

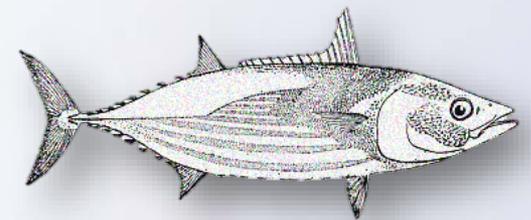
A Strategy for Controlling Histamine Formation at Tuna Precooking

*“Heat treatment to confirm a 5-log reduction of the histamine-forming bacterium *Morganella morganii*”*



INTRODUCTION

“What is the purpose of this control strategy?”



Abstract

- This is a strategy for controlling histamine formation at tuna precooking by applying sufficient heat treatment to achieve a calculated lower limit of 60°C and confirm a 5-log reduction of the histamine-forming bacterium *Morganella morganii*.
- It involves measuring the core temperature of 36 fish after every precook batch, following a variable acceptance sampling plan, with 95% confidence and 99% reliability, and testing the distribution of the results for normality by the Ryan-Joiner method.
- It is presented in an HACCP format, and includes details of procedures for corrective actions and verification.

'Fish & Fisheries Products Hazards & Controls Guidance'

- Chapter 7 “Scombrototoxin (Histamine) Formation” of the US FDA *Fish and Fishery Products Hazards and Controls Guidance* specifies...
 - During processing (e.g., thawing, butchering, cooling, cleaning, packing and seaming)...
 - Histamine-forming fish that have been previously frozen and...
 - ...are processed in a manner where there may be recontamination with histamine-forming bacteria...
 - ...should not be exposed to ambient temperatures above 4.4°C (40°F) for more than 12 hours, cumulatively, if any portion of that time is at temperatures above 21.1°C (70°F)

FDA Fish and Fishery Products Hazards and Controls Guidance, 4th Edition (April, 2011), Chapter 7, Scombrototoxin (Histamine) Formation

Why is this a problem?

- This means that the processor has only 12 hours from the time the fish leaves temperature-control (cold storage); until retorting (canned tuna) or freezing (loins). In other words, once the fish has been exposed to an ambient temperature above 4.4°C (40°F), the 12-hour clock starts.
- This is not sufficient for processing all but the smallest sizes of tuna, as the cumulative time of thawing, cooking and processing for larger fish sizes commonly exceeds 12 hours.

HACCP

“Applying HACCP principles to this control strategy”



HACCP

- This control strategy is intended as a critical control point (CCP) within a company's existing HACCP plan for the production of commercial tuna products.
- It is intended to comply with U.S. FDA Seafood HACCP regulations '*Seafood HACCP Regulation*' (21 CFR 123) and FDA's '*Fish and Fishery Products Hazards and Controls Guidance, 4th edition*'.
- It follows the seven HACCP Principles detailed on the United States Department of Agriculture (USDA) Food Safety and Inspection Service website.

The Seven HACCP Principles

1. Conduct a hazard analysis
2. Identify critical control points
3. Establish critical limits for each critical control point
4. Establish critical control point monitoring requirements
5. Establish corrective actions
6. Establish record keeping procedures
7. Establish procedures for verifying the HACCP system is working as intended

<http://www.fsis.usda.gov/Oa/background/keyhaccp.htm>



HAZARD

“What is histamine?”



Understand the Potential Hazard

- Scombrototoxin (histamine) formation as a result of time and temperature abuse of certain species of fish can cause consumer illness. The illness is closely linked to the development of histamine in these fish. In most cases, histamine levels in illness-causing fish have been above 200 ppm, often above 500 ppm.
- Symptoms of scombrototoxin poisoning include tingling or burning in the mouth or throat; rash or hives on the upper body; headache; dizziness; itching of the skin; nausea; vomiting; diarrhea; and constriction of the air passage. Symptoms usually occur within a few minutes or hours of consumption, and last from 12 hours to a few days.

U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Fish and Fishery Products Hazards and Controls Guidance, 4th Edition (April, 2011), Chapter 7, Scombrototoxin (Histamine) Formation

Scombrotxin (histamine) formation

- Certain bacteria produce the enzyme histidine decarboxylase during growth. This enzyme reacts with histidine, a naturally occurring amino acid that is present in larger quantities in some fish than in others. The result is the formation of scombrotxin (histamine).

U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Fish and Fishery Products Hazards and Controls Guidance, 4th Edition (April, 2011), Chapter 7, Scombrotxin (Histamine) Formation

Hazard

The hazard in this control strategy
is histamine formation

CRITICAL CONTROL POINT

“Controlling histamine formation”

What is a Critical Control Point?

- A critical control point (CCP) is a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, reduced or maintained at an acceptable level.
- A food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

Precooking as a CCP

- This control strategy proposes extending the FDA recommended limit of 12 hours, from thawing until retorting or freezing, by applying sufficient heat treatment at precooking to achieve a 5-log reduction in the histamine-forming bacterium *M. morgani*.
- This effectively resets the clock to allow for a full 12 hours from the end of precooking until retorting or freezing, hence enabling the processing of larger fish sizes.

