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6200 Aurora Ave., Suite 200W, Des Moines, IA 50322-2864

John DeBeer,[1*] Fred Nolte,[2] Christopher W. Lord,[3] James Colton,[4] Javier Colley[5] and Lisa Weddig[6]

[1*]Chicken of the Sea International, Suite 500, 9330 Scranton Road, San Diego, CA 92121, USA
[2]Fred Nolte Consulting, 2503 West 5th Ave., Vancouver, BC, Canada, V6K 1S9
[3]Pro-Tech International Consultants Co. Ltd., Sethiwan Residence 6A, 85 Sukhumvit 13, Klongtoey Nua, Wattana, Bangkok, Thailand
[4]Aerojet Rocketdyne, 8900 De Soto Ave., Canoga Park, CA 91304, USA
[5]COS Georgia Canning, 129 North Commerce Drive, Lyons, GA 30436, USA
[6]National Fisheries Institute, 7918 Jones Branch Drive, #700, McLean, VA 22102, USA

A Strategy for Controlling Histamine Formation at Tuna Precooking

ABSTRACT

This paper presents practical procedures that allow processors to determine when a batch of tuna fish is heated sufficiently to achieve a 5-log reduction in *Morganella morganii*, the most heat-resistant histamine-forming bacteria. The core temperatures of the largest, coldest fish in the batch are chosen to estimate the minimum temperature of the batch, because they will have the slowest heat penetration rate. The prerequisites and validations required for this procedure are presented, as well as the corrective actions that might be needed to comply with FDA seafood HACCP guidelines. An Excel spreadsheet was developed to allow for simple data input and to provide output of a decision as to whether to accept the tuna, wait, or recook the tuna. The consistent use of these procedures will produce a safe precooked tuna product, thereby allowing for an extra 12 h for tuna preparation and processing.

INTRODUCTION

Purpose

The purpose of this paper is to develop: (a) practical procedures for indicating when the fish in a precooking batch are heated to a minimum core (backbone) temperature of sufficient time duration to achieve a 5-log reduction in *Morganella morganii,* (b) examples of risk-based sampling plans for monitoring tuna core temperature Critical Limits (CLs) for the commercial tuna precooking Critical Control Point (CCP), and (c) validation procedures for using such plans and Corrective Actions (CAs) as needed.

HACCP review

All seafood introduced into commerce in the United States (U.S.) must be handled and processed under the U.S. Food and Drug Administration (FDA) Seafood Hazard Analysis Critical Control Point (HACCP) regulations *(10)*. The procedures proposed in this paper comply with HACCP guidelines for processing tuna for canned tuna products. Histamine is a seafood toxin of bacterial origin that forms in tuna left for too long at temperatures that allow for bacterial

*Author for correspondence: Phone: +1 858.597.4211; Fax: +1 858.362.9211; E-mail: john.debeer@thaiunion.com

growth *(11)*. The FDA Seafood HACCP Guidance document *(9)* allows only 12 h of processing from the start of thawing through the start of retorting or refreezing, if the ambient temperature exceeds 70°F (21°C) at any time. The canned tuna industry has found that 12 h is insufficient for processing larger tuna. The FDA guidelines *(9)* allow for a heating step (ex. precooking) to "reset the clock," but offered no temperature or time critical limits (CLs) for a precooking CCP. Historically, the target for the minimum tuna precooking core temperature has been 135°F (57.3°C), based on Peterson's patent *(15)* of 1971.

Morganella morganii is the most histaminogenic *(18)* and most heat resistant *(7)* of the histamine-forming bacteria (HFB) and its growth therefore needs to be prevented during the handling of tuna prior to canning or freezing. The heat resistance and thermal death rates for *M. morganii* grown on irradiated tuna loins were measured by Enache et al. *(7)*. Based on this information, Nolte et al. *(14)* proposed a CL of 60°C for the minimum core temperature of the tuna after precooking in order to achieve a 5-log population reduction of *M. morganii*. DeBeer et al. *(5)* then proposed alternative CLs based on the same 5-log reduction and developed risk-based sampling plans and sample sizes *(6)*. This knowledge base can be integrated into the practical application plan proposed in this paper for monitoring the CL for core temperatures of precooked tuna using various precooking methods.

