution tests on Cookie Processor A's ovens and heat penetration tests on the cookies using a fully loaded oven (each oven rack contained a full tray of cookies, deposited in 28 g portions using a dough depositor). These in-house heat distribution and heat penetration tests showed that all parts of each of Cookie Processor A's oven were at or above 350°F (177°C) when the ovens were set at that temperature and that the coldest cookie temperature was above 230°F (110°C) after 13 minutes. In addition, a_w determinations by an outside laboratory on the cookie dough were equal to or greater than 0.82 using Cookie Processor A's recipes.

Based on the in-house tests, and the published study by Lathrop et al. (Lathrop, 2014), the extension specialist determined that the baking process of 350°F or greater for a minimum of 13 minutes (operating limit of 15 minutes) would provide adequate lethality for *Salmonella* for the recipe tested, so long as cookie dough portions did not exceed 28 g. The extension specialist informed Cookie Processor A that any subsequent change to the cookie recipe should be evaluated to determine whether it would impact these determinations.

Based on the information obtained from the extension specialist, Cookie Processor A's PCQI established three critical limits for the production of the cookies to ensure adequate lethality:

- The critical limit (minimum value) for the baking temperature is 350°F (177°C);

- The critical limit (minimum value) for the baking time is 13 minutes; and

- The critical limit (maximum value) for the cookie dough portion size is 28 g.

Based on the information obtained from the extension specialist, Cookie Processor A's PCQI also established three operating limits for the production of the cookies:

- The operating limit for the baking temperature is 352°F (178°C);

- The operating limit for the baking time is 15 minutes; and

- The operating limit for cookie dough portion size is 27 g.

Cookie Processor A calibrated a dough depositor to deliver 27 g portions of dough onto cookie sheets and produces cookies according to the established operating limits by baking 27 g portions of cookie dough in 352°F (178°C) ovens for 15 minutes.

6.12.3 Cookie Processor A's Monitoring

6.12.3.1 What Cookie Processor A monitors

Cookie Processor A monitors oven temperature, baking time, the dough depositor setting, and the weight of dough deposited.

6.12.3.2 How Cookie Processor A monitors

Cookie Processor A:

- Uses a recording thermometer with recording chart to continuously monitor oven temperature;

- Manually checks the temperature recorder chart and marks it with the batch number; records time when the cookies enter the oven and the oven temperature, calculates and records the time cookies should be removed, records the time the cookies are removed from the oven on baking record sheets, and calculates and records the elapsed baking time;

- Checks the set point of the dough depositor that controls the weight of dough portions deposited; and

- Periodically checks the weight of a few individual raw cookie dough portions using a calibrated scale located near the depositor.

6.12.3.3 How often Cookie Processor A monitors

Cookie Processor A:

- Checks the oven temperature (continuously recorded) before putting each batch of cookies into the oven to ensure it is reading at the minimum specified set point (i.e., at least 350°F (177°C);

- Records the start and end baking times of each batch of cookies;

- Checks the set point of the dough depositor every 2 hours; and

- Checks the weight of a few deposited cookie portions twice per shift.

6.12.3.4 Who monitors critical factors for Cookie Processor A's heat treatment

At Cookie Processor A:

- The baker checks the oven temperature before putting each batch of cookies into the oven and notes and records the start and end times of the baking cycle for each batch of cookies.

- A QC technician checks the set point of the dough depositor and the weight of the raw cookie dough portions.

6.12.4 Cookie Processor A's Corrective Action Procedures

Cookie Processor A's corrective action procedures specify that:

- If cookies were baked in an oven that was not at least 350°F (177°C), the cookies will be diverted to animal food (non-pet food) and employees will be retrained on the importance of ensuring that the oven temperature has reached the set point;

- If the bake time calculated from the start and end times is less than the critical limit of 13 minutes, the cookies will be diverted to animal food (non-pet food) and the PCQI will determine why the bake time was not met to prevent this from happening in the future;

- If the dough depositor is depositing a dough weight that exceeds the critical limit of 28 g:

  o The cookies will be diverted to animal food (non-pet food);

  o The PCQI will take steps to determine (if possible) what caused the depositor to deliver an incorrect weight so that actions can be taken to prevent such occurrences; and

  o The dough depositor will be adjusted to deliver the correct weight.

Cookie Processor A also has adjustment procedures that provide for:

- An assessment of product quality if the bake time is less than the operating limit of 15 minutes but more than the critical limit of 13 minutes, with an investigation of why the bake time was less than the operating limit to prevent this from happening in the future; and

- An adjustment of the dough depositor if the cookie dough weight exceeds the operating limit of 27 g but does not exceed the critical limit of 28 g.

6.12.5 Cookie Processor A's Verification Procedures

At Cookie Processor A:

- The following are calibrated at least annually:

  o The recording thermometer that monitors oven temperature;

  o The dough depositor; and

  o The scales used to check the weights of cookie portions.

- Within a week of their creation, the PCQI:

  o Reviews calibration logs (records of calibrating monitoring equipment) to make sure that the devices are properly calibrated using the appropriate methods and at the appropriate frequencies as specified in the calibration procedures;

  o Checks the baking record sheets and the temperature recording chart for monitoring records for temperature and time (i.e., time when the cookies enter the oven, calculated time for removal, and time the cookies were removed from the oven) to verify that the

oven temperature was at least at the critical limit of 350°F (177°C) and that the cookies were baked for 15 minutes;

- o Checks the dough weight logs for the cookie dough portion weighing records to verify that none of the dough portions exceeded 28 g in weight; and

- o Initials and dates each of the records reviewed in the place marked "Verified by."

- The PCQI reviews the corrective action records within a week of a deviation, and initials and dates each of the records reviewed in the place marked "Verified by."

6.12.6 Cookie Processor A's Monitoring Records

Cookie Processor A keeps:

- The recording charts of the recording thermometer as a record of monitoring the oven temperature;

- The baking record sheets as a record of monitoring the baking times; and

- A dough weight log as a record of the dough depositor setting and the dough portioning weight.

6.12.7 Cookie Processor A's Records of Corrective Actions

Cookie Processor A keeps records:

- Documenting that cookies placed in an oven that was not at least 350°F (177°C) or cookies baked for less than 13 minutes were diverted to animal food (non-pet food);

- Of any investigations of the cause of any deviations;

- Of all changes made to correct a problem and to prevent reoccurrence of deviations; and

- Documenting any retraining.

Cookie Processor A also keeps records of adjustments, because such records could be useful in identifying ongoing production problems that could demonstrate a need to review and change applicable production procedures.

6.12.8 Cookie Processor A's Verification Records

Cookie Processor A maintains records, initialed and dated by the PCQI, of the PCQI's review of:

- The calibration logs;

- The monitoring records (such as the oven temperature recording chart, records containing the bake time for cookies, and dough weight log); and

- The corrective action log.

6.12.9 Summary Process Control Table for Cookie Processor A

Appendix 6-A summarizes the above information for Cookie Processor A on the FSPCA's Process Control Form (Form 2-C (Modified) from Appendix 2).

6.13 Example of Cookie Processor B's Heat Treatment

6.13.1 Cookie Processor B's Product, Hazard Analysis, and Continuous Heat Treatment

Cookie Processor B bakes cookies in a continuous band oven and packages them in boxes of 24 cookies. Cookie dough is made in the dough preparation room and placed in totes that are taken to the dough hopper of an extruder at the front of the continuous band oven in the baking room. The dough extruder automatically deposits the dough across the oven band (solid conveyor), where the cookie dough is conveyed through the heating tunnel (oven). After baking, the band drops the cookies onto a conveyor that cools them and moves them to the packaging room.

Cookie Processor B's PCQI identified *Salmonella* as the hazard associated with the ingredients (e.g., flour, eggs, peanut butter) used in making cookies and determined that baking the cookies was the preventive control that would address this hazard. However, to ensure the adequacy of the baking process used as the preventive control in Cookie Processor B's food safety plan, Cookie Processor B's PCQI needed to determine the appropriate processing parameters, including any critical limits, that would provide adequate lethality for *Salmonella* for a continuous baking process using a band oven. To do so, Cookie Processor B's PCQI consulted with a process design specialist at a food research consulting firm regarding the process design and validation of the heat treatment. Cookie Processor B's PCQI asked the process design specialist to:

- Identify processing parameters that need critical limits for food safety; and

- Determine critical limits for those processing parameters.

6.13.2 Cookie Processor B's Process Design and Validation

The process design specialist provided Cookie Processor B's PCQI with a published study by Lathrop, et al., (2014) on survival of *Salmonella* during baking of peanut butter cookies. The published study showed that peanut butter cookie dough made with peanut butter inoculated with high levels of *Salmonella* (28 g portions of dough, a_w of 0.82) and baked at 350°F (177°C) for 15 minutes had no detectable *Salmonella.* Cookies baked for 13 minutes showed at least a 5.2 log reduction in *Salmonella*. In that published study, the cookie temperature at the end of 15 minutes was 229°F (109°C).

The process design specialist identified the following processing parameters that need critical limits for food safety in Cookie Processor B's heat treatment:

- Band oven temperature (°F) to achieve specified minimum product temperature;

- Baking time in oven (minutes) controlled by the speed of the conveyor belt through the continuous band oven; and

- Dough extrusion process resulting in the specified cookie portion weight (g).