Vogl, F., R. Salazar, F. Nolte, G. Kontoh, G. Ybanez. 2012. Validation for pre-cooking as a control for potential histamine production in tuna loins for subsequent canning. Paper presented at: TAFT 2012. Proceedings of the 4th Trans-Atlantic Fisheries Technology Conference; Oct 30-Nov 2, 2012; Clearwater Beach, Florida

Critical Control Point (CCP)

The CCP in this control strategy is precooking

PREREQUISITE PROGRAMS

“What needs to be done prior to precooking?”



Types of Prerequisite Programs

- Prerequisite programs (PRP) are generic controls established prior to conducting any hazard analysis for HACCP. They are applied to maintain a hygienic environment in order to reduce the risk to food safety. Examples include: design of facilities and production equipment, cleaning and sanitation, hygiene, pest control, training, supplier control, and product recall.
- Steps in the process identified by the hazard analysis as requiring control in order for the CCP to be properly controlled are referred to as 'operational' prerequisite programs (OPRP).

Production Equipment

- The prerequisite program for production equipment, which includes equipment at thawing and precooking, calls for all equipment to be constructed and installed according to sanitary design principles.
- Prerequisite programs for production equipment at thawing and precooking also require validating that the equipment is functioning as intended, which entails...
 - equipment survey
 - temperature distribution testing
 - calibration of temperature monitoring devices
 - preventive maintenance
 - periodic equipment inspections
 - heat penetration studies to develop processing schedules

Operational Prerequisite Programs (OPRP)

- Operational prerequisite programs (OPRP) are controls specific to a particular food process, that are arrived at only after completing the hazard analysis.
- In this case, the process steps identified as requiring control are fish sizing (size sorting) and thawing.
- Control is required at these steps in order to achieve proper thermal response of the product during cooking, the CCP.
- In effect, they become the critical factors when establishing cooking schedules by heat penetration testing... maximum fish size and minimum initial temperature.

ISO 22000-2005(E), Food safety management systems, 7.5 'Establishing the operational prerequisite programmes (PRPs)'

John DeBeer & Christopher W. Lord, 'Precooking Tuna', 3rd IFTPS South East Asia Technical Outreach Seminar, November 16, 2016, Bangkok, Thailand

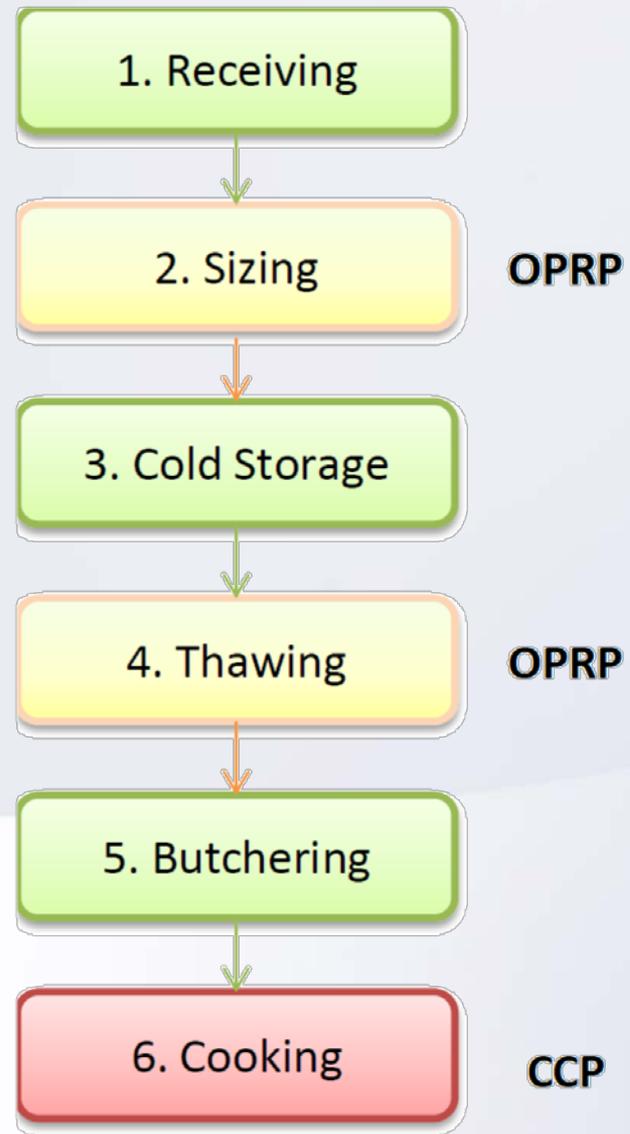
http://www.iftps.org/pdf/guidelines/Retort_Processing_Guidelines_02_13_14.pdf, March 13, 2014

Factors that influence cooking time

- The 1st commandment of tuna precooking is “No frozen fish inside the cooker“. Once this has been accomplished, the initial temperature of the fish has minimal impact on the cooking time. After that...
- ...fish size accounts for 93% of the variation in cooking time.
- Minor variations in ambient steam temperatures in properly functioning cookers have very little influence on the cooking time.