The strategies offered here involve measuring core temperatures and holding times of precooked tuna from a sample from each precooking batch or cycle to confirm that the fish are heated sufficiently to control histamine formation during the ongoing processing. In this paper, the CLs are the *minimum* internal core temperatures and times measured from a batch of precooked fish to achieve at least a 5-log reduction in *M. morganii*.

Monitoring the minimum core temperatures for HACCP CLs during and after precooking tuna requires careful planning and preparation. This planning and preparation consists of correctly following a series of procedures and is needed to minimize the variation in processing parameters *(9, 13)*. In particular, since size and thickness vary within a fish size category, the fish should be sorted into size categories with a relatively narrow range *(3)*. Consistent precooking results are directly dependent on sizing, thawing, butchering, and racking the tuna properly and consistently.

DeBeer et al. *(5)* offered multiple critical temperature and time combinations to achieve a 5-log reduction of the *M. morganii* populations. An initial target minimum core temperature of 60°C held for one min achieves a bacterial population log reduction of 5.68. Essentially one measures the temperatures and, because the temperature measurement itself takes more than one min, in the time it takes to determine that a temperature of 60°C has been reached, a greater than 5-log lethality has already been achieved. Other temperature-time combinations were offered to provide options for the precooker operators if the 60°C requirement had not been met on the first set of measurements. It is far easier to just wait for a prescribed number of minutes, remeasure the temperature of the fish, and use 60°C or an alternative set of CLs *(5)* to verify that a 5-log lethality (ability to reduce the *M. morganii* numbers) has been reached.

With any HACCP system, there are also verification, validation, and record-keeping requirements. These requirements include validating that the process is capable of delivering the required lethality and verifying that the thermometers are measuring temperature accurately. The record-keeping requirements mean that the manufacturer must keep written records of everything, including the validations, thermometer accuracy, and actual temperature measurements.

Precookers

There are primarily two types of precookers, which are reviewed in detail in DeBeer et al. *(3)*. Conventional atmospheric precookers (CAPs) *(Fig. 1)* can use either: (a) a constant heating profile of saturated steam at 100°C or (b) a step-down heating profile characterized by lowering the steam temperature from 100°C to 70°C by letting air into the precooker in a series of timed steps. The vacuum precooker (VPC) *(Fig. 2)* is designed to use a step-down heating profile *(20)*, while either heating or cooling the fish in a controlled partial vacuum. The saturated steam heating at 100°C in CAPs and the VPC steam heating at any temperature have the most uniform and consistent temperature distribution. Practical strategies will be offered for both types of precooking. The strategy for evaluating the CLs from the CAP precooking will involve measuring and analyzing core temperatures and times ***after*** precooking. The strategy for evaluating the CLs from the VPC precooking will involve measuring and analyzing core temperatures and times ***during*** precooking.

Validation of the precooking process

The validation challenge studies for precooking have been completed and published by several authors *(7, 14, 19)*. It is well documented that achieving certain fish core temperature and holding time scenarios will stop histamine formation long enough to allow for processing of tuna of any size *(14, 19)*.

Before relying on precooking to control the histamine formation hazard, processors must first validate their own heating process and processing equipment *(12, 13)*. What is needed are: (a) temperature distributions by precooker type and steam temperature profiles and (b) heat penetration studies of tuna by fish size for CAPs operating at 100°C, CAPs operating with a step-down heating profile, and VPCs.

Figure 1. A conventional atmospheric precooker

In order to heat the fish evenly regardless of its location within the precooker, an accurate temperature distribution is needed for every precooker and for every heating profile *(13)*. If any specific areas or locations consistently heat up more slowly than others, these areas (zones) need to be identified during the temperature distribution studies. Processors should also conduct tests to determine whether the placement and location of individual fish pieces in their precooking racks has a significant impact on the rate of heating for the particular racking arrangement that the factory uses for fish of different size and shape. This difference could be particularly important for racking arrangements in which the individual pieces of fish come in direct contact with each other, as this could affect the heating rate. Likewise, if different types of racks or precooking baskets with different materials or construction are used at a facility or if changes or modifications are made to the precooking equipment, tests should be conducted to determine whether the distribution of temperature is impacted, any "cold spot" location changed, or new cold spots created. These tests will help validate the sample selection strategy the processor uses to ascertain the appropriateness of the heat treatment during routine operations.