To determine the critical limits for these processing parameters for baking cookies in Cookie Processor B's continuous band oven, and demonstrate that these critical limits can be achieved in Cookie Processor B's continuous band oven, the process design specialist conducted in-house oven temperature mapping (heat distribution) studies on the continuous band oven and heat penetration studies on the cookies. The results of these studies, and the recommendations of the process design specialist after conducting these studies, were as follows:

- Results of the in-house oven temperature mapping (heat distribution) study confirmed that the continuous band oven achieved and maintained the desired minimum temperature of 350°F (177°C) at the coldest spot in the oven at a set point temperature of 350°F (177°C) (or higher).

- The in-house heat penetration studies for the baking process used thermocouples with the sensors placed in the geometric center of the cookie dough portions (in 16 cookie dough portions deposited in 28 g portions at different points across the width of the oven band, in each of 3 trials conducted over 3 days). The speed of the conveyor belt in the band oven was set to result in a residence time of cookies in the oven of 13.0 minutes (as a worst case, or conservative, speed setting). Results from the heat penetration study demonstrated that all 28 g cookie dough portions achieved a minimum internal temperature of 231°F at the end of a 13.0-minute baking time.[6]

- Because the operating limit for Cookie Processor B's baking process is 15 minutes, the process design specialist also established the tachometer RPM reading that would result in a residence time of cookies in the continuous band oven of 15-minutes.

- To ensure that the nominal weight of each raw cookie dough portion does not exceed the established process critical parameter weight of 28 g, the process design specialist specified that the cookie dough extruder should be calibrated to deliver 27 g raw cookie dough portions as an operating limit, and that the delivery should be verified by performing weight measurements at startup of the dough extruder each day.

Based on the information derived from this in-house validation study, in combination with the study published by Lathrop et al. (Lathrop, 2014), the process design specialist determined that Cookie Processor B's band oven would provide adequate lethality for *Salmonella* for the specific recipe tested, so long as the weight of the raw cookie dough portion did not exceed 28 g and the cookies were baked for at least 13 minutes at a 350°F (177°C) oven setting.

Based on the information obtained from the process design specialist, Cookie Processor B's PCQI, established three critical limits for the production of the cookies to ensure adequate lethality:

- The critical limit (minimum value) for the baking temperature is 350°F (177°C);

- The critical limit (minimum value) for the baking time is 13 minutes; and

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[6] Note that these data demonstrate that if a deviation results in a baking time less than 15 minutes but 13 or more minutes, the cookies receive more than a 5-log reduction for *Salmonella* (they reach a temperature of 231°F) and are safe for consumption.

- The critical limit (maximum value) for the cookie dough portion size is 28 g.

Based on the information obtained from the process design specialist, Cookie Processor B's PCQI also established three operating limits for the production of the cookies:

- The operating limit for the baking temperature is 352°F (178°C);

- The operating limit for the baking time is 15 minutes; and

- The operating limit for cookie dough portion size is 27 g.

Cookie Processor B calibrated a dough depositor to deliver 27 g portions of dough onto cookie sheets and produces cookies according to the established operating limits by baking 27 g portions of cookie dough in a 352°F (178°C) band oven for 15 minutes.

6.13.3 Cookie Processor B's Monitoring

6.13.3.1 What Cookie Processor B monitors

Cookie Processor B monitors oven temperature (at the identified cold spot), belt speed as indicated by tachometer RPM (for control of baking time), the dough depositor setting, and the weight of dough deposited.

6.13.3.2 How Cookie Processor B monitors

Cookie Processor B:

- Uses a recording thermometer with recording chart to continuously monitor oven temperature at the cold spot; conducts a visual check of the chart and records the check in the operator's baking log;

- Uses an automated tachometer with recorder chart to monitor the speed of the conveyor belt through the band oven (which is tied to the baking time) and conducts a visual check of the tachometer RPM;

- Checks the set point of the dough depositor that controls the weight of the raw cookie dough portions deposited; and

- Periodically checks the weight of a few individual cookie dough portions using a calibrated scale located near the depositor.

6.13.3.3 How often Cookie Processor B monitors

Cookie Processor B:

- Checks the oven continuous temperature-recording device every hour to ensure it is reading at a minimum the specified set point (i.e., at least 350°F) (177°C);

- Monitors the automated tachometer recording (RPM) at start up and twice per shift;

- Checks the set point of the dough depositor at start up and every 2 hours; and

- Checks the weight of deposited cookie portions at least twice per shift.

6.13.3.4 Who monitors critical factors for Cookie Processor B's heat treatment

At Cookie Processor B:

- The baker checks the oven temperatures and monitors the automated tachometer recording; and

- A dough preparer checks the set point of the dough depositor and the weight of the raw cookie dough portions.

6.13.4 Cookie Processor B's Corrective Action Procedures

Cookie Processor B's corrective action procedures specify that:

- If cookies were baked in an oven that was not at least 350°F (177°C):

  o The cookies will be diverted to further processing (e.g., baking for cookie crumbles ingredient production) or to animal food (non-pet food);

  o Maintenance will determine the cause of the low temperature and fix the oven so the temperature is reset to the operating limit of 352°F (178°C) before more cookies are baked; and

  o Employees will be retrained, if necessary, on the importance of ensuring that the oven temperature has reached the set point before allowing the line to run.

- If the tachometer RPM recording indicates that the baking time is less than 13 minutes:

  o The cookies will be put on QC hold. The PCQI will determine whether the product will be diverted to further processing (e.g., baking) to make cookie crumbles as a baking ingredient or to animal food (non-pet food); and

  o The PCQI will conduct an investigation to determine why the bake time was not met and will inform plant management of actions they need to take to prevent this from happening in the future.

  If the dough depositor is depositing a dough weight that exceeds the maximum 28 g:

  o The PCQI will determine whether the product will be further processed into alternative products or be diverted to animal food (non-pet food), and (if possible) determine what caused the depositor to deliver an incorrect weight so that actions can be taken to prevent such occurrences; and

  o The dough depositor will be adjusted by maintenance or by the equipment manufacturer to deliver the correct weight.

Cookie Processor B also has adjustment procedures that provide for:

- An assessment of product quality if the bake time is less than the operating limit of 15 minutes but more than the critical limit of 13 minutes, with an investigation of why the bake time was less than the operating limit to prevent this from happening in the future; and

- An adjustment of the dough depositor if the cookie dough weight exceeds the operating limit of 27 g but does not exceed the critical limit of 28 g.

6.13.5 Cookie Processor B's Verification Procedures

At Cookie Processor B:

- The following are calibrated at least annually:

    o Recording thermometer and chart that monitors oven temperature;

    o The automated tachometer and recorder chart that monitors belt speed (baking time);

    o The dough depositor; and

    o The scales used to check the weights of cookie portions.

- A QC technician checks the recorder charts twice per shift to confirm that the oven is maintained at the specified baking temperature of at least 350°F (177°C) and the tachometer RPM resulted in baking times of 15 minutes; the QC technician writes the date and time on the recorder charts, and initials the recorder charts.

- A QC technician checks the raw cookie dough portion weighing records (dough weight logs) twice per shift to verify that none of the dough portions exceeded 28 g in weight; the QC technician writes the date and time on the dough weight log and initials the dough weight log.

- The PCQI collects the oven recording thermometer charts, operator's baking log, tachometer charts, and dough weight sheets daily for subsequent review within 7 days of their creation.

- Within 7 days of their creation the PCQI reviews the following records, dates and initials the records or a verification cover sheet to document that review, and then files the records:

    o The calibration logs to make sure that the devices are properly calibrated using the appropriate methods and at the appropriate frequencies as specified in the calibration procedures; and

    o The oven recording thermometer charts, operator's baking log, tachometer charts, and dough weight sheets for accuracy and to ensure the parameter values were met.

- The PCQI reviews corrective action records at the end of each week, initials and dates them to document that review, and files them chronologically (based on the date of the deviation) in a folder with other corrective actions.

6.13.6 Cookie Processor B's Monitoring Records

Cookie Processor B keeps:

- The recording charts of the recording thermometer and the operator's baking log as a record of monitoring temperature in the oven;

- The recording charts of the recording tachometer with the visual observation noted on the chart as a record of monitoring the RPMs that achieve the baking time; and

- A dough weight record sheet as a record of monitoring the check of the dough depositor setting and the check of the weight of the raw dough portions deposited.

6.13.7 Cookie Processor B's Records of Corrective Actions

Cookie Processor B keeps records:

- Of any lot of cookies diverted to further processing (e.g., baking for cookie crumbles) or to animal food (non-pet food);

- Of any investigation of the cause of any deviations;

- Of all changes made to correct a problem and to prevent reoccurrence of deviations; and

- Documenting any retraining.

Cookie Processor B also keeps records of adjustments, because such records could be useful in identifying ongoing production problems that could demonstrate a need to review and change applicable production procedures.

6.13.8 Cookie Processor B's Verification Records

Cookie Processor B maintains records initialed and dated by the PCQI, of the review of:

- Calibration logs;

- Oven recording thermometer charts;

- Operator's baking log with the hourly checks of the temperature chart and the twice-per-shift tachometer RPM reading;

- Tachometer charts;

- Dough weight logs; and

- Corrective action logs.

6.13.9 Summary Process Control Table for Cookie Processor B

Appendix 6-B summarizes the above information for Cookie Processor B on the FSPCA's Process Control Form (Form 2-C (Modified) from Appendix 2).