John DeBeer, Fred Nolte, and Christopher Lord. 2015, *“Precooking Tuna: A study of the factors impacting the time required for precooking”*, FPT: 35(6):448-460

Process Flow Canned Tuna



Prerequisites at Sizing (OPRP)

- Calibrate size categories to match the number of fish per cooking tray in Production. For example...
 - 10 fish per tray \approx 1.8 to 2.4 kg
 - 8 fish per tray \approx 2.4 to 3.0 kg
 - 6 fish per tray \approx 3.0 to 4.0 kg
- Conduct size sorting of the fish at receiving
- Keep fish segregated by size inside the cold store
- Schedule fish to thawing and precooking by size

Prerequisites at Thawing (OPRP)

- Thawing equipment should have sufficient circulation or agitation of the water to ensure uniform temperatures, and no fish frozen at the core before precooking.
- PRPs for thawing equipment should be similar to cooking...
 - Conduct a formal equipment survey
 - Conduct temperature distribution testing to confirm temperature uniformity and identify slow-heating zones
 - Calibrate temperature monitoring devices such as thermometers, recorders and gauges
 - Conduct heat penetration studies to develop thawing schedules by size

Prerequisites at Cooking (CCP)

- Steam supply and distribution should be sufficient to ensure uniform temperatures during cooking...
 - Conduct a formal equipment survey
 - Conduct temperature distribution testing to confirm temperature uniformity and identify slow-heating zones
 - Calibrate temperature monitoring devices such as thermometers, recorders and gauges
 - Conduct heat penetration studies to develop cooking schedules by size

Prerequisite Programs › Summary

- **Make sure all equipment is functioning as intended...**
 - Survey equipment at cooking and thawing
 - Calibrate temperature-measuring devices
 - Conduct temperature-distribution testing of thawing and cooking equipment
- **Ensure consistent segregation of fish by size...**
 - Calibrate sizing to match the number of fish per cooking tray
 - Sort fish sizes at receiving
 - Store fish by size
 - Schedule fish by size
- **Establish formal thawing & cooking schedules...**
 - Conduct heat penetration testing at thawing and cooking for each size category of tuna
 - Develop formal thawing and cooking schedules from this data

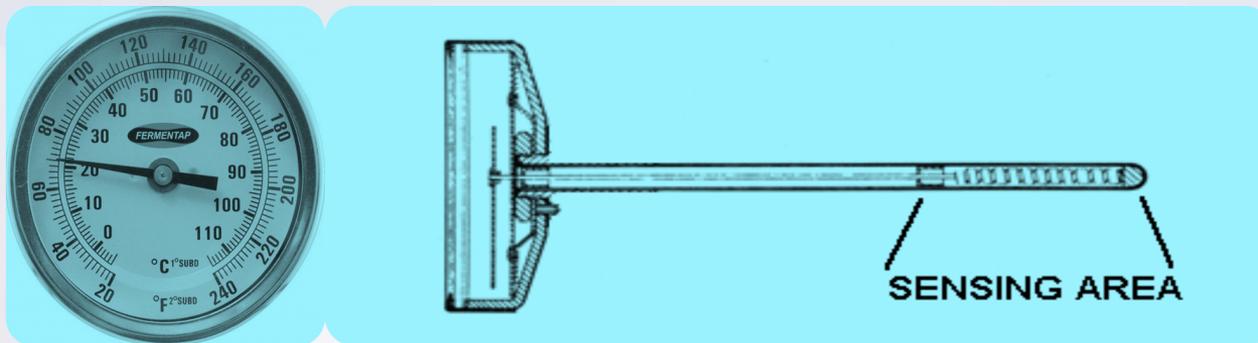
CONTROL MEASURES

“Monitoring control of the hazard”



Monitoring **before** cooking?

- Before precooking, verify the critical factors (i.e., maximum fish size and minimum initial temperature) by measuring and recording the weight and initial temperature of 36 fish.
- Follow the corresponding cooking schedule, established by heat penetration testing.



Monitoring **after** cooking

- After precooking, prepare enough thermometers to have one thermometer for each fish in the sample.
- Check the accuracy of the thermometers before using.
- Insert one thermometer into each sample fish as the trolleys exit the cooker. Do not stop to read them.
- Ten (10) minutes after the steam has been shut off, read the thermometers, in sequence, as quickly as possible.
- Record the temperatures on the tally sheet provided.
- Take the tally sheet to the cooker control center to calculate the lower limit.
- Leave the thermometers in the fish, pending confirmation of acceptance of the batch.

Tally Sheet

				Instructions							
Date		Shift		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							
Precooker		Batch									
Species		Size									
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	/	1	1	73				73			
72	//	2	3	72				72			
71	///	3	6	71				71			
70	////	4	10	70				70			
69	/////	5	15	69				69			
68	//////	6	21	68				68			
67	//////	5	26	67				67			
66	//////	4	30	66				66			
65	////	3	33	65				65			
64	///	2	35	64				64			
63	//	1	36	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			

Who will do the monitoring?

Precook personnel qualified by training and experience

How often is the monitoring?

Every precook batch

How many samples?