After the temperature distribution studies, processors should perform heat penetration studies to determine how long it takes for the slowest heating fish of each size and shape class category to receive enough heat energy for thermal inactivation of organisms that form histamine. These tests should take into consideration the "worst case" conditions for different fish size and shape class category processed by the factory. For example, the lowest initial fish temperature, the thickest piece of fish in the category, the highest number of pieces per precooking basket or rack layer, and the maximum precooker load size possible should be tested. Not every size and shape class category need be specifically tested, as results can be extrapolated

Figure 2. A vacuum precooker

between some categories. For an example of precooking times based on heat penetration studies, see *Table 1*. The precooking times are dependent on the fish size and the initial temperature (IT) of the core *(3)*. Note in *Table 1* how the precooker times are less for fish with higher initial temperatures (ITs), and note how the times change when the larger fish are split into smaller pieces.

These heat penetration tests will help processors estimate how long the fish take to heat; however, precise prediction of precooking time is not really possible because thermodynamically, tuna flesh is a highly variable, so that specimens of the same species, size, shape and initial temperature could heat at slightly different rates, even if heat is applied uniformly *(3)*. For this reason, instead of using the ambient steam temperature and precooker dwell time, commercial tuna processors typically rely on measurements of the core temperatures of the fish to more accurately determine if a batch of fish has been properly precooked.

Although identifying the slowest heating fish in a batch during production is not realistically possible, the processor can still ascertain if a batch of tuna has received sufficient heat treatment to control the histamine-formation hazard by using risk-based sampling plans and acceptance sampling statistical analysis methods *(6)*. With this strategy, finding the actual slowest heating fish of the batch becomes unnecessary, because acceptance sampling techniques adjust the acceptance threshold according to the variability observed in the core temperature at the end of the precooking process.

For processors who will be monitoring the core temperatures after precooking, the precision of the measurement system should be validated by training and testing the employees assigned to take fish temperatures before allowing them to perform the task. For processors who will be monitoring the core temperatures of the fish remotely with thermocouple probes while the fish remain in the precooker, the reliability and placement of the probes should be validated and standardized for each different fish size and shape category.

Preparing the fish for precooking

The fish to be precooked and the heating process itself need to be as uniform as possible in order to reduce core temperature variation. This approach is important, since accepting a batch as being adequately precooked becomes

TABLE 1. Example of tuna precooking times for conventional atmospheric precookers (CAPs)

Tuna Precooking Times (HR:MN)
Target core temperatures 60°C

	Initial Temperatures (°C)			
Fish size (kg)	-2°C – 5°C	5°C – 10°C	10°C – 15°C	15°C – 20°C
0 – 1	0:35	0:30	0:25	0:20
1 – 2	0:40	0:35	0:30	0:25
2 – 3	0:50	0:35	0:30	0:25
3 – 4	1:00	0:45	0:35	0:30
5 – 7	1:10	1:00	0:50	0:40
7 – 10	1:20	1:10	1:00	0:50
10 – 12	2:10	1:40	1:10	1:05
12 – 15	3:05	2:50	2:35	2:25
(15–22) Splits* 1	1:40	1:20	1:10	1:00
(22–30) Splits 2	2:00	1:50	1:35	1:20
(30–40) Splits 3	2:15	2:00	1:45	1:30
(> 40) Splits 4	3:10	2:50	2:30	2:15

*Splits are fish that are cut in half lengthwise or even quartered.

harder as variability in core temperatures increases. In fact, processors typically devote considerable effort to ensuring that each batch of fish processed is as uniform as possible, because this process actually impacts profit by maximizing fish yield and processing efficiency. The sampling strategy being proposed to ascertain the adequacy of the heat treatment should be suitable for the variability resulting from typical commercial tuna processing operations.