6.14 Example of Soup Processor A's Heat Treatment

6.14.1 Soup Processor A's Product, Hazard Analysis, and Batch Heat Treatment

Soup Processor A makes cooked, frozen RTE vegetable soups containing vegetable particles as ingredients. Soup Processor A cooks the soups to a minimum of 180°F (82°C) using a batch process in a 150 gallon steam-jacketed kettle, packages the soups in 8 ounce plastic bowls, and freezes the bowls of soup.

Soup Processor A's PCQI identified *L. monocytogenes* as the hazard associated with the RTE vegetable soups and determined that cooking the soup using a batch process in a steam-jacketed kettle maintained at a minimum of 180°F (82°C) was the preventive control to address this hazard. Soup Processor A's PCQI identified cooking time and vegetable particle size as processing parameters that needed critical limits to provide adequate lethality for *L. monocytogenes* during the batch kettle-cooking process. Soup Processor A's PCQI used Table 3-D in Appendix 3 of this guidance to determine process times for a range of cooking temperatures with *L. monocytogenes* as the target pathogen and arranged for food scientists at Soup Processor A to conduct in-house studies that could be used to determine the critical limits for vegetable particle size.

6.14.2 Soup Processor A's Process Design and Validation

Using Table 3-D in Appendix 3 of this guidance, Soup Processor A's PCQI determined that 0.05 minutes (3 seconds) at 180°F achieves an acceptable 6-log (i.e., 6 logarithm) reduction, typically called a 6D (6 decimal reduction) process. (See Chapter 4 for further details.) Because of the additional lethality during the heating time needed for the soup to reach 180°F (82°C), and because more than 3 seconds would elapse before cooling from 180°F could begin, Soup Processor A's PCQI decided to use an EPIPT and cook the soups until the temperature reaches 180°F rather than to continuously monitor temperature during cooking.

Food scientists at Soup Processor A conducted in-house studies to determine the critical limit for vegetable particle size. Based on those studies, Soup Processor A's PCQI determined that as long as vegetable particles in the soup did not exceed ½ inch (13 mm) square, the particles would also be at 180°F when the liquid portion of the soup reached that temperature, provided that the particles were stored refrigerated (i.e., at least 33°F) (0.6 °C) and not frozen. (Soup Processor A's SOPs specify that vegetable particles are stored refrigerated at a temperature of 33 - 40°F (0.6 - 4 °C).)

Soup Processor A established two critical limits for the production of the soup to ensure adequate lethality:

- Minimum EPIPT of 180°F (82°C); and

- Maximum size of vegetable particles (½ inch (13 mm)).

Soup Processor A determined that a critical limit for the temperature of the particles in the soup is not necessary as long as the production line follows the SOP to store the particles refrigerated.

6.14.3 Soup Processor A's Monitoring

6.14.3.1 What Soup Processor A monitors

Soup Processor A monitors the temperature of soup in the kettle and the size of any particles.

6.14.3.2 How Soup Processor A monitors

Soup Processor A:

- Uses a thermometer to periodically determine the temperature of soup in the top inch (2.5 cm) of the kettle (where it is coldest) until the EPIPT is reached and records the measured temperature in a cook log; and

- Collects a statistically-based sample of vegetable particles (e.g., diced carrots, potatoes, onions), uses digital calipers to ensure they do not exceed ½ inch (13 mm) in any direction, and records the measured size of the vegetable particles in a log.

6.14.3.3 How often Soup Processor A monitors

Soup Processor A:

- Begins measuring the temperature of the soup after approximately 30 minutes of heating;

- Measures the temperature approximately every 10 minutes after the temperature of the soup reaches approximately 170°F (77°C), until the temperature reaches 180°F (82°C); and

- Checks the particle size of every third lot of vegetable particles used as an ingredient in production upon receipt of the ingredient.

6.14.3.4 Who monitors critical factors for Soup Processor A's heat treatment

At Soup Processor A:

- The kettle cook operator measures the temperature of the soup during processing; and

- A formulation control operator checks the vegetable particle size.

6.14.4 Soup Processor A's Corrective Action Procedures

Soup Processor A's corrective action procedures specify that:

- If it is determined that the EPIPT did not reach 180°F (82°C) while the soup is being packaged but has not been frozen, packaging will be stopped and the remaining soup, including soup returned to the kettle from packages that have been filled but not frozen, will be reprocessed until the EPIPT reaches 180°F. Any packages that have already been frozen will be destroyed;

- If it is determined that the EPIPT did not reach 180°F (82°C) after the soup is packaged and frozen, the PCQI will assess the safety of the product to determine appropriate disposition. If the PCQI determines that the process delivered was inadequate to ensure product safety, the soup will be diverted to animal food (non-pet food) or destroyed;

- When soup is packaged before the EPIPT reaches 180°F (82°C) due to operator error, the kettle cook operator will be retrained, as appropriate, in proper procedures for, and the importance of, ensuring the product is not packaged before the EPIPT reaches 180°F; and

- If it is determined that the mean plus 2.5 standard deviation of the vegetable particle sizes exceeds ½ inch (13 mm) the lot of vegetables is rejected. The unopened packages will be returned to the supplier, and the PCQI will discuss the issue with the supplier so the supplier can investigate the root cause for incorrect particle size. The formulation control operator will check the vegetable particle size of every lot for the next 15 lots to verify particle sizes meet specification. If all 15 lots meet specification, the formulation control operator will return to monitoring every third lot.

6.14.5 Soup Processor A's Verification Procedures

At Soup Processor A:

- The thermometers used to measure soup temperature are:

  o Checked for accuracy at least daily by the QC technician; and

  o Calibrated by the QC technician against a NIST-calibrated reference thermometer at least annually or whenever an accuracy check shows that recalibration is needed. The PCQI reviews, dates, and initials the calibration log within a week of the calibration.

- The accuracy of digital calipers is checked by the QC technician before use by verifying that when fully closed the caliper reads zero (if not, the caliper is sent for repair or replaced);

- When calibration and accuracy checks of the thermometers and calipers are performed, the date and time are recorded in a log;

- On a weekly basis, the PCQI:

  o Reviews monitoring records (cook logs) to confirm that all soups were cooked to a minimum temperature of 180°F (82°C) as indicated by the records of the EPIPT readings;

  o Reviews the accuracy checks of the thermometers and the digital calipers;

- o Reviews the particle measurement logs to verify that vegetable particles used in the soup did not exceed ½ inch (13 mm) in size; and

- Before a lot of soup is released, the PCQI reviews corrective action records as part of a pre-shipment review to ensure all lot records are in order. (Because Soup Processor A uses an EPIPT and employees have been with Soup Processor A for many years, Soup Processor A experiences few deviations, so the PCQI has determined and documented that this timeframe, rather than 7 working days, is reasonable.)

6.14.6 Soup Processor A's Monitoring Records

Soup Processor A keeps:

- A production line cook log as a record of monitoring the temperatures; and

- A log of the size of vegetable particles checked upon receipt for the lots of raw materials used in production.

6.14.7 Soup Processor A's Records of Corrective Actions

Soup Processor A keeps records:

- Of the reprocessing of product (e.g., recooked to 180°F) (82°C) if a soup was filled before the process-specified EPIPT was achieved and had not been frozen;

- Of any product safety assessment by the PCQI (e.g., soup that had been filled before reaching the EPIPT but that had been frozen) and the disposition of such product;

- Of any investigations of the cause of any deviations (including investigation into the supplier's procedures for control of particle size);

- Of all changes made to correct a problem and to prevent reoccurrence of deviations; and

- Documenting any retraining.

6.14.8 Soup Processor A's Verification Records

Soup Processor A maintains records with the date and initials of the PCQI for the review of:

- The log of the accuracy checks and calibration of the thermometer;

- The cook log for monitoring the soup temperatures;

- The log of the accuracy checks of the digital calipers; and

- The log of vegetable particle size;

- Corrective action records.

6.14.9 Summary Process Control Table for Soup Processor A

Appendix 6-C summarizes the above information for Soup Processor A on the FSPCA's Process Control Form (Form 2-C (Modified) from Appendix 2).

6.15 Example of Soup Processor B's Heat Treatment

6.15.1 Soup Processor B's Product, Hazard Analysis, and Continuous Heat Treatment

Soup Processor B makes RTE clear broths and RTE creamed vegetable soups (with no particles) that are cooked using a continuous process (in a continuous flow heat exchanger), hot-filled into 5 gallon bags, and refrigerated. The ingredients include dehydrated vegetable powders, pasteurized liquid fresh cream, spice blends, starch, and other thickeners.

Soup Processor B's PCQI, a food scientist/food engineer who functions as the facility's food processing expert[7], identified *Salmonella, L. monocytogenes, C. botulinum* type A, *C. botulinum* proteolytic type B, and *C. botulinum* non-proteolytic type B as hazards associated with the soups. Soup Processor B's PCQI determined that cooking the soups using a continuous process (in a continuous flow heat exchanger) was a preventive control to address most of these hazards. (Refrigeration will be needed to control *C. botulinum* type A and *C. botulinum* proteolytic type B in the heat-treated soups.) In identifying the processing parameters and determining the critical limits for these processing parameters, Soup Processor B's PCQI/food processing expert needed to evaluate which of the potential hazards would be the target organism.