36 fish per precook batch

Attribute Acceptance Sampling

- Attribute sampling requires that all temperatures measured must be greater than or equal to the critical limit.
- If any fish fail, corrective action is required.
- Attribute acceptance sampling requires a much larger sample size than variable acceptance sampling.
- Attribute acceptance sampling does not require a normal distribution of sample values.

Variable Acceptance Sampling

- Variable acceptance sampling is based on the statistical parameters of the temperature values measured...
 - The mean or average of the temperatures
 - The standard deviation of the temperatures
- Temperature values must be normally, or near normally, distributed.
- The calculated lower limit, or acceptance value, must be greater than or equal to the critical limit

How many samples?

- Comparison of sample sizes for attribute and variable acceptance sampling plans...

Acceptance Sampling Sample Sizes 95% confidence that x% of the lot is acceptable						
	Conf Level	95% Reliability	99% Reliability	99.5% Reliability	Notes	Source
Attribute	95%	59	299	593	Infinite lot size	DeBeer et al Sampling paper – submitted for publication
Variable	95%	10	35	86	\bar{x} , s	

Testing for normality

- Variable samples must be normally distributed
- Normality can be tested by the Ryan-Joiner* method
- The Ryan-Joiner method depends upon the sample size and is easy to calculate on a computer
- As long as the critical factors are in control, tuna precook batches should be normally distributed. Out of more than 300 batches tested, only 6 failed the Ryan-Joiner normality test

* Thomas Ryan & Brian Joiner, professors at Penn State University, were two of the founders of Minitab

Ryan-Joiner Test - Pass

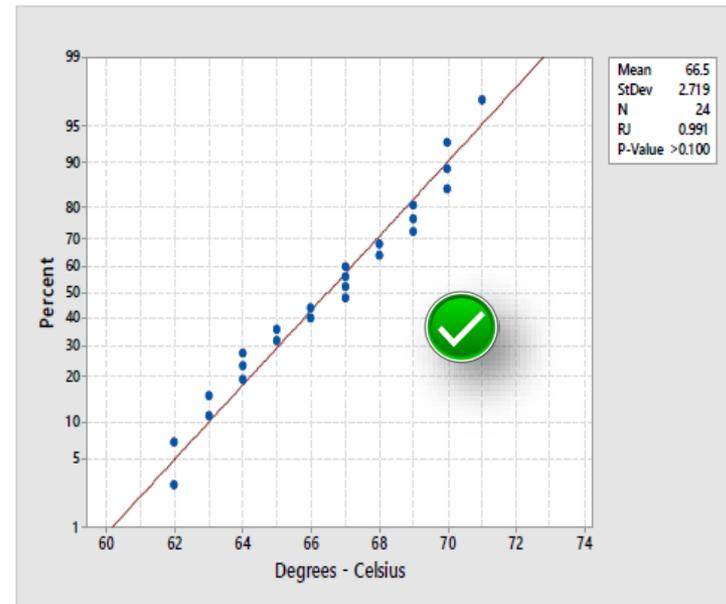
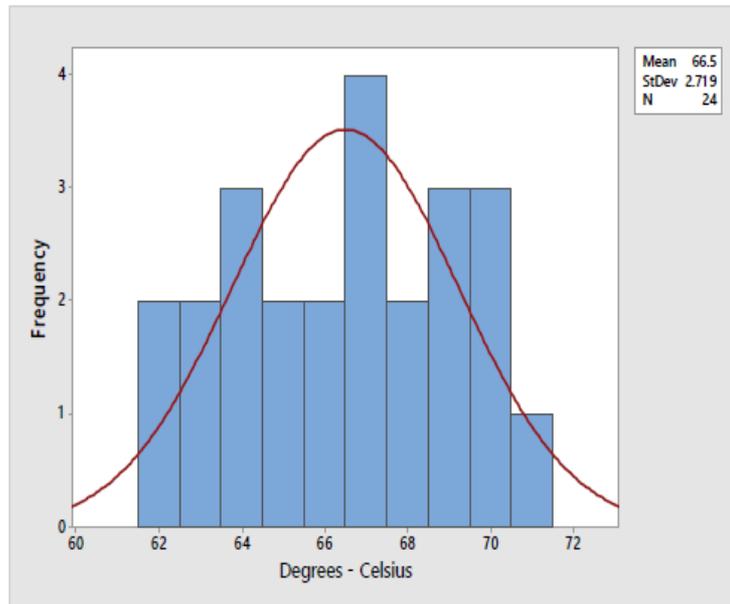


Chart 2: Testing the distribution of tuna core temperatures after precooking - Pass