Prior to the start of the process, the fish should be segregated by species and then sorted by weight (i.e., "sized") into pre-established weight class categories. Fish from each size category should be processed together in batches of like-weight fish of the same species. Sizing cascades to provide consistent post-thawing fish temperatures and consistent precooking initial temperatures (ITs), thereby providing consistent precooking heating rates during precooking and consistent post precooking core temperatures. The suggested maximum ranges of weight for sorting the fish are one or two kg for smaller fish (under 10 kg) and five kg for larger fish (over 10 kg) *(3)*.

Efficient reliable equipment and techniques for thawing the fish are needed to reduce IT variability. The thawing water should be temperature-controlled and should have adequate circulation *(8)* to provide consistent thawed fish temperatures. Optimizing the efficiency of the thawing equipment results in uniformly thawed fish, which helps to make the rest of steps in the process more efficient.

Processors typically establish stringent operating parameters and monitor the thawing process and the fish exiting the thawing step to ensure the fish have thawed sufficiently to continue processing. In particular, processors should ensure that no individual fish are still frozen at the core because this (a) makes the fish difficult to butcher and split, if required, and (b) may cause a very slow and variable precooking time.

The personnel assigned to work on the butchering line are typically trained to detect and alert management if the fish gets too hard to butcher because it is still partially frozen internally. Partially-frozen fish should be segregated from properly-thawed fish, as they might need to be precooked as a separate batch or held back until they finish thawing and before they can be precooked. The personnel should also be trained to alert the management if the fish arriving from the thawing step are not properly "sized" or have been assigned the wrong size class category, i.e., in the lot identification documentation available for the fish.

For the larger fish sizes that require splitting and cutting, the cutting equipment must be properly adjusted and capable of consistently cutting the fish into pieces of uniform size and shape. The allowed variation for cut pieces should be pre-determined, and the splitting and cutting operation should be monitored to ensure the fish pieces conform to the specifications.

After butchering and splitting, the fish must be divided into batches made up of individual pieces of uniform size, shape, and racking arrangement. At the fish racking station, individual pieces from each batch should be sampled by measuring and/or weighing to make sure the correct precooking time is selected. The size and shape class category and the racking arrangement of each batch should be documented in the precooking records. Any piece that is significantly larger than the rest in the batch should be checked by measuring and/or weighing prior to racking to make sure that it belongs to the same size/shape class category as the rest of the fish in the batch. Pieces that belong to a different category should be culled out and precooked as a separate batch; otherwise, the precooking time applied to the batch should be chosen according to the largest fish size category in the batch, because the larger pieces will have slower heating rates *(3)*.

Each precooking rack or trolley that will be used to take the fish into the precooker must be loaded only with fish that belong to the same batch. To minimize heating variation during precooking, the precooking racks and baskets must have essentially the same construction and physical characteristics, and all the fish in the batch must be arranged in the racks with the same loading configuration, i.e., same orientation and disposition of individual pieces and same number of pieces per layer or per precooking basket.

If the batch has some individual pieces that are noticeably larger than the average piece size, then the racking personnel would have to ensure these larger pieces are located in specific pre-established positions in the racks or marked in some consistent fashion so their core temperatures can be measured before and after precooking. Likewise, if the precooker has any consistent "cold spots" that were identified during the temperature distribution studies, then the rack(s) that will be located in this area of the precooker during the process must be tagged or marked to ensure that their fish are included in the sample that will have its core temperature measured after precooking.

ACCEPTANCE SAMPLING

There are two methods of acceptance sampling: sampling by attribute or sampling by variable *(17)*. A simple technique that uses attribute sampling to measure temperature and time for the vacuum precooker (VPC) is described. For conventional atmospheric precookers (CAPs), an Excel spreadsheet using the variable sampling method *(6)* was developed to be used to analyze the core temperatures of the fish exiting the precooker. This spreadsheet will analyze the log-lethality of the heat treatment of precooking and test the core temperatures for normality. As an alternative, for a factory that has no computer support, an acceptance technique was developed using the median and range/d_2 method described by

TABLE 2. Sample sizes for variables acceptance (VA) sampling plan using the calculated mean and standard deviation

Confidence Level	Minimum percent acceptable to be demonstrated		
	95%	99%	99.5%
90%	7	23	54
95%	10	35	86
99%	17	65	100+

Source *(6)*

DeBeer et al. *(6)*, but this technique will not be discussed further in this paper.

