HOW TO VALIDATE YOUR BLANCHER

This document is intended for use by frozen food manufacturers. It outlines a template to be used by frozen food processors for the application of blanching equipment as a process preventive control to address risks associated particularly with *Listeria monocytogenes* (*Lm*) but also other pathogens. It highlights key information (blanching equipment, blanching process, achieving desired lethality, and verification) to be documented by food processors to establish blanching as a process preventive control. The template and checklist may be incorporated to a facility's food safety plan to showcase your facility's understanding of the blanching process and steps to control the process to achieve desired lethality. All validation studies should be conducted by an expert microbiologist utilizing relevant statistical design and data analyses. The document is focused on and limited to the application of blanching equipment and processes as a preventive control measure. This document is the result of expert discussions among food safety professionals, microbiologists, food engineers, and food processing specialists in the industry.

AFFI AMERICAN FROZEN FOOD INSTITUTE

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IMPORTANT NOTICE

This document represents a user-friendly comprehensive guide designed to assist members of the American Frozen Food Institute (AFFI) with reviewing and understanding key components of managing food safety in frozen food and beverage products and in frozen food manufacturing facilities. Nonetheless, members are cautioned that this guidance does not purport to provide fail-safe solutions for all issues related to sanitation, sanitary design, environmental monitoring and process validation. While the guidance endeavors to present current industry food safety practices, it is not intended to be a substitute for careful review or analysis of the food safety risks as it relates to each member's own products and operations; nor does adherence to this guidance ensure compliance with applicable statutory and regulatory requirements. **THIS DOCUMENT PROVIDES GENERAL INFORMATION AND GUIDANCE BUT IS NEITHER INTENDED AS NOR DOES IT CONSTITUTE LEGAL ADVICE.**

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Introduction to Blanching as a Process Preventive Control

Blanching has historically been used as a unit operation in food processing to deliver higher quality food products. Notably, heat treatments such as blanching are used to inactivate enzymes that cause loss in color, flavor and texture. More recently, blanching for food safety purposes has become relevant, as have questions surrounding its routine application as a pathogen kill step in food processing. Some of these questions include:

- What is the potential purpose and role of blanching equipment as it relates to controlling a specific biological hazard?
- What are the appropriate factors that must be considered for validating a blancher as a process preventive control?
- What attributes must be considered as it relates to impact of different raw materials on achieving desired pathogen lethality?
- What pre-blanch and post-blanch considerations are important to maximize the utility of a blancher as a process preventive control?
- What are the appropriate conditions and potential limitations of blancher application as a kill step in my food safety plan?
- What are the specific features of a blancher that are important to understand and control during the process?
- What tools and recording devices can be added to the blanching equipment for validation and verification activities?
- What elements are important to report in my validation study?

Establishing Blanching Parameters

Blanching process parameters, i.e., a specific time and temperature combination to achieve five-log reduction of an identified pathogen (example: *Listeria monocytogenes*), for treatment of a specific raw material (vegetable or other product of particular size or cut dimensions), may be established by one or more of the following means: utilizing a previously established time and temperature combination that achieves the desired lethality, which is documented in a scientific or trade reference(s); a laboratory or pilot-scale study with the specific raw material conducted by your company or by a third-party expert to determine desired lethality; or an in-plant study conducted in the facility's blancher to achieve the 5-log pathogen reduction standard with an appropriate surrogate microorganism.

As a start, manufacturers may include the following scientific references in the final blancher validation report as support of their blanching parameters.

- Ceylan et al., Thermal Inactivation of *Listeria monocytogenes* and *Salmonella* during Water and Steam Blanching of Vegetables. 2017, Journal of Food Protection, Vol. 80. No. 9, p. 1550-1556
- Mazzotta. A., Heat Resistance of *Listeria monocytogenes* in Vegetables: Evaluation of Blanching Processes. 2001, Journal of Food Protection, Vol. 64, No. 3, p. 385-387
- Fish and Fishery Products Hazards and Control Guidance. 4th Edition; Appendix 4. Bacterial Pathogen Growth and Inactivation, Table A-3, Inactivation of *Listeria monocytogenes* (p.422) (https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM251970.pdf)
- Fish and Fishery Products Hazards and Control Guidance. 4th Edition; Appendix 4. Bacterial Pathogen Growth and Inactivation, Table A-4, Inactivation of Non-Proteolytic *Clostridium botulinum* Type B (p.423)
- AFFI blanching survey: A list of currently used blanching parameters in the frozen food industry (see resource #1).

Establishing the Objectives of a Blancher Validation Study

Potential objectives to consider and document prior to a blancher validation study include:

- Confirm the time and temperature parameters set for a specific product to meet the minimum 5-log reduction criteria are achieved in the blancher.
- Identify potential cold spots or paths in the blancher that may impact achieving these time and temperature parameters.
- Define operating blancher parameters (ranges are acceptable) and identify verification methodologies to ensure consistent results can be obtained over repeated production runs.

Description of Product and Process

In this section, manufacturers should identify raw material(s) and provide a comprehensive overview of their manufacturing process. This information may include specific product characteristics that could impact heat kinetics and penetration, process steps performed prior to and after blanching, and the sequence of unit operations.

Product Characteristics

Type of raw material or vegetable: _____

Shape: _____

Size (whole) or (cut): _____

Density: _____

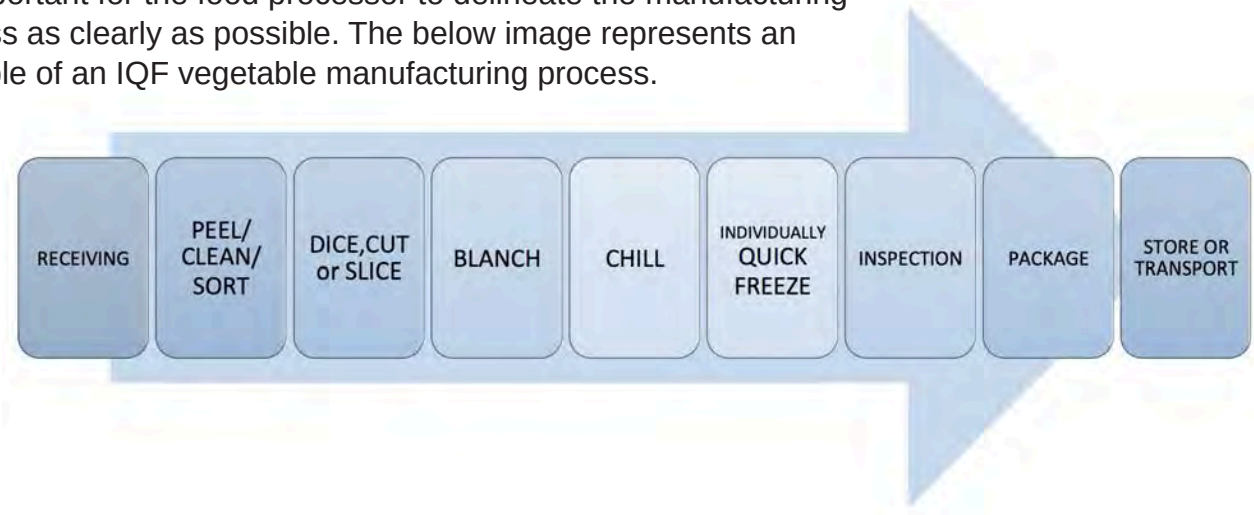
Product variability: _____

Product composition: _____

Other: _____

Process Flow

It's important for the food processor to delineate the manufacturing process as clearly as possible. The below image represents an example of an IQF vegetable manufacturing process.