Because hot-filling into 5-gallon bags would result in reduced oxygen packaging, and because the soups will be distributed refrigerated, Soup Processor B's PCQI/food processing expert determined that *C. botulinum* non-proteolytic type B is an appropriate target organism for the soup heat treatment.[8]

6.15.2 Soup Processor B's Process Design and Validation

Using Table 3-E of Appendix 3 of this guidance, Soup Processor B's PCQI/food processing expert determined that a heat treatment that targeted *C. botulinum* non-proteolytic type B as the most heat resistant pathogen would also address *Salmonella* and *L. monocytogenes* and that hot-filling at 185°F (85°C) would minimize risk of recontamination after the heat treatment.

Based on an assessment and review of the scientific literature, Soup Processor B's PCQI/ food processing expert decided to use a process of 205°F (96°C) for 2.5 minutes (equivalent to a

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[7] The individual who identifies critical limits, and establishes a heat treatment in a continuous flow system, for a product such as Soup Processor B's soup, should have specialized experience adequate to evaluate processing parameters, establish appropriate minimum/maximum values (e.g., the residence time in the hold tube based on flow characteristics of the product and the length and diameter of the hold tube) and ensure the safety of an RTE product packaged in reduced oxygen packaging. When the regulatory framework does not require that the individual be a "process authority," individuals with a variety of backgrounds (in this case, a food engineering background) could have such specialized experience.

[8] Annex 6 of the Food Code (FDA, 2013) is a source of additional information about selection of the target organism.

minimum temperature of 194°F (90°C) for a minimum of 10 minutes) based on Table 3-E of in Appendix 3 of this guidance. This time and temperature combination will deliver a 6D process for the most heat resistant spores for strains of *C. botulinum* non-proteolytic type B.

Briefly, the procedure for the continuous heat and hot-fill process for clear broths and creamed vegetable soups is as follows:

- Add the dry ingredients to the blend tank with the volume of water specified in the formulation and mix at a high speed (> 2000 rpm) for 30 minutes to ensure all dry materials are wetted and in solution (no clumps), and then blend in fresh cream that has been refrigerated to 40°F - 45°F (4°C- 7°C);

- Pump the untreated soup from the blend tank to the pre-process agitated surge tank (which is water jacketed to control the contents at the set process Initial Temperature (IT) (between 40°F and 45°F) (4°C- 7°C)) through in-line sieves to ensure no mix particles larger than 0.1 inch (2.5 mm) pass to the pre-process agitated surge tank;

- Pump the untreated soup via a metering pump (at a flow rate specified in gal/min) from the pre-process agitated surge tank to the indirect continuous heat exchanger (scraped surface) and then to the hold tube (which is sized to ensure the soup mix is held at the process temperature for a minimum of 2.5 minutes);

- The heat-treated soup flows from the hold tube into an agitated hot-holding surge tank that keeps the soup at $\geq$ 185°F (85°C); the heat-treated soup is then pumped to the filling hopper for the hot-fill process;

- Hot fill the heat-treated soup into 5-gallon pre-labeled bags and seal the bags; and

- Cool the sealed, hot-filled soup bags, pack them in a carton, and store the carton under refrigeration prior to distribution.

Soup Processor B's PCQI/ food processing expert determined that five process parameters are critical to the safety of the food product and established critical limits for each of these process parameters:

- IT of product held in the pre-process agitated surge tank (between 40°F and 45°F) (4°C- 7°C);

- Metering pump speed (RPM) to deliver process-specified flow rate (gal/min);

- Hold tube size (must deliver a minimum 2.5 minute product hold time prior to hot-filling);

- Temperature of the heat-treated soup at discharge end of hold tube (minimum value of 205°F) (96°C); and

- Temperature of the heat-treated soup in the agitated hot-holding surge tank (minimum value of 185°F) (85°C).

6.15.3 Soup Processor B's Monitoring

6.15.3.1 What Soup Processor B monitors

Soup Processor B:

- Monitors the IT in the surge tank;

- Checks the pump speed RPM setting;

- Checks that the correct hold tube is in place prior to production;

- Checks the temperature of the heat-treated soup exiting the hold tube using an RTD probe connected to a recording device; and

- Monitors the temperature of the heat-treated soup held in the agitated hot-holding surge tank prior to final packaging (i.e., hot fill).

6.15.3.2 How Soup Processor B monitors

Soup Processor B:

- Uses a Resistance Temperature Detector (RTD) probe attached to a recording chart to monitor the IT of the untreated soup in the pre-processing surge tank;

- Visually observes that the RPM dial setting on the pump (i.e., pump speed in RPM) is appropriate to achieve the process-specified flow rate of the soup;

- Visually observes that the correct hold tube is in place (hold tubes are numbered and each numbered hold tube is assigned to specific soup recipes);

- Uses an RTD probe attached to a recording chart to monitor the temperature of the heat-treated soup exiting the hold tube; and

- Uses another RTD probe attached to a recording chart to monitor the temperature of the heat-treated soup in the hot-holding surge tank.

6.15.3.3 How often Soup Processor B monitors

Soup Processor B:

- Checks the continuously recorded IT (RTD chart recorder) of the untreated soup in the pre-process surge tank twice per shift;

- Checks and records the pump speed setting (flow rate) at the beginning of production and twice per shift;

- Notes the hold tube used on the pump speed log at the beginning of production and whenever the variety of soup being produced changes;

- Checks the continuously recorded temperature (RTD chart recorder) of the heat-treated soup at the exit of the hold tube twice per shift; and

- Checks the continuously recorded temperature (RTD chart recorder) of the heat-treated soup in the filling surge tank twice per shift.

6.15.3.4 Who monitors critical factors for Soup Processor B's heat treatment

At Soup Processor B, the line operator monitors the recorded temperature data (IT of the untreated soup, temperature of the heat-treated soup exiting the hold tube, and temperature of the heat-treated soup in the agitated hot-holding surge tank), the pump speed setting, and the hold tube identification.

6.15.4 Soup Processor B's Corrective Action Procedures

Soup Processor B's corrective action procedures specify:

- A list of:

  o Those soups that can be fully reprocessed in instances where soup was under-processed; and

  o Those soups that cannot be fully reprocessed and therefore will be diverted to animal food (non-pet food) or destroyed if the PCQI determines that the process delivered was inadequate to ensure product safety.

- If the IT of the untreated soup was too low during the production of that soup:

  o The product will be held until the PCQI determines whether the process was adequate or if the soup can be reprocessed; and

  o The production manager will investigate why the IT was too low and take appropriate actions to prevent the situation from reoccurring.

- If the metering pump speed during production of the soup was too fast:

  o Any ongoing production will be stopped and affected product will be held until the PCQI evaluates the safety of the product;

  o The PCQI will assess the safety of the product and determine whether it will be released, re-processed, diverted to animal food (non-pet food), or destroyed; and

  o The production manager will investigate why the pump speed was too fast and take appropriate actions to prevent the situation from reoccurring.

- If the incorrect hold tube was used:

  o The PCQI will assess the safety of the product to determine appropriate disposition;

  o The production manager will investigate why the incorrect hold tube was used; and

o Employees will be retrained if necessary in light of the reason the incorrect hold tube was used.

- If the RTD at the end of the hold tube recorded a low temperature and the soup was not diverted to the batch tank for automatic reprocessing:

  o The PCQI will assess the safety of the product to determine appropriate disposition; and

  o The production manager will investigate the low temperature and the diversion failure and take appropriate action to fix the problem.

- If the temperature of the heat-treated soup in the agitated hot-holding surge tank is below the process set point:

  o The product will be held until the PCQI determines whether the temperature was adequate for safety or if the soup should be reprocessed, diverted to animal food (non-pet food), or destroyed.

  o The production manager will investigate why the temperature was too low and take appropriate actions to prevent the situation from reoccurring.

6.15.5 Soup Processor B's Verification Procedures

At Soup Processor B:

- An outside calibration service annually performs on-site calibration of the RTDs and recording devices used to measure IT of the untreated soup, the temperature of the heat-treated soup at the exit of the hold tube, and the hot-fill temperature. A sticker with the calibration date is affixed to each recording device and the date and results are recorded in a calibration log. Soup Processor B's PCQI also reviews, initials, and dates the monitoring device calibration logs within a week of their creation;

- The Quality Assurance Manager or designee verifies twice a year that the pump speed provides the correct flow rate for the hold tubes used for the different soups, and the PCQI reviews this within one week;

- On a daily basis, the PCQI :

  o Reviews recorder charts and pump speed log with the hold tube identification to confirm that the soup was cooked at the specified temperature of 205°F (96°C) for a minimum of 2.5 minutes; and

  o Checks the other process logs to confirm that the soup in the pre-process agitated surge tank was maintained at an IT between 40°F and 45°F (4°C- 7°C), that the temperature of the heat-treated soup at hold tube exit was at least 205 °F (96°C), and that the temperature of the heat-treated soup held in the agitated hot-holding surge tank prior to hot-filling was maintained at the specified process temperature of $\geq 185^{o}$F (852°C), and also checks that process log temperatures agree with the recorder charts;

- The PCQI reviews corrective action records within one week of when the deviation occurred; and

- Soup Processor B does not conduct product testing for pathogens or environmental monitoring because the product, which is subjected to a heat treatment validated to be highly lethal to vegetative pathogens and filled hot, is not exposed to the environment after the heat treatment.