Acceptance sampling of core temperatures

The practical acceptance sampling techniques are different for conventional atmospheric precookers (CAPs) and vacuum precookers (VPCs). For CAPs, the temperature measurements and analysis are completed *after* precooking, since the fish temperatures can be measured after the fish have been removed from the precooker. For VPCs, the temperatures are measured continuously *during* precooking. The operators start the cooling phase inside the VPC, so the minimum core temperatures can be measured only with temperature probes. The VPCs use temperature probes for continuous temperature recording, with the smallest number of samples required. Both the CAP and VPC methods use the average and standard deviation and also require computers, either for continuous recording or for statistical analysis. All methods measure and record the core temperatures of the tuna or pieces, but the sample size *(Table 2)* and analysis may differ. Either method should stop histamine formation, if used properly. Note: for a VPC, if there is no vacuum cooling phase, the CAP method of evaluation of core temperatures after precooking may be used.

As indicated earlier, the fish need to be precooked to a minimum temperature and time combination, such as 60°C with a time zero (T-0) (first choice) or some other temperature and time combination *(5)*, to achieve a 5-log reduction of *M. morganii*. The spreadsheet developed for CAPs uses a 60°C Critical Limit and Acceptance Value (AV) for ease of use and consistency for the precooker operators, although other CLs will also achieve a 5-log reduction of *M. morganii (5)*. The alternative temperature and time scenarios are included as a backup in case they may be needed to clear a batch of precooked fish.

METHODS AND MATERIALS

Collecting and analyzing the core temperatures after precooking with an atmospheric precooker

Since most precooking is done in CAPs, a spreadsheet was developed to analyze the core-temperature data collected from the fish. The resulting histogram allows the operators to make quick decisions. For example, a precooker operator collects the core temperatures of the precooked fish *(4)* and records the temperature tally marks on a data collection sheet. The operator or someone else enters the tally numbers in a computer, and the spreadsheet calculates the mean and standard deviation (SD) and assesses the normality of the distribution using the Ryan-Joiner test *(1, 16)*. This method uses the lowest actual core temperature, sample average, and SD for the decision making. The sample size must be predetermined *(Table 2)*, based on the desired confidence level and percent acceptable.

The sequence of events will start at the butcher table where all the fish are individually evaluated, prior to being placed in precooking racks. The sampling plans for tuna precooked in a CAP require that the operators:

1. Determine the largest, coldest fish prior to precooking, measure the weight and core temperatures of a minimum of 24 fish, and record the weights and ITs on the tally sheets, based on the form provided in *Appendix A-1*.
2. Precook the tuna, using the times based on the largest and coldest fish. For examples of precooking times, see *Table 1*.
3. Measure the core temperatures *(4)* after precooking. Use as many thermometers as sampled fish. For example, if the sample size is 24 fish, use 24 thermometers; if the sample size is 36 fish, use 36 thermometers; etc. Place all the thermometers in the fish first, stabilize for 1 minute, and read the results.
4. Record the core temperatures on a simple tally data collection form, as shown in *Appendix A-2*.

5. If any individual fish has not reached a core temperature of 56°C return the batch to the precooker for further heating.
6. Determine the statistics of the core temperature distribution and normality test with the suggested spreadsheet (see *Appendix A-3*).
   a. Statistics *(6)* will be based on the:
      i. Sample mean ($\bar{x}$) and standard deviation(s).
         1. Predicted minimum core temperature ($\bar{x}$ - (3*s).
         2. The normality of the data is tested with the Ryan-Joiner test.
7. Make decisions that depend on the time of measurement, i.e., T-0, T-10, T-15, as follows.
   a. T-0
      i. If the actual minimum core temperature of any sample or the Acceptance Value (AV) is < 56°C, immediately return the batch to the precooker for continued heating and subsequent retesting.
      ii. If the minimum actual temperature is >= 56°C, but the CL or Acceptance Value (AV) is less than 60°C, wait 10 min and remeasure. Note: A conservative way to measure core temperatures is to measure the elapsed time between when the last temperature was collected at Time-0 (T-0) and the first temperature at T-10 or T-15.
      iii. If the AV is >= 60°C, release the product.
   b. T-10
      i. If the calculated AV produces > 60°C, release the product.
      ii. If the calculated AV produces < 60°C, wait another 5 min and retest.
   c. T-15
      i. If the AV > 60°C, release the product.
      ii. If the AV is still < 60°C, reheat and retest.