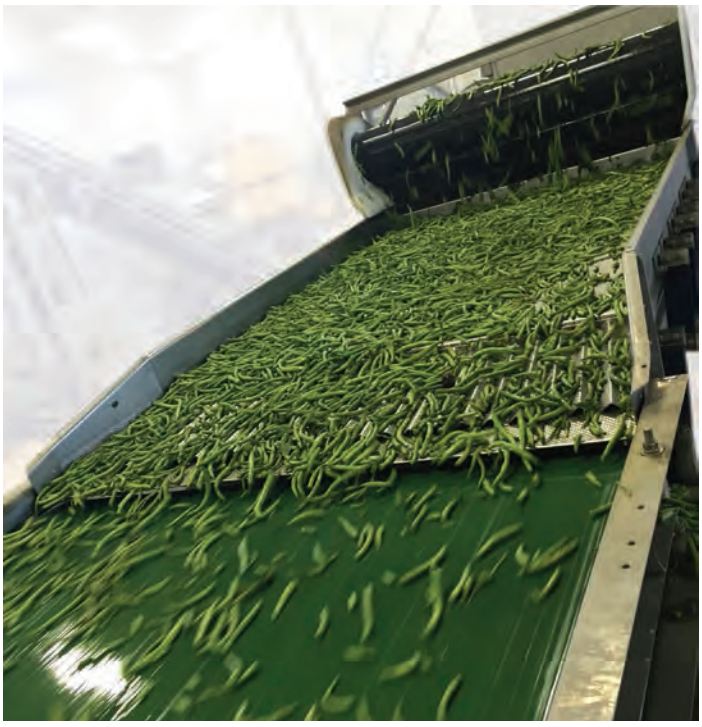
Identification of Pre-Blanching, Blanching, and Post-Blanching Steps

The purpose of this section is to outline key equipment, unit operations and procedures involved in the pre-blanching, blanching and post-blanching process components.

Pre-Blanching

Identify any wash, rinse, cutting and sorting steps and provide information about related equipment. Examples include:

- Hopper to store raw vegetables intended for blanching and to collect cut vegetables
- Raw material transfer (may include a conveyor belt to transfer raw vegetables to the blancher)
- Dicer/Slicer/Auger
  - Type
  - Speed
- Sorter/Shaker (indicate use of any water)



Indicate any product-related data. Examples include:

- Moisture content or water activity of raw materials
- Temperature of raw material or raw vegetables
- Typical batch size
- Typical volume processed through a continuous blancher in a single run

Blanching

Identify specific blanching equipment information. A typical continuous steam blancher would comprise an infeed, preheat zone, blanching/cooking, and cooling sections. Examples include:

- Blancher Type (batch, continuous rotary water or continuous belt steam)
- Manufacturer
- Model and Year

- Heating Type (water/Steam)
  - Steam (force circulated steam?)
- Blanching Temperature Range
- Process Duration Range
- Agitators (yes/no)
- Automation (steam, control of product input, belt speed controllers)
- Indicators (temperature, pressure; manual or continuous chart recorders)
- Type of Cooling (evaporative/mechanically chilled air/chilled water)
- Steam Consumption
- Equipment Modifications
- Capacity (lbs. or lbs. per hour)
- CIP capable (yes/no)

Manufacturers should also provide images and figures of blanching equipment as available.

Post-Blanching

Identify all washing, cooling and transport steps applied after blanching and provide information about related equipment (it is important to consider the physical separation between cooked and uncooked products in the process). Examples include:

- Chiller/Cooler
  - Type (chiller chain or chiller vessel)
    - Chill chain (product flow rate and dwell time)
  - Diagrams and dimensions
  - Product temperature at inlet
  - Temperature of water (mode of application - spray, nozzle, etc.)

- Additional Equipment
  - Shakers, dryers, etc. (to remove excess water)
  - Diagrams and dimensions
  - Product flow rate
  - Dwell time
- Freezer Tunnel
  - Type of freezer
  - Diagrams and dimensions
  - Product flow rate (chain speed) and dwell time for each belt
- Product exit mechanism
  - Metal detection
  - Other quality testing
- Packaging
  - Type (bulk, box, liners, etc.)
  - Unit weight
  - Storage conditions

Considerations in Validating a Blancher

Time and temperature are the two most important parameters that dictate the use of blanching as a process preventive control. Thus, measurements related to time and temperature are essential to validating a blancher. Typically, a set of time and temperature parameters to be used in a blancher are established prior to a blancher validation study as stated earlier. The purpose of this section is to provide approaches for conducting a blancher validation exercise and the nature of data needed to determine whether the product has received the appropriate time and temperature treatment. First, the manufacturer should provide a general description of the blanching equipment (provide figures or images of the blancher, describe functionality of each component and the process) and outline the following features of the blancher:

- Equipment dimensions
  - Heat zone and hold zone dimensions
- Process of steam injection or hot water treatment (the manufacturer may add any relevant diagrams or images)

- Create a data table of blanching parameters for each product (type, size, and density) measured using scientific methods. Determine the critical control points in the blanching process and methods to measure and monitor them. Below are some considerations:
  - Set point temperature at a given location in the blancher
  - Set point temperature at other locations in the blancher
  - Indicate types of temperature measurement and recording devices at these locations:
    - Data loggers
    - Data tracers
    - Resistance Temperature Detectors (RTD) probes
    - Thermocouples
    - Infrared temperature devices
  - Steam pressure (psi)
  - Dwell time for specific raw material (vegetable or other product) and size/cut/dimensions. Dwell time may be defined as the residence time of the product within the heat zone of the blancher. Using dwell time combined with set point temperature measurements at specific locations within the blancher can help determine product exposure to a given time and temperature cycle.
    - This may be dependent on endpoint temperature and data trace logs.
    - For continuous rotary water blanchers, drop a golf ball and

measure the time it takes for the ball to exit the blancher (repeat to obtain an average of five measurements)

- Recommend that the facility prepare a chart representing these parameters including bed depth and dwell time for each product material

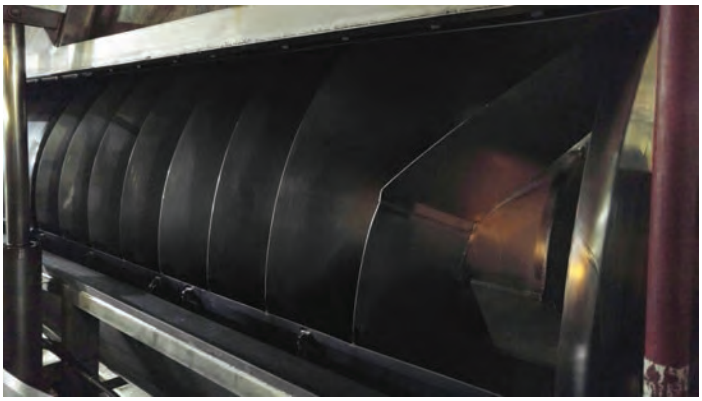
- Blancher chain speed/product feed rate and product flow rate (lbs per hour or bed depth). This represents the volume/weight of vegetables passed through in unit time (product inflow vs. output). Use the following devices and considerations to measure:
  - A hopper that meters the product
  - A shaker table with a dam
  - A bucket system with weights
  - A belt with a weighing mechanism
  - Inverters to control belt speed and rate at which product is fed to the blancher
  - Be aware that you are not measuring occasional surges in product feed
  - Volume/Weight of vegetables passed through in unit time (product inflow to output)
- Endpoint product temperature (consider monitoring as a verification system)
- Process deviations or extreme conditions, such as:
  - Steam pressure fluctuation
  - Input temperature of the product; i.e., Test the process using pre-cooled raw material (approximately 45°F or other low temperature).
  - Volume of raw material; i.e., Test the process using a higher, pounds per hour throughput, than standard practice.
  - Volume of raw material: i.e., Test the process at a varied product flow speeds or varied product bed depths.
  - During the validation cycle, consider an endpoint temperature that is higher or lower than the target temperature.
- Moisture content and water activity measurements
  - The moisture content and water activity of the raw material may have a significant impact on heat resistance and kinetics of heat transfer. Sampling and testing moisture content of raw materials at multiple points across the blancher may be invaluable in understanding any temperature fluctuations that may be observed in the validation study.
  - As an example, raw materials may be tested at the beginning, middle, and end of the blanching process. Additionally, temperature of the product should be tested along with any moisture or water activity measurements.
- Relative humidity
  - A minimum relative humidity may be a requirement of the blancher to be able to achieve the temperature parameters set for validation. If this is a critical attribute, the validation study should include obtaining relative humidity readings from specific locations across the path of the blancher.
  - Data logger manufacturers have applicable relative humidity testing equipment and tools that can be placed at these locations for real-time measurement and relative humidity profiling during operation.