6.15.6 Soup Processor B's Monitoring Records

Soup Processor B keeps:

- The recording charts from the RTDs used to monitor the IT of the untreated soup exiting the pre-process agitated surge tank, the temperature of heat-treated soup exiting the hold tube, and the temperature at the agitated hot-holding surge tank;

- The process logs for the temperature checks (IT of the untreated soup, temperature of the heat-treated soup exiting the hold tube, and temperature at the agitated hot-holding surge tank); and

- A process log for each line to record pump speeds and hold tube number for the product being processed.

6.15.7 Soup Processor B's Records of Corrective Actions

Soup Processor B keeps records:

- Of any product safety assessment by the PCQI of the safety of product to determine appropriate disposition if:

  o The IT of the untreated soup was too low;

  o The metering pump speed was too fast;

  o An incorrect hold tube was used;

  o The RTD at the end of the hold tube recorded a low temperature and the heat-treated soup was not diverted to the batch tank for automatic reprocessing; or

  o The temperature for the heat-treated soup held in the agitated hot-holding surge tank prior to hot-filling was too low.

- Of the reprocessing of a soup that can be reprocessed if the RTD at the end of the hold tube recorded a low temperature and the soup was not diverted to the batch tank for automatic reprocessing;

- Of any soup that cannot be reprocessed and thus is sent to animal food (non-pet food) or destroyed;

- Of any investigations of the cause of any deviations;

- Of all changes made to correct a problem and to prevent reoccurrence of deviations; and

- Documenting any retraining.

6.15.8 Soup Processor B's Verification Records

Soup Processor B maintains the following records with the date and initials of the PCQI for the review of:

- The monitoring records - i.e.:

  o The temperature recording chart for all RTD probes (IT of the untreated soup exiting the pre-process agitated surge tank, the temperature of heat-treated soup exiting the hold tube, and the temperature at the agitated hot-holding surge tank);

  o The process logs for the temperature checks (IT of the untreated soup exiting the blend tank, the temperature of heat-treated soup exiting the hold tube, and temperature at the agitated hot-holding surge tank); and

  o The process logs for each line with pump speeds and hold tube number for the product being processed;

- The calibration logs, including notes of the actions taken when any adjustments were needed;

- The semi-annual verification tests that the pump speed provides the correct flow rate for the hold tubes used for the different soups, including notes of when any adjustments to the pump speed were needed; and

- The corrective action records.

6.15.9 Summary Process Control Table of Soup Processor B

Appendix 6-D summarizes the above information for Soup Processor B on the FSPCA's Process Control Form (Form 2-C (Modified) from Appendix 2).

6.16 Example of Salsa Processor A's Heat Treatment

6.16.1 Salsa Processor A's Product, Hazard Analysis, and Heat Treatment

Salsa Processor A manufactures a shelf-stable chopped mixed vegetable salsa product that is an acidified food subject to the requirements of 21 CFR part 114 (part 114). Our regulations for acidified foods in part 114 require that an acidified food be manufactured, processed, and packaged so that the finished equilibrium pH value of 4.6 or lower is achieved within the time designated in the scheduled process and maintained in all finished products. (See 21 CFR 114.80(a)(1).) Acidified foods are shelf-stable foods and must be thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user. (See 21 CFR 114.80(a)(1).) The "scheduled process" (i.e., the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance) includes control of pH and other critical factors equivalent to the process established by a competent processing

authority (21 CFR 114.3). Salsa Processor A's PCQI is also a thermal process authority for the purpose of establishing a scheduled process in accordance with part 114.[9]

Salsa Processor A's product consists of chopped vegetables (i.e., tomatoes, long green chilies, onions, jalapeño peppers, and garlic), salt, spices, and vinegar. Each batch is directly acidified, cooked in a kettle, and then hot-filled into glass jars. The hermetically sealed jars are shelf stable under ambient storage temperatures.

Salsa Processor A's PCQI/process authority identified *Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes* and *Clostridium botulinum* as hazards associated with the salsa because these pathogenic bacteria can be present on some of the ingredients and can be a hazard if the salsa is not properly acidified to a pH that is low enough to prevent the germination of spores of *C. botulinum* and if the heat treatment is not adequate to kill vegetative cells of the pathogenic bacteria.

Salsa Processor A's PCQI/process authority consulted the scientific literature and found that some sporeforming microorganisms that are generally associated with spoilage (such as *Bacillus subtilis* (*B. subtilis)*, and *B. licheniformis*) could potentially affect the safety of an acidified food if spores that are not destroyed during the product heat treatment germinate, grow, and cause the pH to increase above 4.6 such that spores of *C. botulinum* could germinate, grow and produce toxin (Rodriguez et al, 1992). However, the scientific literature indicated that these sporeformers do not grow at pH 4.2 or less and require oxygen for growth at pH 4.4 (Rodriguez et al, 1992). Salsa Processor A's salsa is acidified to pH 4.1; thus Salsa Processor A's PCQI/process authority determined that the heat treatment should target vegetative pathogens such as *Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes.* Salsa Processor A's PCQI/process authority also determined that there were non-pathogenic sporeformers that would survive a heat treatment designed for vegetative pathogens that could spoil the product under ambient conditions.

6.16.2 Salsa Processor A's Process Design and Validation

Based on an assessment and review of scientific literature, Salsa Processor A's PCQI/ process authority selected a process (158°F (70°C) for 1.5 minutes) that will deliver a 5D process for *Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes* at a product pH of no higher than 4.1 (Breidt et al., 2010). Salsa Processor A's PCQI/process authority also determined that the pH of 4.1 would control sporeforming pathogens such as *C. botulinum,* as well as sporeformers that could potentially grow and raise the pH of the salsa. (See Chapter 8 – "Use of Formulation as a Process Control" for information on the use of acidification to control *C. botulinum*.) Salsa Processor A's PCQI/process authority also determined that a process that delivers 200°F (93°C) for 2 minutes is adequate to destroy any other sporeformers that could survive the process and potentially spoil the product, and thus achieve a shelf-stable product.

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[9] Our regulations require that a commercial processor engaged in the processing of acidified foods provide us with information, submitted on Form FDA 2541e, on the scheduled processes for each acidified food in each container size. (See 21 CFR 108.25(c)(2).) For additional information about submitting a "process filing" for an acidified food using Form FDA 2541e, see our guidance for industry entitled "Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format" (FDA, 2015).

In-house studies determined that as long as the chopped vegetable particles in the salsa did not exceed 1.0 cm (0.4 inch) square, the particles would also be at 158°F (70°C) when the liquid portion of the salsa reached that temperature, provided that the particles were stored refrigerated (i.e., at least 33°F (0.6°C)) and not frozen. (Salsa Processor A's SOPs specify that vegetables to be chopped are stored refrigerated (at a temperature of 33 - 40°F (0.6 - 4 °C)) until used.) Salsa Processor A determined that the size of the particles in the vegetable salsa is a parameter requiring a critical limit (i.e., a maximum value of 1.0 cm square). However, Salsa Processor A's PCQI/process authority determined that a critical limit for the temperature of the particles in the vegetable salsa is not necessary as long as the production line follows the SOP to store the particles refrigerated.

Briefly, the procedure for the production of the mixed vegetable salsa is as follows:

- All vegetables, which have been held refrigerated, are washed and or peeled, cored or seeded, and chopped;

- Vinegar (5 percent acetic acid), salt, and spices are prepped and weighed per recipe;

- Salsa is made by combining all ingredients in an agitated 150 gallon steam-jacketed cook kettle that heats the salsa to 200°F (93°C); the salsa is then held for at least 2 minutes;

- Heat-treated salsa is pumped from the cook kettle to a temperature-controlled filling surge tank and equilibrated to 200°F (93°C);

- The heat-treated salsa is then hot-filled into clean pint glass jars via a volumetric filler. Jars are capped under flowing steam, then inverted and conveyed for one minute (to kill microorganisms on the container) prior to being re-inverted, and conveyed through a cold water shower for cooling; and

- Cooled and sealed jars are then dried prior to being labelled, packed 12 to a carton, and stored on pallets.

Salsa Processor A's PCQI/ process authority determined that the following process parameters related to the heat treatment are critical to the safety of the chopped vegetable salsa[10] and established critical limits for each of these process parameters:

- Maximum particle size of chopped vegetables (1.0 cm) (0.4 inch);

- Minimum process temperature for the salsa (158°F) (70°C)[11];

- Minimum process time for the salsa (1.5 minutes);

- Minimum temperature of the heat-treated salsa in the filling surge tank (158°F) (70°C); and

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[10] See Chapter 8 – Use of Formulation as a Process Control – for additional information about pH as a critical factor in the production of an acidified food, including the preventive control management components.

[11] This is the process for safety. However, the acidified foods regulation requires the destruction of spoilage organisms such that the food is shelf-stable. Thus the operating limits are actually 200°F (93°C) for 2 minutes.

- Minimum inverted jar hold time (1 minute).

Because Salsa Processor A needs to make a shelf-stable food, Salsa Processor A treats the operating limits established for shelf-stability as if they were the critical limits established for food safety.

6.16.3 Salsa Processor A's Monitoring

6.16.3.1 What Salsa Processor A monitors

Salsa Processor A:

- Monitors the particle size of the chopped vegetables;

- Monitors the temperature of the in-process salsa in the cook kettle;

- Monitors the time that the in-process salsa is at the process temperature (operating limit) of 200°F (93°C) or higher in the cook kettle (which ensures that the critical limit of 158°F (70°C) will be met);

- Monitors the temperature of the heat-treated salsa held in the filling surge tank prior to final packaging (i.e., hot fill); and

- Checks conveyor belt speed as indicated by automated tachometer RPM (for control of inversion time) for inverted jars.