Corrective actions if the data are NOT normally distributed

The most important outcome of the precooking process is that all the fish have received heat treatment greater than or equal to what is required to cause a 5-log reduction in *M. morganii*. An important condition of the variable sampling method is to test whether the temperature distribution is normal; if it is not normal, the operators can move from a variable sampling plan to an attribute sampling plan *(Table 3)* to accept the fish *(2)*, based on a larger sample size.

1. If the lowest actual core temperature or AV is < 56°C, reheat the batch and retest.
2. If the lowest actual core temperature is > 56°C but less than 60°C, wait 10 min and remeasure the core temperatures of 60 fish. If all are >= 60°C, release the lot.
   a. If any are below 60°C, wait another 5 min and remeasure. If there are any less than 60°C, reheat and retest, or
   b. Release if all are > 60°C.
3. If the lowest actual core temperature is > 60°C, remeasure enough fish to reach a total sample size of 60 fish. If all are > 60°C, release. If any are below 60°C, follow the instructions in point 2 (see above) of this section.
4. To be conservative, remeasure 60 fish when retesting.

Testing the core temperatures while vacuum precooking

The vacuum precooker has the simplest acceptance program because of its computer-controlled equipment and continuous temperature recording ability. All of the preparation procedures previously listed must be met for this technique to work. The 5-log lethality temperature and time scenarios are listed in *Table 4*. The employee will put thermocouple probes in a minimum of 6 of the largest fish or in the thickest pieces of fish in that batch being precooked, per the Seafood HACCP Guide *(9)*. The fish is then precooked until the minimum probe temperature passes the correct temperature for the correct time period, using the information from *Table 4*. For the purposes of this paper, the authors suggest using 60°C as the endpoint for the slowest heating probe. This temperature can be easily programmed into the precooking computer's control system by the manufacturer's representative. The key features of VPCs are continuous recording of temperatures and slower heating in general.

RESULTS AND DISCUSSION

Work by Vogl et al. *(19)* demonstrated that precooking of fish delayed histamine formation. This paper developed the practical acceptance sampling methods needed, based on either variable or attribute methods. An example of a precooking CCP following the National Fisheries Institute (NFI) CCP format *(13)* is shown in Appendix B. If the procedures in this example CCP are followed, the precooking heating process will control histamine formation for a minimum of an additional 12 h.

Using this CL sampling technique depends on preparation, but collecting the temperatures may take less time than preparation. The operators should fill only one precooker at a time with uniformly-sized and thawed fish; if the operator precooks some partially frozen fish and some completely thawed fish, the core (backbone) temperatures will be quite variable at the end of precooking. The core temperature variation of a batch of tuna needs to be minimized in every step of the process. The fish should be loaded into the precooker quickly to minimize variations in the ITs. The fish ITs should be tested at both ends of the precooker, because the fish loaded into the precooker

TABLE 3. Sample sizes for c = 0 attribute acceptance sampling plans – lot size – infinite

Confidence Level	Minimum percent acceptable to be demonstrated		
	95%	99%	99.5%
90%	45	230	460
95%	59	299	598
99%	90	459	919

Source *(6)*

TABLE 4. Critical limits of time and temperature to achieve a 5-log reduction of *Morganella morganii*

Minimum Core Temperature	Elapsed Time	Minimum Log Reduction
60°C	1 min	5.68
59°C	2 min	5.41
58°C	4 min	5.59
57°C	7 min	5.30
56°C	12 min	5.06

Source *(6)*

first may have warmed up and the last fish loaded will generally have the coldest IT; then again, the last fish unloaded has waited longer in a hot precooker. Therefore, the fish unloaded first will naturally cool faster than the fish unloaded last.

CONCLUSIONS

A heating CL has been developed for precooking tuna so that the time allowed for processing can be extended by another 12 h. The procedure depends on the measuring of core temperatures of precooked tuna samples and statistical determination of whether the entire batch has been cooked enough to suppress histamine formation for a period of at least 12 h.