Blancher Validation Tools and Procedures

This section provides information regarding useful devices and tools needed to conduct time and temperature measurement activities. As stated above, these two parameters are critical to determining applicability of a blancher as a process preventive control. It also covers some examples and other considerations in conducting blancher validation procedures.

Dwell Time Measurement (continuous-flow belt blanchers)

- Monitoring the drive shaft rotational velocity with a proximity sensor will confirm the distance traveled on the conveyor belt over a given time-period
  - It is recommended to conduct a periodic product dwell time confirmation test
    - Frequency (Depends upon the manufacturer's discretion)
    - Methodology
      i. Place test object on belt at blancher infeed and begin timer
      ii. Collect object at discharge of blancher and record dwell time
      iii. Repeat process
    - Records
      i. Designated operations representative should review and maintain records of periodic product dwell time confirmation tests

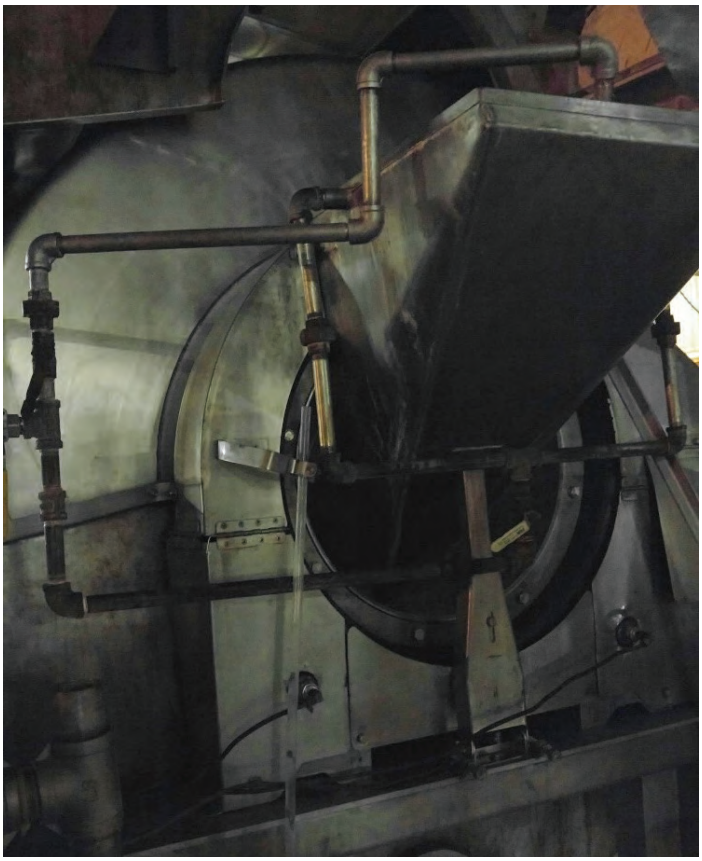


Temperature Measurement

Several points of temperature measurement are relevant when considering both blancher validation as well as more routine blancher verification activities. For example, valuable data includes: real-time temperature measurement of the product (both internal and surface temperature), measurement within a bed or layer of product, and measuring the temperature of the chamber (environment) within the blancher. All these measurements may be performed using wireless continuous recording or in situ devices.

Wireless Continuous Temperature Recording Devices: These are programmed to record temperature at a designated frequency (i.e. minutes, seconds) to provide a temperature profile of a lethality (blanching) process from beginning to end across product flow in a blancher.

- Identify the manufacturer and model of temperature recording devices appropriate for validation of blanching equipment
- Cost ~ software, protective case and 1-3 probes - $10K



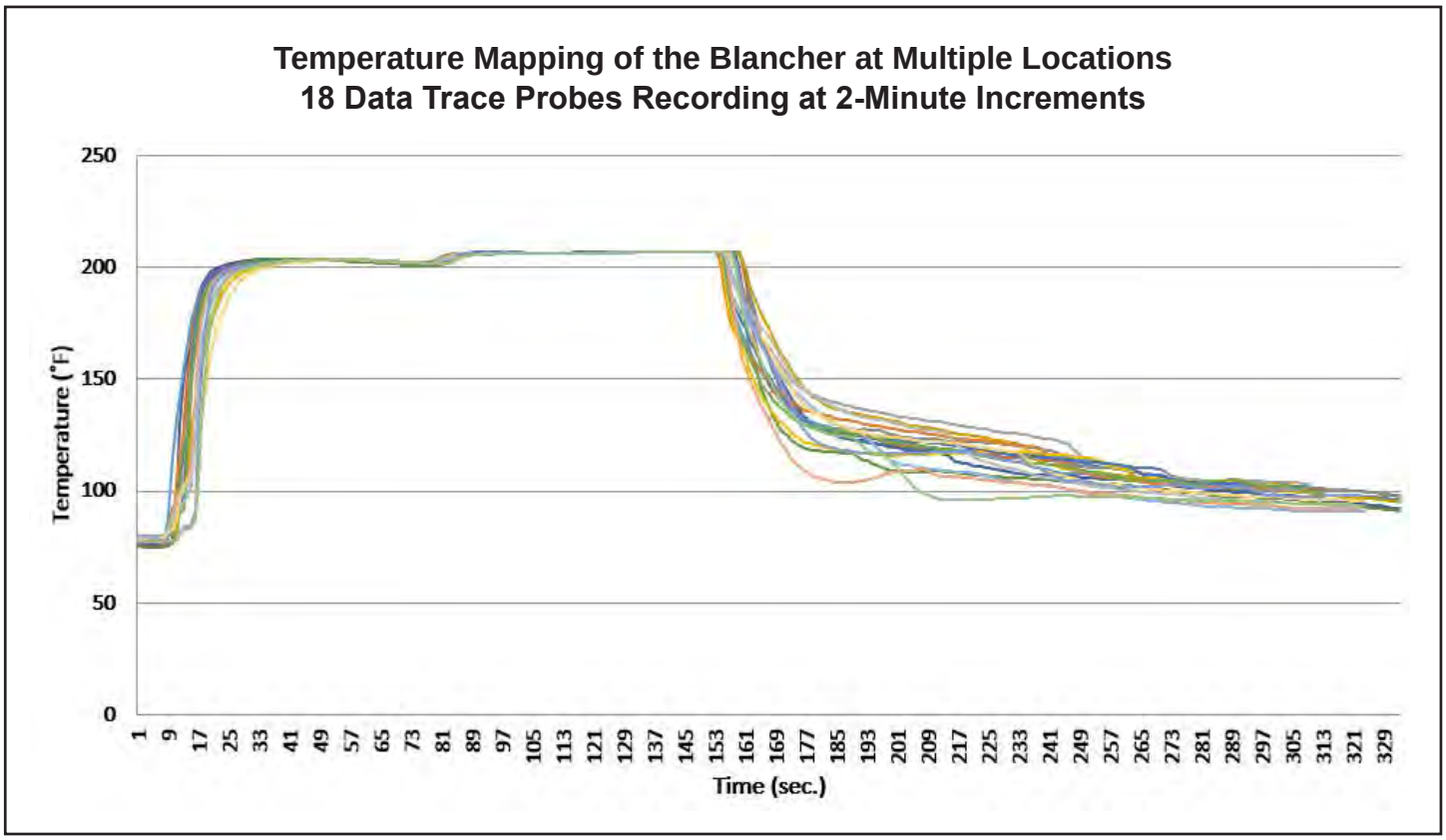
- Examples of data logger manufacturers:
  https://www.testo.com/en-US/
  https://datatrace.mesalabs.com/
  https://www.seika.com/en/
  https://www.cik-solutions.com/en/
  www.dicksondata.com
  www.ecklund-harrison.com
  www.ellab.com
  www.ecd.com
  www.madgetech.com
  www.tmi-orion.com
  www.tcal.com