Ryan-Joiner Test - Fail

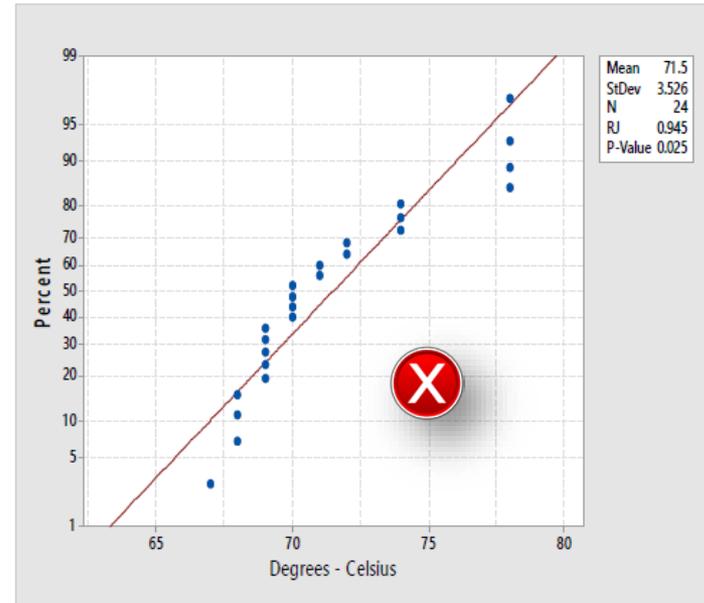
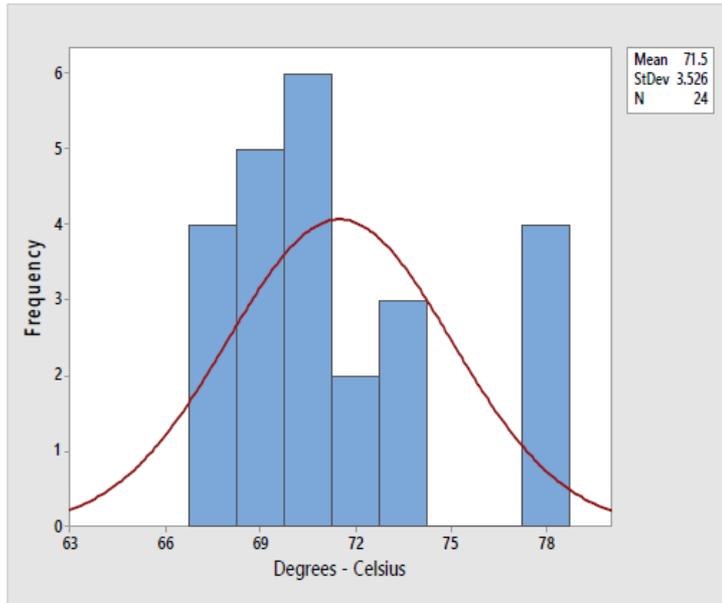


Chart 3: Testing the distribution of tuna core temperatures after precooking - Fail

Non-Normal Distribution

- If the sample fails the Ryan-Joiner test for normality after cooking...
 - Revert to an attribute sampling plan with a sample size of 299 fish, or...
 - Return the fish to the cooker for further cooking and then resampling.

SMART Board

Sampling › Summary

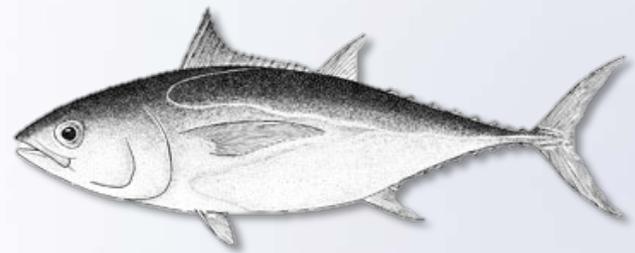
- This control strategy follows a variable acceptance sampling plan with 95% confidence and 99% reliability.
- The sample size is 36 fish from every precook batch.
- The distribution of temperatures from each batch is tested for normality using the Ryan-Joiner test.

Control Measures

The control measure in this control strategy is measuring fish core temperatures after precooking

CRITICAL LIMIT

“How much cooking is enough?”



Histamine-Forming Bacteria

- As stated above, histamine is a toxin produced by bacterial growth.
- A study by Vogl et al. validated that the growth of histamine-forming bacteria can be suppressed or paused sufficiently long enough to enable sufficient time for subsequent processing of the fish from precooking until retorting.
- Enache et al. developed thermal death time profiles for *Morganella morganii*, the most histaminogenic and heat resistant histamine-forming bacterium.

Enache, E., A. Kataoka, D. G. Black, M. Hayman, L. Weddig, and K. Bjornsdottir-Butler. 2013. "Heat resistance of histamine producing bacteria in irradiated tuna loins." Food Protection Journal 76:1608-1614

Vogl, F., R. Salazar, F. Nolte, G. Kontoh, and G. Ybanez, Validation of Pre-Cooking as a Control for Potential Histamine Production in Tuna Loins for Subsequent Canning. Paper presented at: TAFT 2012. Proceedings of the 4th Trans-Atlantic Fisheries Technology Conference; Oct 30-Nov 2, 2012; Clearwater Beach, Florida

EPIPT

- Based on these studies, Nolte et al. developed a technique validating that a 60°C End Point Internal Product Temperature (EPIPT) was sufficient to reduce the *M. morganii* population by 5 logs.
- With this technique, tuna processors are able to use precooking, with proper heating temperatures and times, as a critical control point to extend FDA's 12-hour time limit.