Proper preparation of the fish in sizing, thawing, butchering, precooking, sidespray, and cooling prepares the fish so that skinning and cleaning is easier and improves productivity immensely. Achieving good results for precooking depends on the preparation of sizing, storing the fish by size, scheduling the fish properly, and knowing the heating rates of the different-sized fish. This approach also helps produce consistent thawing.

One danger of precooking frozen fish is that, to precook it completely and safely, the outside of the fish will be overcooked and the factory will lose recovery and efficiency. The loss of efficiency occurs if the fish has to be returned to the precooker for corrective action (reheating). It is far more efficient to thaw the fish properly in the thaw chamber than to use the precooker to thaw the fish.

The procedures proposed in this paper will require slight adjustments in the factory and very little change from what has been done previously. The proposed procedures of precooking will provide additional processing time of at least 12 h.

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APPENDIX A-1 – FISH SIZING AND INITIAL CORE TEMPERATURE (IT) TALL SHEET

Fish Sizing & IT Chart
SPC chart
Fish Size Sample By Lot

Date -

Time- Hr:mn									Time- Hr:mn
Lot #									Lot #
bin #									bin #
Target Size									Target Size
Fish Size- KGs >40									
35 - 39									
30 - 34									
25 - 29									
20 - 24									
15 - 19									
12 - 14									
9 - 11									
7 - 8									
5 -6									
4									
3									
2									
1									
Initial Temps °C > 10									
10									
9									
8									
7									
6									
5									
4									
3									
2									
1									
0									
-1									
-2									
-3									
-4									
<= -5									
Corrective Action & Comments									Corrective Action & Comments

1 - Sampling Location - Sorting Table	Data Collector:
2 - Sample Size - Min 5 fish per Size	SPC Auditor:
	NOS #:
	Reviewed by:

APPENDIX A-2 – TALLY SHEET FOR COLLECTING CORE TEMPERATURES

Date		Shift	
Precooker		Batch	
Species		Size	

Instructions

Enter the temperature data in the FREQ column of the of each test.

Then click the button to run to data

Read the results below

1st Measurement				2nd Measurement				3rd Measurement			
DegC	Tally Marks	Freq	CumFrq	DegC	Tally Marks	Freq	CumFrq	DegC	Tally Marks	Freq	CumFrq
85				85				85			
84				84				84			
83				83				83			
82				82				82			
81				81				81			
80				80				80			
79				79				79			
78				78				78			
77				77				77			
76				76				76			
75				75				75			
74				74				74			
73				73				73			
72				72				72			
71				71				71			
70				70				70			
69				69				69			
68				68				68			
67				67				67			
66				66				66			
65				65				65			
64				64				64			
63				63				63			
62				62				62			
61				61				61			
60				60				60			
59				59				59			
58				58				58			
57				57				57			
56				56				56			
55				55				55			
54				54				54			
53				53				53			
52				52				52			
51				51				51			
50				50				50			

APPENDIX A-3 – SPREADSHEET FOR ANALYZING CORE TEMPERATURES FOR A CRITICAL LIMIT

Date		Shift	
Precooker		Batch	
Species		Size	

Instructions

Enter the temperature data in the FREQ column of the of each test.

Then click the button to run to data

Read the results below

1st Measurement			
DegC	Tally Marks	Freq	CumFrq
85			
84			
83			
82			
81			
80			
79			
78			
77			
76			
75			
74			
73			
72			
71			
70			
69	/	1	1
68	//	2	3
67	///	3	6
66	////	4	10
65	/////	5	15
64	//////	6	21
63	/////	5	26
62	////	4	30
61	///	3	33
60	//	2	35
59	/	1	36
58			
57			
56			
55			
54			
53			
52			
51			
50			

2nd Measurement			
DegC	Tally Marks	Freq	CumFrq
85			
84			
83			
82			
81			
80			
79			
78			
77			
76			
75			
74			
73			
72			
71	/	1	1
70	//	2	3
69	///	3	6
68	////	4	10
67	/////	5	15
66	//////	6	21
65	/////	5	26
64	////	4	30
63	///	3	33
62	//	2	35
61	/	1	36
60			
59			
58			
57			
56			
55			
54			
53			
52			
51			
50			