Best practices for utilizing a Wireless Continuous Temperature Recording Device:

- Type of probe: use certifiable and calibrated probes designed for heating, capable to measure internal temperature (IT) of product,
- Frequency of data capture: seconds, minutes
- Frequency of lethality verification: A minimal of annual verification after initial validation
- Below is an example procedure that may be used to support a blancher validation process as well as to conduct verification studies:
  - First place a recording device(s) directly in the product flow/bed for real-time temperature measurement.

- Then, obtain multiple readings per day across multiple days to identify and understand potential variability. If using a belt blancher, consider using multiple probes or a single probe applied in multiple passes to collect readings from different segments of the belt (outside and inside locations across the belt). Parameters to consider include:
  - Total time
  - Initial (incoming) product temperature
  - Come up time (time to reach target lethality temperature)
  - Hold time (time at or above target lethality temperature)
  - Water temperature (obtained from any installed blancher recording device(s))
  - Auger or Belt speed
    i. Monitoring the drive shaft rotational velocity with a proximity sensor will confirm the distance of conveyor belt travel over a given time-period
  - Volume and/or depth of product at inlet
  - Temperature of product at blancher exit (equilibrated or internal temperature)
  - Confirm with enzyme inactivation assay

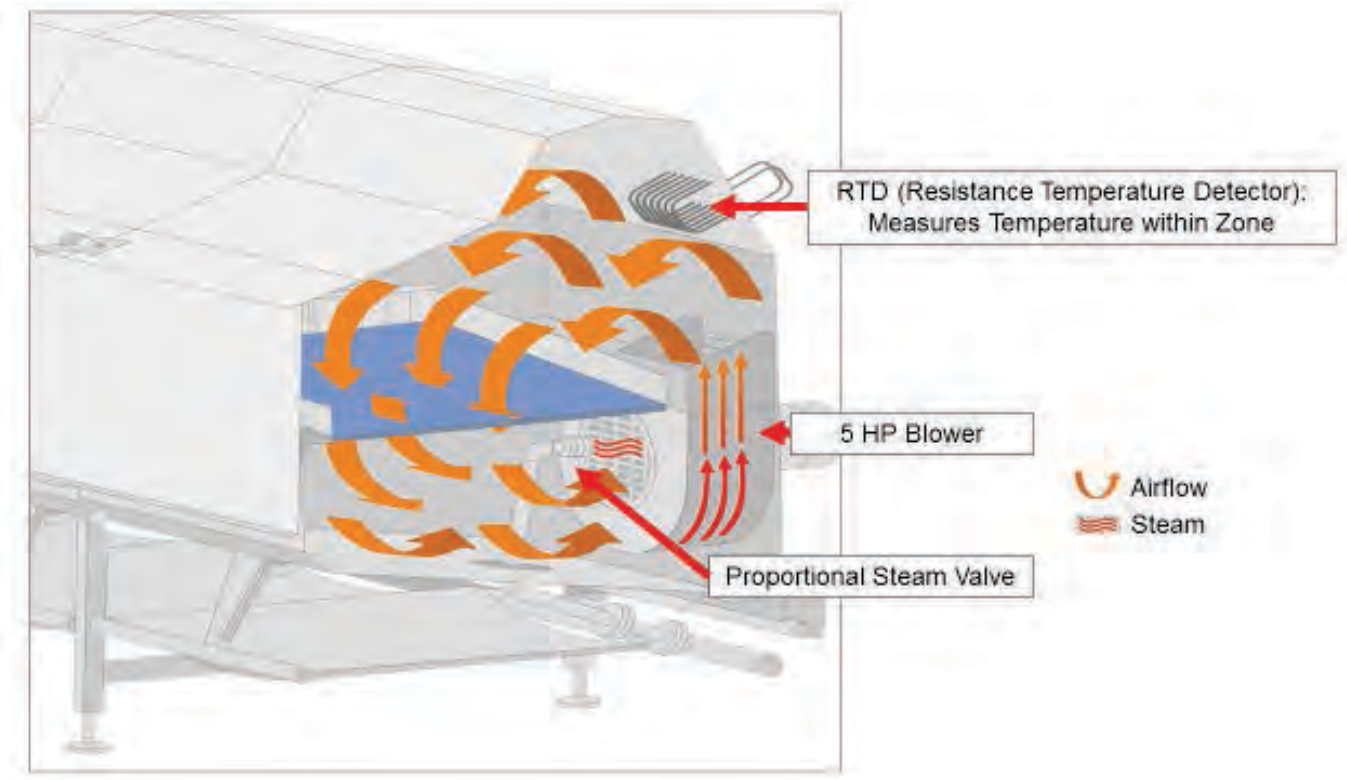
Lastly, compare the profiles of separate passes to identify consistency of processing and highlight any variability. The below graph represents data across multiple passes, demonstrating a consistent trend in temperature recording.