Nolte, Fred, D. Glenn Black, John DeBeer, Elena Enache. 2014. *'Use of end point internal product temperature to control histamine formation in tuna at pre-cooking step'*. Food Protection Trends. 03/2014. 34:94-100

Critical Limit

- The National Fisheries Institute's Tuna Council, "HACCP Guidance for Canned Tuna" followed suit by recommending a minimum 60° C pre-cooker exit fish core temperature to provide at least 12 hours from the end of pre-cooking to the start of retorting without histamine formation.
- In addition, the work of Kanki et al. (2007) indicated that the activity of the enzyme histidine decarboxylase is substantially reduced at 60° C.

National Fisheries Institute's Tuna Council. 2013. HACCP Guidance for Canned Tuna, 1st edition, pre-release. CCP3: Precooking. Pg. 6-30.

Masashi Kanki, Tomoko Yoda, Teizo Tsukamoto, and Eiichiroh Baba. 2012. Histidine Decarboxylases and Their Role in Accumulation of Histamine in Tuna and Dried Saury. Applied and Environmental Microbiology, Mar. 2007, Vol. 73, No. 5, 0099-2240/07

Lower Limit

- As previously stated, variable acceptance sampling is based on the statistical parameters of the temperature values measured...
 - The mean or average of the temperatures
 - The standard deviation of the temperatures
- The **lower limit** is defined as the mean minus 3 standard deviations:
$$\text{Calculated lower limit} = [\bar{X} - (3 \times \text{Std Dev})]$$
- If all core temperatures and the lower limit are $\geq 60^{\circ}\text{C}$, the batch is deemed to be acceptable.

Acceptance Value - Examples

- Example 1: The average of the temperature values is 70°C, with a standard deviation of $\pm 3.0^\circ\text{C}$
 - Lower limit = $70^\circ\text{C} - (3.0^\circ\text{C} \times 3) = 61^\circ\text{C}$
- Example 2: The average of the temperature values is 65°C, with a standard deviation of $\pm 2.5^\circ\text{C}$
 - Lower limit = $65^\circ\text{C} - (2.5^\circ\text{C} \times 3) = 57.5^\circ\text{C}$
- The batch in example 1 would be acceptable, while the batch in example 2 would require corrective action.

Rules for Acceptance Sampling at T-0

- Measure the core temperatures of all 36 fish in the sample...
 - If the core temperature of any sample is below 56°C , return the batch to the cooker for further cooking.
 - If all core temperatures are $\geq 56^{\circ}\text{C}$, but any are below 60°C , **WAIT 10 minutes** and re-measure.
 - If all core temperatures are $\geq 60^{\circ}\text{C}$...
- Calculate the lower limit...
 - If the calculated lower limit is below 60°C , **WAIT 10 minutes** and re-measure.
 - If the calculated lower limit is $\geq 60^{\circ}\text{C}$, **RELEASE** the batch for normal processing.

Acceptance Rules – Test 1 at T-0

Enter the data and click 'Time 0 – Calculation'... the worksheet automatically determines...

- Lowest actual core temperature = 63.0°C
- Mean = 68.0°C
- Std. deviation = $\pm 2.4^{\circ}\text{C}$
- Lower limit = 60.7°C

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

Time 0 Calculation Click

Results 1st Test		
Time 1	12:00	
N	36	
Mean	68.0	
StDev	2.4	
Lower Limit = Avg - (3*SD)	60.7	
Lowest ACTUAL core Temp	63	
R - Correl Coef	0.999	
Normal?	Yes, Normal, p>= .100	
RJ_Crit_.10 N=	36	0.975
RJ_Crit_.05 N=	36	0.969
Minimum Log Lethality	5.7	
Decision	RELEASE	

Disposition – Test 1

- In this case, all core temperatures and the Lower Limit were $\geq 60.0^{\circ}\text{C}$, so the worksheet determined that the disposition of the batch was **RELEASE**.
- What if the lower limit was below 60.0°C ?
- Let's look at another example...

Acceptance Rules – Test 2 at T-0

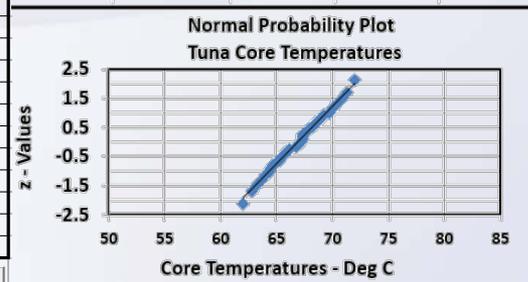
Enter the data and click 'Time 0 – Calculation'... this time the worksheet determines...

- Lowest actual core temperature = 62.0° C
- Mean = 67.0° C
- Std. deviation = ± 2.4° C
- Lower limit = 59.7° C

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

Time 0 Calculation Click

Results 1st Test		
Time 1	12:00	
N	36	
Mean	67.0	
StDev	2.4	
Lower Limit = Avg - (3*SD)	59.7	
Lowest ACTUAL core Temp	62.0	
R - Correl Coef	0.998	
Normal?	Yes, Normal, p>= .100	
RJ_Crit_.10 N=	36	0.975
RJ_Crit_.05 N=	36	0.969
Minimum Log Lethality	3.2	
Decision	WAIT	



Disposition – Test 2

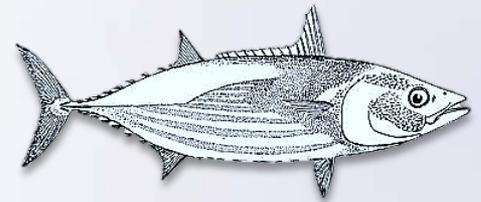
- Even though all the core temperatures measured were $\geq 60.0^{\circ}\text{C}$, the worksheet determined that the lower limit was 59.7°C , so the disposition of the batch was **WAIT**.
- In other words, **corrective action** must be taken before the batch may be released, but...
- ...this corrective action need not be returning the batch to the cooker, it can be simply to wait and re-measure the temperatures at a later time.