6.16.3.2 How Salsa Processor A monitors

Salsa Processor A:

- Collects a statistically-based sample of vegetable particles (e.g., chopped tomatoes, green chilies, onions, jalapeño peppers), uses digital calipers to ensure they do not exceed 1 cm (0.4 inch) in any direction, and records the results in the process log;

- Uses an RTD probe attached to a recording chart to monitor the temperature of the in-process salsa at the cold point in the cook kettle (in top inch (2.5 cm) of kettle), visually checks the chart and records the observed temperature in the process log;

- Visually checks the temperature recorder chart and marks it with the batch number, records the time when the in-process salsa reaches the process temperature in the process log, calculates the processing time, records the processing time on the recorder chart and in the process log, notes when product should be transferred from cook kettle in the process log, and records the time when product is transferred from the cook kettle to the filling surge tank in the process log;

- Uses another RTD probe attached to a recording chart to monitor the temperature of the heat-treated salsa in the filling surge tank, visually checks the chart, and records the temperature in the process log; and

- Uses an automated tachometer with recorder chart to monitor the conveyor speed (which is tied to the jar inversion time), visually checks the tachometer RPM, and records the RPM in the process log.

6.16.3.3 How often Salsa Processor A monitors

Salsa Processor A:

- Checks the particle size of one in-process lot of each chopped vegetable once per production shift;

- Checks the continuously recorded temperature (RTD chart recorder) of the in-process salsa in the cook kettle once for each batch;

- Checks the processing time once for each batch;

- Checks the continuously recorded temperature (RTD chart recorder) of the in-process salsa in the filling surge tank twice per shift; and

- Monitors the automated tachometer RPM (inversion conveyor belt speed) at the beginning of production and twice per shift.

6.16.3.4 Who monitors critical factors for Salsa Processor A's heat treatment

At Salsa Processor A:

- A formulation control operator checks the particle size of the chopped vegetables; and

- The line operator monitors the recorded temperature and time data (in-process salsa in cook kettle and filling surge tank, and the automated tachometer RPM (conveyor belt speed) for jar inversion.

6.16.4 Salsa Processor A's Corrective Action Procedures

Salsa Processor A's corrective action procedures specify:

- If it is determined that the mean plus 2.5 standard deviation of the vegetable particle sizes exceeds 1 cm (0.4 inch), the in-process lot of chopped vegetables is rejected and will be reworked for a different recipe. The PQCI will check with the vegetable processing operator to investigate the root cause of the incorrect particle size and, when applicable, notify maintenance to reset the vegetable chopper operation to specification. The formulation control operator will check the vegetable particle size of every in-process lot for the next 15 in-process lots to verify particle sizes meet specification. If all 15 lots meet specification, the formulation control operator will return to monitoring one in-process lot of each chopped vegetable once per production shift;

- If the RTD at the cook kettle records a low temperature or a shortened process time:

- o The product will be held until the PCQI determines whether the process was adequate for safety or if the product should be reprocessed or destroyed;

- o The production manager will investigate why the under-processing occurred and take appropriate actions to prevent the situation from reoccurring; and

- o Employees will be retrained if necessary in light of the reason for the under-processing;

- If the temperature at the filling surge tank is below the process set point:

  - o The product will be held until the PCQI determines whether the fill temperature was adequate for safety or if the product should be reprocessed or destroyed;

  - o The production manager will investigate why the fill temperature was too low and take appropriate actions to prevent the situation from reoccurring; and

  - o Employees will be retrained if necessary; and

- If it is determined that the jar inversion time is below the process set point:

  - o The product will be held until the PCQI determines whether the process was adequate or if the product can be reprocessed;

  - o The production manager will investigate why the belt speed deviated from the process set point and take appropriate actions to prevent the situation from reoccurring; and

  - o Employees will be retrained if necessary in light of the reason for the belt speed deviation.

6.16.5 Salsa Processor A's Verification Procedures

At Salsa Processor A:

- An outside calibration service annually performs on-site calibration of the RTDs, tachometer, and recording charts used to measure the temperature at the cook kettle and the hot-fill surge tank, and the belt speed of the jar inversion conveyor. A sticker with the calibration date is affixed to each recording device and the date and results are recorded in a calibration log. The PCQI reviews, initials, and dates the monitoring device calibration logs within a week of their creation;

- The Quality Assurance Manager or designee verifies the jar inversion belt speed and time twice each year, and the PCQI reviews this within one week;

- On a daily basis, the PCQI :

  - o Checks process logs to confirm that the particle size of the chopped vegetables was at the specified value of < 1 cm (0.4 inch);

  - o Reviews process logs and recorder charts to confirm that the in-process salsa was cooked to 200°F (93°C) for a minimum of 2.0 minutes, and checks that process log temperatures agree with the recorder;

- o Reviews process logs and recorder charts to confirm that the jars were filled at the specified temperature of $\geq$200°F (93°C), and checks that process log temperatures agree with the recorder charts; and

- o Reviews the recorded RPM for the conveyor belt to confirm that the jars were inverted for the minimum specified time of 1 minute;

- The PCQI reviews corrective action records within one week of when the deviation occurred and

- Salsa Processor A does not conduct product testing for pathogens or environmental monitoring because the product, which is acidified and subjected to a heat treatment validated to be highly lethal to vegetative pathogens and filled hot, is not exposed to the environment after the heat treatment.

6.16.6 Salsa Processor A's Monitoring Records

Salsa Processor A keeps:

- The process logs for checks of the particle size of the chopped vegetables;

- The recording charts from the RTDs used to monitor the temperature and time of the in-process salsa in the cook kettle and in the filling surge tank;

- The recording chart from the automated tachometer used to monitor the jar inversion conveyor belt speed;

- The process logs for temperature checks (cook kettle and filling surge tank) and process times in the cook kettle; and

- The process logs for the belt speed for the jar inversion conveyor belt.

6.16.7 Salsa Processor A's Records of Corrective Actions

Salsa Processor A keeps records:

- Of any product safety assessment by the PCQI of the safety of product to determine appropriate disposition if:

- o The RTD at the cook kettle recorded a low temperature;

- o The cooking process time was less than the minimum specified time;

- o The product temperature in the filling surge tank was too low; or

- o The jar inversion time was too short;

- Of the reprocessing of a product that can be reprocessed if:

- o Particle size of the chopped vegetables exceeded process set point;

- o The process temperature of the in-process salsa in the cook kettle was too low;

- o The process time was less than the minimum specified time;

- o The temperature of the heat-treated salsa in the filling surge tank was too low; or

- o The jar inversion time was too short;

- Of any product that cannot be reprocessed and thus is destroyed;

- Of any investigations of the cause of any deviations;

- Of all changes made to correct problems and to prevent reoccurrence of deviations; and

- Documenting any retraining.

6.16.8 Salsa Processor A's Verification Records

Salsa Processor A maintains the following verification records:

- The date and initials of the PCQI on the monitoring record (e.g., on the charts or in the logs) for the review of:

- o Each temperature recording chart for all RTD probes (cook kettle and filling surge tank);

- o The process logs for the temperature checks (cook kettle and filling surge tank);

- o The recording charts for the automated tachometer on the jar inversion conveyor belt;

- o The process logs for checks of the particle size of the chopped vegetables and belt speed of the jar inversion conveyor belt; and

- The date and initials in the calibration log of the PCQI's review of the results of the outside calibration service's calibration of the RTDs and automated tachometer, as well as any notes by the PCQI of the actions taken when any adjustments were needed;

- The date and initials of the PCQI's review of the results of the semi-annual verification tests that the jar inversion conveyor belt speed is correct, as well as any notes by the PCQI when any adjustments to the conveyor belt were needed; and

- The date and initials of the PCQI's review of corrective action records.

6.16.9 Summary Process Control Table for Salsa Processor A

Appendix 6-E summarizes the above information for Salsa Processor A on the FSPCA's Process Control Form (Form 2-C (Modified) from Appendix 2).

6.17 References

FDA. 2013. FDA Food Code 2013: Annex 6 Food processing criteria.
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Appendix 6.   Summary Process Control Tables for the Examples in Chapter 6

Appendix 6-A: Summary Process Control Table for Baking; Cookie Processor A

FORM 2-C (Modified)[12] PROCESS CONTROLS

PAGE _____

PRODUCTS: Cookies baked in batches on trays in ovens and packaged by wrapping the cookies by twos in plastic

PLANT NAME: _____

ADDRESS: _____

ISSUE DATE: (mm/dd/yy)_____

SUPERSEDES: (mm/dd/yy)_____

PROCESS CONTROL STEP: __Baking_____

HAZARD(S): ___*Salmonella*_____

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[13]
Minimum oven temperature of 350°F (177°C) (operating limit is 352°F (178°C))	Temperature of oven	• Recording thermometer in oven • Manual check of recording chart and mark the recording with the batch number • Record temperature on baking record sheet	Continuous recording during each batch; manual check before putting cookies in oven	Baker	If oven was not at least 350°F (177°C): • Cookies will be diverted to cattle feed; and • Employees will be retrained on the importance of ensuring that the oven temperature has reached the set point.	• Annual calibration of thermometer • Records review by PCQI within one week of record creation (baking sheets, temperature recording chart, calibration logs) • Review of corrective action records within one week of a deviation	• Baking record sheets • Temperature recording charts • Calibration records • Corrective action records

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[12] Modified from Form 2-C in Appendix 2 to address a single process control step. Form 2-C in Appendix 2 can be used to list multiple process control steps.