Measuring the temperature inside the blanching chamber (general blanching environment):

- Environmental temperature within blanching equipment should be continuously measured with a certifiable calibrated temperature probe
- Temperature probes should be calibrated annually or as recommended by manufacturer
- Strategic placement of temperature probes should be able to measure the air temperate above the product
- Temperature probes for continuous measurement may include Resistance Temperature Detectors (RTD) or thermocouples

Example of RTD Location in the Blancher



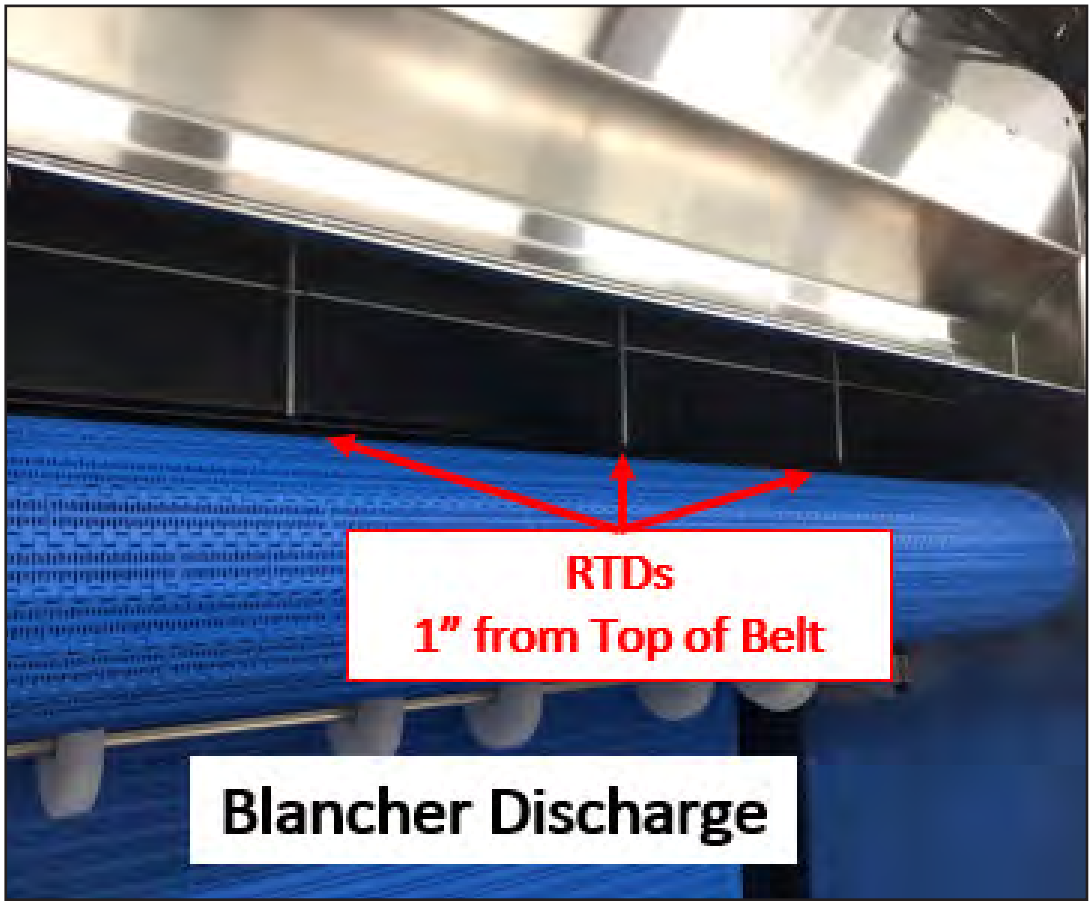
You may also install continuous temperature recording devices, such as thermocouples inside the blanching chamber at specific positions. Other considerations:

- Use the profiles obtained via the wireless recording device to potentially determine possible “cold” spots
- For any cold spots identified either modify blancher to reduce/eliminate or install thermocouple in cold spot
- Record placement of installed recording devices

Measuring the temperature of the product bed/ layer:

- Temperature within the product bed should be continuously measured with a certifiable calibrated temperature probe
- Temperature probes should be calibrated annually or as recommended by the manufacturer
- Strategic placement of temperature probes should reflect the following parameters:
  - Measures the center of the product bed across multiple locations
  - Measures temperature closest to the discharge of the blancher to reflect an end-point temperature
  - Temperature probes for continuous measurement may include RTDs or thermocouples
  - Consider continuously measuring actual product temperature at the discharge of the blancher to reflect an end-point temperature

Example of RTD Location in the Blancher



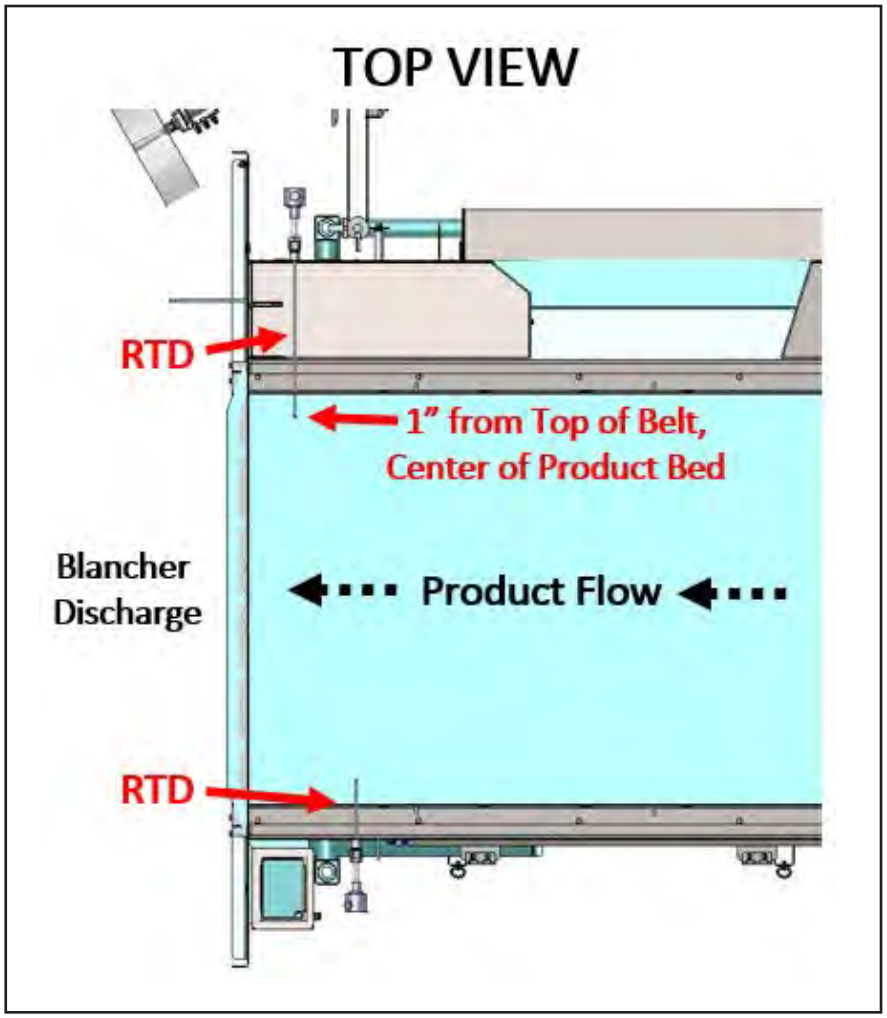
Temperature uniformity

- Temperature uniformity both within and across the product bed should be checked periodically, as determined by the plant
- Example test methodology:
  - Place data logger probes in center of product bed at fixed increments across the width of the belt
  - Graph temperature rise of each data trace measurement (*see example of Temperature Mapping with Data Trace graph above*)
  - Review to verify uniform temperature rise within and along the product bed

Care of data logger equipment:

- Clean, sanitize, and inspect all data loggers prior to installation and use
- Ensure data loggers are inserted and connected properly
- Re-check data logger functionality and cleanliness between runs, and allow for sufficient time to cool before collecting data again

Example of RTD Location in the Blancher



Testing Results and Interpretation

This section involves logging the data obtained from the above validation procedures.