Critical Limit

The critical limit in this control strategy is all core temperatures and the calculated lower limit must be $\geq 60^{\circ}\text{C}$ after precooking

CORRECTIVE ACTION

“What if the batch fails?”



Proposed rules for Acceptance Sampling at T-10

- When the disposition is “Wait” at the first data collection time (T-0), wait ten (10) minutes. Measure the core temperatures of all 36 fish in the sample again...
 - If the core temperature of any sample is below 60°C, WAIT another 5 minutes.
 - If all core temperatures are $\geq 60^\circ\text{C}$...
- Calculate the lower limit...
 - If the calculated lower limit is below 60°C, WAIT another 5 minutes and re-measure.
 - If the calculated lower limit is $\geq 60^\circ\text{C}$, RELEASE the batch for normal processing.

Acceptance Rules at T-10

Enter the data. click 'Time – 10 minutes – Calculation'... this time the worksheet determines...

- Lowest actual core temperature = 65° C
- Mean = 70.0° C
- Std. deviation = ± 2.4° C
- Lower limit = 62.7° C

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

Time 0 Calculation Click

Time - 10 Minutes - Calculation Click

Results 1st Test	
Time 1	12:00
N	36
Mean	67.0
StDev	2.4
Lower Limit = Avg - (3*SD)	59.7
Lowest ACTUAL core Temp	62.0
R - Correl Coef	0.998
Normal?	Yes, Normal, p>= .100
RJ_Crit_.10 N=	36 0.975
RJ_Crit_.05 N=	36 0.969

Results 2nd Test	
Time 2	12:10
Elapsed Time (Min)	00:10
N	36
Mean	70.0
StDev	2.4
Lower Limit = Avg - (3*SD)	62.7
R - Correl Coef	0.998
Normal?	Yes, Normal, p>= .100
Decision Criteria	
1st Test Lower limit	59.7
2nd Test Lower Limit	62.7

Print Work Sheet

Clear Ranges

Minimum Log Lethality	3.2
Decision	WAIT

Minimum Log Lethality	>> 19
Decision	RELEASE



Disposition at T-10

- At T-10, the core temperature of all samples was $\geq 60.0^{\circ}\text{C}$, and the worksheet determined that the Lower Limit was 62.7°C , so the disposition of the batch was **RELEASE**.
- If the core temperature of any sample or the calculated lower limit had been below 60°C , the disposition would have been **WAIT**, and corrective action would have been required before the batch could be released.
- Once again, this corrective action could be to wait and re-measure the temperatures.

Rules for Acceptance Sampling at T-15

- When the disposition is “Wait” at the second data collection time (T-10), wait five (5) more minutes. Measure the core temperatures of all 36 fish in the sample again...
 - If the core temperature of any sample is below 60°C, return the batch to the cooker for further cooking.
 - If all core temperatures are $\geq 60^{\circ}\text{C}$...
- Calculate the lower limit...
 - If the calculated lower limit is below 60°C, return the batch to the cooker for further cooking.
 - If the calculated lower limit is $\geq 60^{\circ}\text{C}$, **RELEASE** the batch for normal processing.

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

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

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

Time 0 Calculation Click

Time - 10 Minutes - Calculation Click

Time - 15 Minutes - Calculation Click

Results 1st Test		
Time 1	12:00	
Elapsed Time (Min)		
N	36	
Mean	62.0	
StDev	2.4	
Lower Limit = Avg - (3*SD)	54.7	
Lowest ACTUAL core Temp	57.0	
R - Correl Coef	0.998	
Normal?	Yes, Normal, p>= .100	
RJ_Crit_.10 N=	36	0.975
RJ_Crit_.05 N=	36	0.969
Minimum Log Lethality	0.2	
Decision	WAIT	

Results 2nd Test		
Time 2	12:10	
Elapsed Time (Min)	00:10	
N	36	
Mean	65.0	
StDev	2.4	
Lower Limit = Avg - (3*SD)	57.7	
R - Correl Coef	0.998	
Normal?	Yes, Normal, p>= .100	
<i>Decision Criteria</i>		
1st Test Lower limit	54.7	
2nd Test Lower Limit	57.7	
Minimum Log Lethality	< 5	
Decision	WAIT	

Results 3rd Test		
Time 3	12:15	
Elapsed Time (Min)	00:15	
N	36	
Mean	68.0	
StDev	2.4	
Lower Limit = Avg - (3*SD)	60.7	
R - Correl Coef	0.998	
Normal?	Yes, Normal, p>= .100	
<i>Decision Criteria</i>		
1st Test Lower limit	54.7	
2nd Test Lower Limit	60.7	
Minimum Log Lethality	18.6	
Decision	RELEASE	