3rd Measurement			
DegC	Tally Marks	Freq	CumFrq
85			
84			
83			
82			
81			
80			
79			
78			
77			
76			
75			
74			
73			
72			
71			
70			
69			
68			
67			
66			
65			
64			
63			
62			
61			
60			
59			
58			
57			
56			
55			
54			
53			
52			
51			
50			

Results 1st Test		
Time 1		12:00
N		36
Mean		64.0
StDev		2.45
Lower Limit = Avg - (3*SD)		56.7
Lowest ACTUAL core Temp		59
R - Correl Coef		0.999
RJ_Crit_.10 N=	36	0.975
RJ_Crit_.05 N=	36	0.969
Normal?	Yes, Normal, p>= .100	
Minimum Log Lethality		0.6
Decision	WAIT	

Results 2nd Test		
Time 2		12:10
Elapsed Time (Min)		0:10
N		36
Mean		66.0
StDev		2.45
Lower Limit = Avg - (3*SD)		58.7
R - Correl Coef		0.999
RJ_Crit_.10 N=	36	0.975
RJ_Crit_.05 N=	36	0.969
Normal?	Yes, Normal, p>= .100	
Decision Criteria		
1st Test Lower limit		56.7
2nd Test Lower Limit		58.7
Minimum Log Lethality		8.4
Decision	RELEASE	

Results 3rd Test		
Time 3		12:15
Elapsed Time (Min)		0:15
N		
Mean		
StDev		
Lower Limit = Avg - (3*SD)		
R - Correl Coef		
RJ_Crit_.10 N=		
RJ_Crit_.05 N=		
Normal?		
Decision Criteria		
1st Test Lower limit		
2nd Test Lower Limit		
Minimum Log Lethality		
Decision		

Operator: Manager: HACCP:

APPENDIX B. EXAMPLE CCP FOR PRECOOKING TUNA

CCP		**CCP X – Precooking**	
Hazard		**Histamine Formation**	
Preventive Measures		Ensure all fish are heated sufficiently to achieve 5-log reduction of *M. morganii* at the slowest heating point, i.e., at core or geometric center.	
Critical Limits		Core fish temperature at or above 60˚C	
Monitoring	**What**	**Core Fish Temperature of the slowest heating fish/fish piece from a statistically valid sample**	
	How	Visually verify the temperature indicated by a dial stem thermometer (or temperature indicating device probe).	If core fish temperature has not reached 60˚C, then visually verify and track time of holding displayed by the reference time instrument (or calibrated chronometer).
	Frequency	Each precooker batch	
	Who	Precooker operator	
Monitoring Records		Precooker Exit Fish Temperature/Holding Time Monitoring Record	
Corrective Action(s)		Destroy the affected batch of fish, or load it back into a precooker, re-vent and continue cooking until critical limit is met.	
		If the CL is determined after precooking, isolate affected batch and pack separately. Collect 60 cans of finished product from each sub-batch packed from the affected batch and test for histamine. Destroy any product containing affected fish material if any sample has over 49 ppm histamine.	
		Identify and correct the root cause of the non-conformance.	
Verification Actions		Perform temperature distribution studies prior to using precookers after initial installation or modification of equipment, or changes in the established precooking procedures.	
		Establish sampling plan for each fish size/shape category based on heat penetration studies, and risk of failing to reach 5-log reduction for *M. morganii.*	
		Verify setup, condition, and function of steam valves, piping, vents, water drains, bleeders, water level sensors and general condition of each precooker at least semi-annually and after any repairs and modifications.	
		Recertify annually standard reference thermometer used to verify calibration of fish core temperature monitoring instruments.	
		Verify daily accuracy of the instruments used for monitoring fish core temperature and holding time.	
		Ensure that monitoring records are reviewed by designated employee trained and qualified as per 21CFR 123.10 before shipping any product.	
		Ensure that verification records are reviewed within one week of preparation by Production Manager and/or QC Manager.	
		Ensure that corrective action records are reviewed by QC Manager before releasing and shipping any potentially affected product.	
		Monitor initial training and assessment of initial training or performance of precooker operators.	