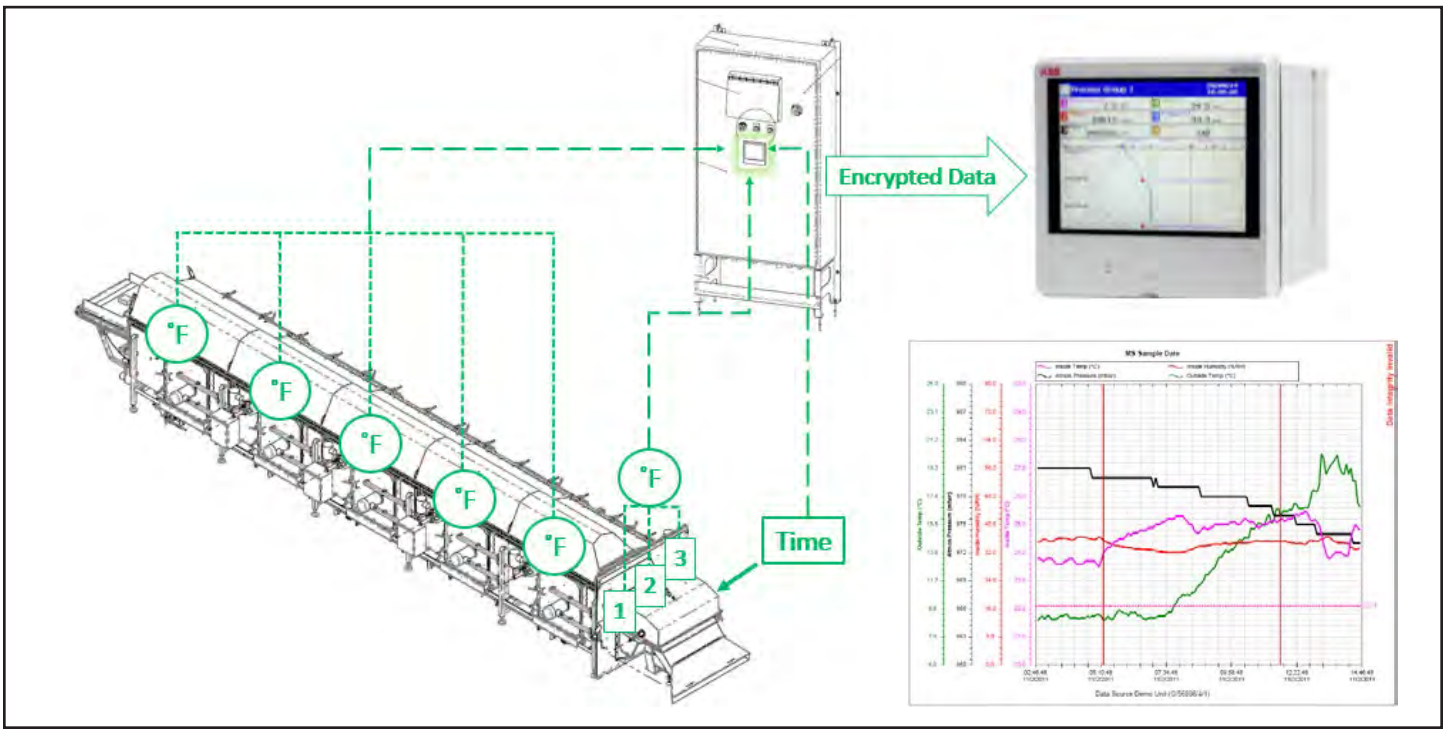
Documentation of these records is in important component of the final blancher validation report incorporated into the facility's food safety plan. In addition, it is necessary to document monitoring results as they verify an effective blancher operation. Some types of maintenance records include:

- Continuous monitoring and logging of all critical operating parameters is recommended
- Daily monitoring records should be reviewed and approved by designated operations representatives
- Digital and/or paper monitoring records should be maintained for a defined period of time per U.S. FDA regulations
- Circular chart recorders or paperless chart recorders, such as the Screen Master RVG200 (www.new.abb.com), are recommended for continuous monitoring and recording

Example of a monitoring record

Date:	Product Temp 1	Product Temp 2	Product Temp 3	Product Temp 4
1/4/2017	37	36	38	36
1/24/2017	47	47	46	45
3/28/2017	53	52	51	53

The image below illustrates the location of multiple temperature recording devices and the collection of real-time data for trend analysis.



Interpretation of Temperature Profile Data

Recorded data should point to indications of temperature fluctuations through the process. Identify coldest spots within the blancher and across the product flow through the blancher. Variances may be a result of blancher functionality, recording device variability, product flow or other factors.

Manufacturers may notice variability from test to test, batch to batch, and season to season, but it is important to consider seasonal temperature variations in the facility, blancher adjustments, boiler capacity and other equipment-related changes.

Example of a test results chart

Incoming Product Temperature		
Date	**Time**	**Temp.**
1/28/2018	7:30 PM	45°F
12/15/2017	5:00 AM	48°F

Operational Set Points for this Study		
Parameter	**Date /Time**	**Date / Time**
Flow Speed		
Blanch Set point		
Steam PSI		
Water Temp.		
Blancher Chain Speed		

Data Trace Temperature Profile Summary						
Date	**Probe Time**	**West**	**Probe Time**	**Center**	**Probe Time**	**East**
12/15/2017	5:10 AM	202°F	5:25 AM	198°F	5:45 AM	197°F

Microbiological Testing - Coliforms					
Test#	**Date:**	**Cut Size:**	**Sample Collection point**	**Coliforms Before Blanch:**	**Coliforms After Blanch:**
1	12/15/2017	3/8” Dice	West	1000	<10

Microbiological Testing - Finished Product								
Test#	**Date:**	**Cut Size:**	**Sample Collection point**	**IQF APC**	**E. Coli**	**Yeast Mold**	**Salmonella**	**LM**
1	12/15/2017	3/8” Dice	West	100	<10	<100	Neg.	Neg.

Data Trace Probe Calibration Schedule		
Probe ID	**Date of Calibration**	**Next Calibration Due**
M3T11778	6/10/2016	6/10/2017
M3T48344	11/9/2016	11/9/2017
M3T48353	11/9/2016	11/9/2017

Summary Report

Blancher validation studies must generate a summary of their work and results with adequate information for internal and external evaluation. The report may include an introduction, purpose of study (validation), experimental design (materials and methods), data analysis and interpretation, and conclusions on achieving the objectives presented at the outset of the study. The checklist for validating a blancher (resource #2) may also be utilized by the validation team during the validation process and included in the final summary report.

This template may be used to provide product and process information, as well as data presentations on dwell time and temperature measurements. A discussion section may provide a clear interpretation of the results concluding the blanching equipment can be used to deliver desired pathogen lethality (5-log reduction criteria) under a given set of parameters (time and temperature conditions tested). The analysis may also point to identification of the coldest spot or path for each specific blancher.

Finally, the validation study should define an operating range of blancher parameters to be used by manufacturing to achieve the time and temperature requirements set for each specific product. The report may also contain limitations of the study and recommendations on when a new validation study is warranted.

Conclusions

Understanding how your process control system operates is an important starting point and you should rely on the equipment manufacturer to assist with understanding the blancher's capabilities and limitations. Capturing real-time temperature recordings of your process with the use of data tracers will provide the best insights on successful application of the equipment for blanching vegetables and to serve as a process preventive control.