[13] Records include the date and initials of the PCQI (or designee) as verification.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[13]
Minimum process time of 13 minutes (operating limit is 15 minutes)	Time in oven	On baking record sheets: • Record time that cookies are placed in the oven • Calculate and record the time when the cookies should be removed from oven • Record time that cookies are removed from the oven • Calculate the elapsed baking time	Each batch	Baker	If the bake time is less than 13 minutes: • Cookies will be diverted to cattle feed; and • PCQI determines why the bake time was not met to prevent this from happening in the future.	• Records review by PCQI within one week of record creation (Baking record sheets) • Review of corrective action records within one week of a deviation	• Baking record sheets • Corrective action records
Dough weight ≤28 g (operating limit is ≤27 g)	• Dough depositor setting • Dough weight	• Check set point of depositor • Weigh dough portions	• Check set point every 2 hours • Weigh dough portions twice per shift	QC technician	If dough weight exceeds 28 g: • Product will be diverted to cattle feed; • PCQI will determine (if possible) what caused the depositor to deliver an incorrect weight; and. • Dough depositor adjusted to deliver correct weight.	• Annual calibration of dough depositor and scales • Records review by PCQI within one week of record creation (calibration logs, dough weight logs) • Review of corrective action records within one week of a deviation	• Dough weight log • Calibration records • Corrective action records

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Appendix 6-B: Summary Process Control Table for Baking; Cookie Processor B

FORM 2-C (Modified)[14] PROCESS CONTROLS

PAGE _____

PRODUCTS: Cookies baked in a continuous band oven and packaged in boxes of 24 cookies
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

PROCESS CONTROL STEP: __Baking_____
HAZARD(S): ___*Salmonella*_____

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[15]
Minimum oven temperature of 350°F (177°C) (operating limit is 352°F (178°C))	Temperature of oven at the identified cold spot	Recording thermometer in oven, visual check of recording chart, with a note of the check in the operator's baking log	Continuous recording during each batch with visual check every hour	Baker	If oven was not at least 350°F (177°C): • Cookies will be diverted to further processing (baking for cookie crumbles) or cattle feed; • Maintenance will determine the cause of the low temperature and fix the oven so the temperature is at least 350 °F (177°C) before more cookies are baked; and • Employees will be retrained if necessary.	• Annual calibration of oven thermometer and temperature recording chart • QC technician check of thermometer recording chart • Records review by PCQI within 7 days of record creation (operator's baking log, temperature recording chart, calibration log) • Review of corrective action records at the end of each week	• Operator's baking log • Temperature recording chart • Calibration records for thermometer and temperature recording chart • Corrective action records

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[14] Modified from Form 2-C in Appendix 2 to address a single process control step. Form 2-C in Appendix 2 can be used to list multiple process control steps.

[15] Records include the date and initials of the PCQI (or designee) as verification.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[15]
Maximum belt speed (tachometer RPM) to achieve a minimum process time of 13 minutes (operating limit is maximum tachometer RPM to achieve a process time of 15 minutes)	Belt speed (tachometer RPM)	Automated tachometer with recorder chart and visual observation of tachometer RPM	Continuous recording during each batch with visual check at start-up and twice per shift	Baker	If the tachometer reading indicates that the baking time is less than 13 minutes: • The cookies are placed on hold; • The PCQI assesses whether the cookies will be diverted to bake as cookie crumbles or diverted to cattle feed; and • The PCQI determines why the bake time was not met and informs management of actions they need to take to prevent this from happening.	• Annual calibration of tachometer and its recorder chart • QC technician check of tachometer recording chart • Records review by PCQI within 7 days of record creation (tachometer chart, calibration logs) • Review of corrective action records at the end of each week	• Recording chart for automated tachometer • Calibration records for tachometer and its recording chart • Corrective action records
Dough weight ≤28 g (operating limit is ≤27 g)	• Dough depositor setting • Dough weight	• Check set point of depositor • Weigh dough portions	• Check set point at start-up and every 2 hours • Weigh dough portions twice per shift	Dough preparer	If dough weight exceeds 28 g: • PCQI will determine whether the product will be further processed or diverted to cattle feed; and • PCQI will determine (if possible) what caused the depositor to deliver an incorrect weight. • Dough depositor adjusted to deliver correct weight.	• Annual calibration of dough depositor and scales • QC technician check of dough weight log twice per shift • Records review by PCQI within 7 days of record creation (calibration logs, dough weight logs) • Review of corrective action at the end of each week	• Dough weight record sheets • Calibration records for dough depositor and scales • Corrective action records

Appendix 6-C: Summary Process Control Table for Cooking; Soup Processor A

FORM 2-C (Modified)[16] PROCESS CONTROLS

PAGE _____

PRODUCTS: Soup cooked in a kettle, packaged in 8 ounce plastic bowls, and frozen _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

PROCESS CONTROL STEP: ___Cooking_____
HAZARD(S): ___*Listeria monocytogenes*_____

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[16] Modified from Form 2-C in Appendix 2 to address a single process control step. Form 2-C in Appendix 2 can be used to list multiple process control steps.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[17]
Minimum soup temperature of 180°F (82°C) (EPIPT)	Temperature of soup in kettle	Thermometer inserted into soup in top inch (2,5 cm) of kettle; measured temperature is recorded in the cook log	Begin after 30 min; then every 10 min after reaching 170°F (77°C) until the EPIPT is reached (180°F (82°C))	Kettle cook operator	• If EPIPT did not reach 180°F (82°C) and soup is being packaged but has not been frozen: stop packaging and reprocess soup until the EPIPT reaches 180°F. Packages that have been frozen will be destroyed. • If EPIPT did not reach 180°F (82°C) and soup has been packaged and frozen, the PCQI will assess the safety of the product to determine appropriate disposition. If process delivered was inadequate to ensure product safety, soup will be diverted to animal food or destroyed. • If soup is packaged before the EPIPT reaches 180°F (82°C) due to operator error, the kettle cook operator will be retrained.	• PCQI reviews cook log weekly. • QC technician calibrates thermometers against NIST reference thermometer at least annually; PCQI reviews the calibration log within a week of the calibration. • QC technician checks accuracy of thermometers daily; PCQI reviews these accuracy checks on a weekly basis. • PCQI reviews corrective action records before shipment of each lot of soup.	• Cook log of monitoring temperature • Thermometer calibration and accuracy checks log • Corrective action records
Maximum particle size no greater than ½ inch (13 mm) in any direction	Size of diced carrots, potatoes, onions	Collect a statistically-based sample of vegetable particles and then use digital calipers to ensure they do not exceed ½ inch (13 mm) in any direction; record the measurement in a log	Every third lot on receipt	Formulation control operator	If vegetable particle sizes exceed ½ inch (13 mm): • The lot of vegetables is rejected and unopened packages are returned to the supplier; • PCQI discusses with the supplier so the supplier can investigate the root cause for incorrect particle size; and • Formulation control operator checks vegetable particle size of every lot for the next 15 lots. If all 15 lots meet specification, the formulation control operator will return to monitoring every third lot.	• QC technician checks accuracy of digital calipers before use. • PCQI reviews particle measurement log and accuracy checks of the digital calipers weekly. • PCQI reviews corrective action records before shipment of each lot of soup	• Vegetable particle size log • Digital caliper accuracy check logs • Corrective action records

Appendix 6-D: Summary Process Control Table for Cooking; Soup Processor B

FORM 2-C (Modified)[18] PROCESS CONTROLS

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[17] Records include the date and initials of the PCQI (or designee) as verification.

PAGE _____

PRODUCTS: Soup cooked in a continuous flow heat exchanger, packaged in 5 gallon bag, and refrigerated
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

PROCESS CONTROL STEP: __Cooking_____
HAZARD(S): __Vegetative pathogens such as *Salmonella* and *Listeria monocytogenes*; and *Clostridium botulinum* (especially non-proteolytic type B)

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[18] Modified from Form 2-C in Appendix 2 to address a single process control step. Form 2-C in Appendix 2 can be used to list multiple process control steps.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[19]
Minimum soup IT of 40°F (4°C)	IT in pre-process agitated surge tank	RTD probe with recording chart monitors IT	Continuous recording of IT checked twice per shift	Line operator	If the IT of a batch of soup was too low during the processing of that soup: • Product will be held until the PCQI determines whether the process was adequate or if the soup can be reprocessed; and • Production manager will investigate why the IT was too low and take appropriate actions to prevent the situation from reoccurring.	• Outside service calibrates RTDs and recorder charts annually. • PCQI reviews calibration logs within 1 week of creation. • PCQI reviews recorder charts and the process logs containing IT daily. • PCQI reviews corrective action records within one week of when deviation occurs.	• Process logs for temperature checks of IT • Recording charts of IT • Calibration records for RTDs and recorder charts • Corrective action records
Metering pump speed to deliver process-specified flow rate (gal/min)	Pump RPM setting	Visual observation of RPM dial setting	At beginning of production and twice per shift	Line operator	If the metering pump speed during production of the soup was too fast: • Any ongoing production will be stopped and affected product will be held until the PCQI evaluates the safety of the product; and • The PCQI will assess the safety of the product and determine whether it will be released, re-processed, diverted to animal food, or destroyed. • Production manager will investigate why the pump speed was too fast and take appropriate actions to prevent the situation from reoccurring	• QA manager verifies pump speed provides correct flow rate for the hold tubes twice a year and PCQI reviews this within 1 week. • PCQI reviews pump speed log daily. • PCQI reviews corrective action records within one week of when deviation occurs.	• Process logs for pump speeds • Calibration records for flow rates • Corrective action records
Correct hold tube to deliver 2.5 minute hold time at specified pump speed	Correct hold tube in place	Visual observation that hold tube number is correct for the specific soup recipe	At beginning of production and when soup variety changes	Line operator	If the incorrect hold tube was used: • PCQI will assess the safety and determine disposition of the product; • Production manager will investigate why the incorrect hold tube was used; and • Employees will be retrained if necessary	• PCQI reviews pump speed log with hold tube identification daily. • PCQI reviews corrective action records within one week of when deviation occurs.	• Process logs containing hold tube number for the product being processed (i.e., the pump speed log) • Corrective action records