Your initial studies should focus on validating a time-temperature combination to have a lethal effect on the identified biological hazard in the blancher and upon the product. Once validated, you'll want to consider verification systems and schedules to ensure your process repeatedly achieves the desired lethal effect. During the validation process, it's important to consider atypical scenarios determined by such characteristics including but not limited to:

- Temperature of incoming product (initial temperature). Does the raw material entering the system need to be at a specific temperature?
- Product bed depth
- Consistency of the bed depth through the blancher
- Spread on your conveyor belt or system and velocity of the conveyor belt through the blancher
- Product volume per unit time
- Product variability from batch to batch
- Amount of free moisture or water associated with your incoming product
- Thickness or cut size of the product being processed
- Other conditions that potentially impact heat distribution kinetics of your process.
    - Is a minimum relative humidity within the blancher required for the process?
    - Is there a requirement for a specific range of product moisture or water activity?

What if the validation study is unsuccessful?

In the event the validation study does not provide evidence of achieving the required time and temperature combination in the blancher and/or the product, review the following preliminary questions:

- Is the desired temperature within the equipment's range of temperature capability?
- Have all the temperature recording devices been calibrated?
- Did you observe any inconsistency in product depth or product spread?
    - Is the raw material size, shape, or cut consistent across the product volume passed through the blancher?
- Was the belt speed too fast?
    - Did too much product pass through the blancher in too little time?
    - Do you need to increase the dwell time?
- What was the incoming raw material temperature?
- Was there a product surge during product feed?
- Was steam pressure within range?

- Were there any other system failures such as malfunction of any of the temperature recording devices or other data loggers?

The checklist for validating a blancher (resource #2) will be useful in identifying specific deviations during the blancher validation process.

In documenting any of the above deviations, be sure to provide supporting rationale as to why they may have occurred and whether they are acceptable or not. If not acceptable, determine a remediation step (process adjustment) and repeat the validation study. If you were unable to identify any of the above as potential issues, repeat the validation exercise on a different batch of product on a different day, consider alternate time and temperature parameters, or contact the blancher manufacturer and seek external expertise for further guidance.

Additional Information and Considerations

Scientific research to support a given time-temperature combination that is to be used for the validation study for a specific type of vegetable may be challenging, but a good starting point is using existing data related to products that have similar characteristics. Applying higher time-temperature combinations can be sufficient. However, care should be taken to ensure product quality is not impacted by the excessive heat treatment. AFFI's lab-scale blanching study provides information to support specific parameters for peas, corn, carrots, and spinach for water and steam blanching processes. Furthermore, AFFI's food safety working group has developed a table of commonly used time-temperature combinations for different vegetables (resource #1).

Frozen vegetable manufacturers should draw from all available resources, including:

- In-house experience
- Enzyme inactivation studies
- Scientific literature and references to support their process parameters (provided above).
- Laboratory or pilot scale blanching validation study report

Lastly, maintaining process documentation, testing records, and any corrective interventions provides your company the ability to demonstrate the effectiveness of your manufacturing process in delivering safe and high-quality products.

Enzyme Inactivation and Correlation Studies

Thermal inactivation kinetics of key vegetable enzymes, such as peroxidase and lipoxygenase may be correlated with the kinetics of microbial lethality. The time-temperature combination required to achieve a five-log pathogen reduction may be sufficient to destroy even these heat-resistant enzymes in different vegetables, and chemical assays are available to detect the amounts of these enzymes that might survive the blanching treatment. AFFI's blanching study was expanded to investigate enzyme inactivation under the conditions used to determine microbial lethality and this work will soon be published.

Additional Microbiological Testing

Microbiological verification and monitoring of blanched products is also a valuable practice. A range of indicator microorganisms can be tested, dependent on the type of vegetable. While no specific guidance can be provided, appropriate considerations may include the use of Aerobic Plate Counts, Enterobacteriaceae, Coliforms, *E. coli*, or other non-pathogenic microorganisms as indicators of pathogen reduction. Over time, this data sets the historical precedent for the effectiveness of a blanching process in achieving microbial lethality needed for the product.

Suggested information that may be included with the blancher validation report

In addition to the documentation of blancher validation, include the following elements of your food safety program related to post-processing/ post-lethality environment sanitation and environmental monitoring.

- Laboratory or pilot scale blanching validation study report
- Airflow in the production environment
- Hygienic zoning
- GMPs
- Daily Sanitation Checklist
- Environmental Monitoring Program
- Process Control - Calibration, Monitoring, and Verification Mechanisms

References

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Resource #1

AFFI BLANCHING SURVEY 2017- Blanching Parameters Currently Used in the Industry

PRODUCT	RESIDENCE TIME (MM:SS)	TEMP °F	TYPE
PEAS	0:30	167	STEAM
PEAS	1:40	195-200	STEAM
CORN	3:20	200	STEAM
CARROTS	2:00-2:50	190-195	STEAM
ASPARAGUS	1:00-4:00	194	STEAM
GREEN BEAN	4:00	195-200	WATER
LIMA BEAN	1:40	195	WATER
BROCCOLI	2:00-3:00	185-212	STEAM
BELL PEPPER, ZUCCHINI	1:00	163	WATER
SPINACH	1:00-1:30	194-201	STEAM
PEA/CORN/CARROTS	1:55	200	STEAM
PEA/CORN/CARROTS	1:30	200	WATER
POTATOES	10:00	175	WATER
BROCCOLI, SUGAR SNAP PEAS, ZUCCHINI, PEAS, CAULIFLOWER	2:00-2:20	185-205	STEAM
BROCCOLI, CAULIFLOWER, SPINACH, BELL PEPPER, KALE	3:00	190-210	STEAM
BROCCOLI, BELL PEPPER	3:30-6:00	183-201	STEAM
BROCCOLI, CAULIFLOWER	1:30	188	STEAM
BRUSSEL SPROUTS	1:30	183	STEAM
QUINOA	10:00	194	STEAM
PASTA	1:00	185	WATER
STUFFED PASTA	3:00-6:00	196-203	WATER
GRATIN	8:00-10:00	176-194	STEAM

Note: These time and temperature combinations may be dependent on the type of blancher, raw material size and other product attributes. Manufacturers should consider their own validation studies and additional scientific references to determine blanching parameters for specific products.

Resource #2

Checklist for Validating a Blancher

*indicates critical conditions

Considerations	Response	Additional Comments
Product Characteristics		
Type (Vegetable, Raw Material, Product)	Peas	
Shape	Spherical	
Whole or Cut (dimensions)	Whole (diameter: 9-11 mm)	
Density (if available in native form – not wet)	NA	
What is the identified biological hazard associated with the product?	*Listeria monocytogenes*	Provide reference
What is the desired lethality (log reduction) required to establish blanching as a process preventive control for this specific product?	5-log reduction at 185°F for 45 s	Provide reference
Process Characteristics		
Pre-Blanching		
Raw material treatment	Rinsed with water prior to blanching	Examples include washing, rinsing, cutting, sorting
Is water used prior to blanching?	Yes, but water is drained	
Batch size/volume of product	3 tons or 6000 lbs./h	
Temperature of raw materials	60°F	
Temperature of 'raw' zone in the facility	58F°	
Blanching		
Type of Blancher	Continuous	Batch or continuous
Name of the manufacturer	Laitram	
Model # and Year	1999	
Heating source	Steam	Water or Steam
Length of blanching tunnel	20 m	
Width of blanching tunnel	1.5 m	
Are agitators used inside the blancher to shake product?	No	
To what extent is the equipment automated?	Feeding, blanching and chilling controls	Examples include: steam controller, product input controller, belt speed controllers, etc.

Considerations	Response	Additional Comments
Which indicators are installed and functional?	4 type T themocouples (temperature) at beginning, left middle, right middle, and end of the belt. A pressure gauge inside the chamber. Microprocessor controls belt speed and blanching temperature	Examples include: temperature and pressure gauges, chart recorders, etc.
Amount of steam consumed per batch or per run	Approximately 1 kg steam for 10 kg product	
*Temperature (range) to be achieved for desired lethality	182-187 °F	Specific to this product
*Time of exposure (range) to be achieved for desired lethality	42-47 s	Specific to this product
Do you have a lab, pilot, or plant study to substantiate the time and temperature (ranges) combination established to achieve desired lethality (5-log reduction)?	No	Provide a detailed report of this study in your food safety plan
If not, do you have a scientific reference to substantiate the time and temperature (ranges) combination established to achieve desired lethality (5-log reduction)?	Utilizing parameters from a published lab scale study on Peas (reference is available)	Provide the scientific reference in your food safety plan
Capacity of the blancher	3 tons or 6000 lbs./h	Total Lbs. or Lbs./hr.
Type of cooling	Chilled cooling water	Evaporative; chilled water; mechanically chilled air
Clean-in-place (CIP) capability	Yes	
Provide any equipment modifications	None	
Are any images or figures available?	Yes	

Post-Blanching		
Type of Chiller	Heat exchanger to cool water	Chiller chain or chiller vessel (Provide any images or figures)
Capacity and dimensions		
Product temperature at inlet	<45°C or < 113°F	
Water temperature		
Mode of water application	Fog spray	Spray, nozzle, drip, etc.
Product flow rate or duration of treatment (dwell time in chiller)	60 s	
Are any shakers or dryers used to remove excess water?	Yes	Provide any images or figures

Considerations	Response	Additional Comments
Type of Freezer	IQF OctoFrost Freezing Tunnel	Provide any images or figures
Product flow rate or duration of treatment (dwell time in freezer) for each belt	180 s	Specific to this product
Is any metal testing done at product exit?	Yes	
Are any other quality tests performed after freezing?	No	
Type of packaging	Bag in a box	Bulk, box, liners, etc.
Unit wt. or vol.	2,200 lbs	
Product storage conditions	Freezer	

Blancher Validation		
Blancher Description		
Dimension of the heating and holding zones	20 x 1.5 m	
Do you understand the process of steam injection or hot water treatment as applied in the blancher?	Yes	Can you provide an relevant diagrams, flow charts or images to substantiate this process
Batch size/volume of product	6,000 lbs/h	
Temperature of raw materials	60°F	

Temperature Measurement		
*Temperature (range) to be achieved for desired lethality	182-187°F	Specific to this product
Have you determined a given location in the blancher with a set point temperature?	Yes	
Do you have a temperature recording device at this given location in the blancher?	Yes (thermocouple)	Indicate which type(s) of temperature recording device(s) you are using
Have you recorded the temperature at this given location in the blancher during several passes of product?	Yes	Preferably multiple passes on the same or different days
What is the average temperature measured at this given location in the blancher?	190°F	
Does this temperature fall within the temperature range set to achieve desired lethality?	Yes	
Do you have additional locations in the blancher with appropriate set point temperatures?	Yes	
Do you have a temperature recording device at these additional locations in the blancher?	Yes (thermocouples)	Indicate which type(s) of temperature recording device(s) you are using

Considerations	Response	Additional Comments
Have you recorded the temperature at these additional locations in the blancher during several passes of product?	Yes	Preferably multiple passes on the same or different days
What is the average temperature measured at each of these additional locations in the blancher?	186°F	
Do these temperatures fall within the temperature range set to achieve desired lethality?	Yes	
What is the steam pressure (psi)?	8 psi @ 185°F	Calculate the average steam pressure over multiple passes and establish a range to be
Have you calibrated all the temperature recording devices used in the validation process?	Yes	How often do you calibrate these recording devices in routine manufacturing
Are you able to measure product bed depth during product flow in the blancher?	Yes	
What is the desired product bed depth?	25 mm	

Time Measurement		
*Time of exposure (range) to be achieved for desired lethality	42-47 s	Specific to this product
What is the product input rate (or batch volume)?		
What is the product feed rate?		
How long does it take for your product to exit the blancher?	120 s	
What is the product volume per unit time that has passed through the blancher?		Indicate which type(s) of temperature recording device(s) you are using
What is the dwell (residence) time?	52 s	
Is the dwell time longer than the time of exposure set above for this specific product?	Yes	
Are you able to establish a consistent temperature range (approximately within 2-5°F) between any two locations in the blancher?	Yes	
Is this temperature range within the temperature range to be achieved for lethality?	Yes	
Have you measured the dwell time over multiple passes in the blancher?	Yes	Preferably multiple passes on the same or different days
What is the average temperature measured at each of these additional locations in the blancher?	186°F	

Considerations	Response	Additional Comments
Do these temperatures fall within the temperature range set to achieve desired lethality?	Yes	
Can you measure the product bed depth during passage through the blancher?	Yes	
Have you measured the product bed depth during multiple passes in the blancher?	Yes	
What is the average product depth?	25 mm	
Is the product bed depth consistent for a given volume of product flow?	Yes	
Do you have an endpoint temperature recording device at product output?	Yes	Indicate which type(s) of temperature recording device(s) you are using
Have you measured the endpoint temperature over multiple passes in the blancher?	Yes	Preferably multiple passes on the same or different days
What is the average endpoint temperature after blanch but before chilling/cooling?	170°F	
Does the endpoint temperature fall within the temperature range set to achieve desired lethality?	No	

Other Methodologies		
*Other methods to establish achieving a desired time and temperature combination		Specific to this product
Is the product bed depth and product flow amenable to using a remote temperature probe placed within the product bed for real-time measurement during product flow within the blancher?	Yes	Indicate which type of probe or recording device being placed in the product bed
If so, have you collected real-time temperature measurements from a probe placed within the product bed?	Yes	
Have you collected real-time temperature measurements from a probe placed within the product bed on multiple passes?	Yes	Preferably multiple passes on the same or different days
When data from multiple passes is graphed, do you see a trend?	Yes	Is there a consistent pattern?
Can you conduct enzyme inactivation assays on the product at the end of blanching?	Yes; Peroxidase	Which enzyme inactivation assay did you perform?
Do you have a scientific reference to substantiate the application of this particular enzyme for this purpose?	Yes	

Considerations	Response	Additional Comments
Do you have a standard assay to conduct enzyme inactivation studies?	Yes	Examples include peroxidase, lipoxygenase, etc.;
Have you conducted the assay on blanched product from multiple passes?	Yes	Preferably multiple passes on the same or different days
Do the results from multiple inactivation studies allow you to conclude this assay is a suitable indicator of product exposure to the time and temperature combination desired to achieve lethality?	Yes	If so, this data can provide scientific support for application of the enzyme inactivation assay for routine verification purposes

Pass-Fail Criteria		
* Based on the above, are you able to establish validation of your blancher?	Yes	Blancher validation relative to the specific time-temperature combination for this specific product
If no, have you verified if all the temperature recording devices were calibrated?		
If no, did you observe or note any inconsistency in product depth or product spread?		
If no, did you record any sudden changes in belt speed?		
If no, was there a sudden product surge at some point in the validation study that led to an excessive amount of product to be passed through the blancher?		
If no, can you confirm incoming raw material temperature was not lower than usual?		
If no, have you rechecked to ensure there were not additional system failures?		
If no, consult an expert to develop a process adjustment and repeat the validation study?		
Next steps may include running a different batch of product on a different day with alternate parameters		