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[19] Records include the date and initials of the PCQI (or designee) as verification.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[19]
Minimum product temperature at end of hold tube of 205°F (96°C)	Temperature at end of hold tube	RTD probe with recording chart monitors temperature at hold tube exit	Continuous recording of product at hold tube exit checked twice per shift	Line operator	If soup is not automatically diverted for reprocessing when the temperature at the end of the hold tube is low: • PCQI will assess the safety of the product and determine appropriate disposition; and • Production manager will investigate the low temperature and the diversion failure and take appropriate action to fix the problem.	• Outside service calibrates RTDs and recorder charts annually. • PCQI reviews calibration logs within 1 week of creation. • PCQI reviews recorder charts and the process logs containing temperature at hold tube exit daily. • PCQI reviews corrective action records within one week of when deviation occurs.	• Process logs for temperature checks of hold tube exit temperature • Recording charts of product exiting hold tube • Calibration records for RTDs and recorder charts • Corrective action records
Minimum product temperature in agitated hot holding surge tank of 185°F (85°C)	Temperature in agitated hot holding surge tank	RTD probe with recording chart monitors temperature of product in agitated hot-holding surge tank	Continuous recording of fill temperature checked twice per shift	Line operator	If the temperature in the agitated hot-holding surge tank was below the process set point: • Product will be held until the PCQI determines whether the temperature was adequate for safety or if the soup should be reprocessed or destroyed; and • Production manager will investigate why the temperature in the agitated hot-holding surge tank was too low and take appropriate actions to prevent the situation from reoccurring.	• Outside service calibrates RTDs and recorder charts annually. • PCQI reviews calibration logs within 1 week of creation. • PCQI reviews recorder charts and the process logs containing temperature in the agitated hot-holding surge tank daily. • PCQI reviews corrective action records within one week of when deviation occurs.	• Process logs for temperature checks of filling temperature • Recording charts of filling temperature • Calibration records for RTDs and recorder charts • Corrective action records

Appendix 6-E: Summary Process Control Table for Heat Treatment; Salsa Processor A

FORM 2-C (Modified)[20] PROCESS CONTROLS

PAGE _____

PRODUCTS: Chopped mixed vegetable salsa that is an acidified food _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

PROCESS CONTROL STEP: __Heat treatment_____
HAZARD(S): *Salmonella, E. coli* O157:H7, *Listeria monocytogenes* and *Clostridium botulinum* _____

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[20] Modified from Form 2-C in Appendix 2 to address a single process control step. Form 2-C in Appendix 2 can be used to list multiple process control steps.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[21]
Maximum particle size of chopped vegetables (1.0 cm) (0.4 inch)	Particle size of the chopped vegetables	• Collect statistically-based sample of vegetable particles; • Use digital calipers to measure particle size; and • Record results in the process log	Check one in-process lot of each chopped vegetable once per production shift	Formulation control operator	If the mean plus 2.5 standard deviation of the vegetable particle sizes exceeds 1 cm (0.4 inch): • The in-process lot of chopped vegetables is rejected and will be reworked for a different recipe. • The PQCI will check with the vegetable processing operator to investigate the root cause of the incorrect particle size and, when applicable, notify maintenance to reset the vegetable chopper operation to specification. • The formulation control operator will check the vegetable particle size of every in-process lot for the next 15 in-process lots to verify particle sizes meet specification. If all 15 lots meet specification, the formulation control operator will return to monitoring every one lot per vegetable per production shift.	On a daily basis, the PCQI checks process logs to confirm that the particle size of the chopped vegetables was at the specified value	• The process logs for checks of the particle size of the chopped vegetables • Corrective action records

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[21] Records include the date and initials of the PCQI (or designee) as verification.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[21]
Minimum process temperature for the salsa (200°F) (93°C)	Temperature of the in-process salsa in the cook kettle	• RTD probe with recording chart monitors temperature of the in-process salsa (in top inch (2.5 cm) of kettle); • Visual check of the chart; • Record temperature in process log	Once for each batch	Line operator	If the RTD at the cook kettle records a low temperature: • The product will be held until the PCQI determines whether the process was adequate for safety or if the product should be reprocessed or destroyed. • The production manager will investigate why the under-processing occurred and take appropriate actions to prevent the situation from reoccurring. • Employees will be retrained if necessary in light of the reason for the under-processing.	• Annual calibration of the RTDs and recording chart used to measure temperature at the cook kettle, with the date and results recorded in a calibration log. The PCQI reviews, initials, and dates the calibration logs within a week of their creation. • On a daily basis, the PCQI reviews recorder charts and process logs to confirm that the in-process salsa was cooked at the specified temperature, and checks that process log temperatures agree with the recorder charts.	• The recording charts from the RTDs used to monitor the temperature of the in-process salsa in the cook kettle • The process logs for temperature checks of the cook kettle • Corrective action records • Of calibration of the RTDs and recording charts, with any notes by the PCQI about adjustments

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[21]
Minimum process time at 200°F (93°C) for the salsa (2 minutes)	Time that the in-process salsa is at the process temperature	• Visual checks of recorder chart; • Mark chart with batch number; • Record time when in-process salsa reaches process temperature in process log; • Calculate processing time; • Record processing time on the recorder chart and in the process log; • Note when product should be transferred to filling surge tank in the process log; • Record the time when product is transferred from to the filling surge tank in the process log	Once for each batch	Line operator	If the RTD at the cook kettle records a shortened process time: • The product will be held until the PCQI determines whether the process was adequate for safety or if the product should be reprocessed or destroyed. • The production manager will investigate why the under-processing occurred and take appropriate actions to prevent the situation from reoccurring. • Employees will be retrained if necessary in light of the reason for the under-processing.	On a daily basis, the PCQI reviews recorder charts and process logs to confirm that the in-process salsa was cooked for the specified time	• Of the temperature recording chart marked with various times, and the process log, • Corrective action records

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[21]
Minimum temperature of the heat-treated salsa in the filling surge tank (200°F) (93°C)	Temperature of the heat-treated salsa held in the filling surge tank	• RTD probe with recording chart monitors temperature of heat-treated salsa in filling surge tank; • Visual check of chart; • Record temperature in process log	Twice per shift	Line operator	If the temperature at the filling surge tank is below the process set point: • The product will be held until the PCQI determines whether the fill temperature was adequate for safety or if the product should be reprocessed or destroyed. • The production manager will investigate why the fill temperature was too low and take appropriate actions to prevent the situation from reoccurring. • Employees will be retrained if necessary	• Annual calibration of the RTDs and recording chart used to measure the temperature at the filling surge tank, with the date and results recorded in a calibration log. The PCQI reviews, initials, and dates the calibration logs within a week of their creation • On a daily basis, the PCQI reviews process logs and recorder charts to confirm that the jars were filled at the specified temperature, and checks that process log temperatures agree with the recorder charts.	• The recording charts from the RTDs used to monitor the temperature of the filling surge tank • The process logs for temperature checks of the filling surge tank • Corrective action records • Of calibration of the RTDs and recording charts, with any notes by the PCQI about adjustments

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[21]
Minimum inverted jar hold time (1 minute)	Conveyor belt speed as indicated by automated tachometer RPM	• Automated tachometer with recorder chart monitors conveyor speed; • Visual check of chart • Record RPM in process log	At the beginning of production and twice per shift	Line operator	If it is determined that the jar inversion time is below the process set point: • The product will be held until the PCQI determines whether the process was adequate or if the product can be reprocessed. • The production manager will investigate why the belt speed deviated from the process set point and take appropriate actions to prevent the situation from reoccurring. • Employees will be retrained if necessary in light of the reason for the belt speed deviation	• Annual calibration of the tachometer and recording chart used to measure belt speed of the jar inversion conveyor, with the date and results recorded in a calibration log. The PCQI reviews, initials, and dates the calibration logs within a week of their creation. • The QA Manager verifies the jar inversion belt speed and time twice each year, and the PCQI reviews this within one week. • On a daily basis, the PCQI reviews the recorded RPM for the conveyor belt	• The recording chart from the automated tachometer used to monitor the jar inversion conveyor belt speed • The process logs for checks of the belt speed for the jar inversion conveyor belt • Corrective action records • Of calibration of the tachometer and recording charts, and verification tests that the jar inversion time is correct, with any notes by the PCQI about adjustments