Print Work Sheet
Clear Ranges

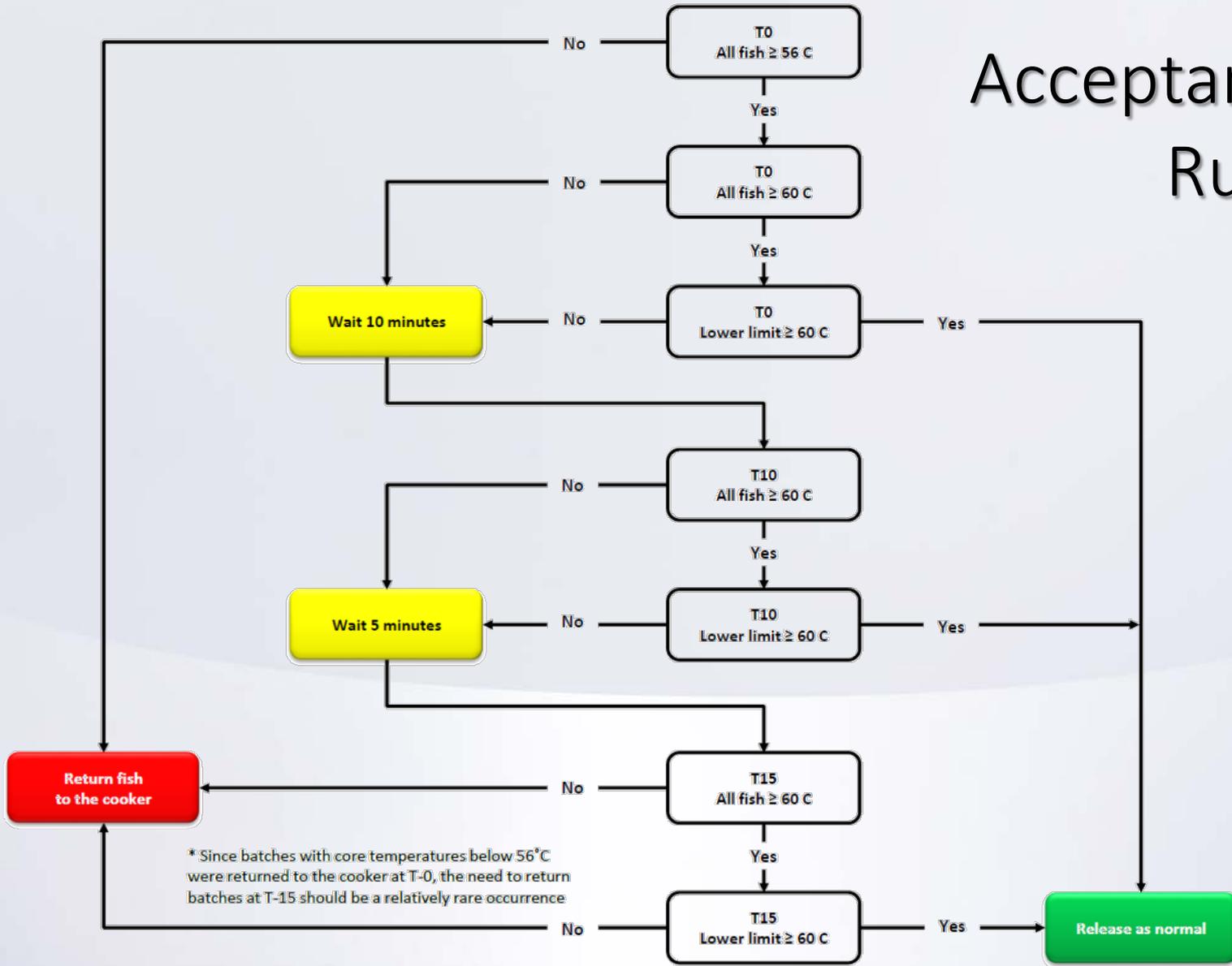
Print Work Sheet



Disposition at T-15

- At T-15, the core temperature of all samples was $\geq 60.0^{\circ}\text{C}$, and the worksheet determined that the Lower Limit was 60.7°C , so the disposition of the batch was **RELEASE**.
- If the core temperature of any sample or the calculated lower limit had been below 60°C , the disposition would have been to return the batch to the cooker for further cooking.
- However, because batches with core temperatures below 56°C were already returned to the cooker for further cooking at T-0, the need to return batches at T-15 should be a relatively rare occurrence.

Acceptance Rules



* Since batches with core temperatures below 56°C were returned to the cooker at T-0, the need to return batches at T-15 should be a relatively rare occurrence

Corrective Action

Corrective actions in this control strategy are...

- Wait until all core temperatures and the calculated lower limit are $\geq 60^{\circ}\text{C}$ after precooking, or...
- Return the batch to the cooker for further cooking

VERIFICATION

“Did the cook achieve what was intended?”



Thermal Death Times

- Nolte et al. developed a linear heating and cooling model was to determine a critical limit for precooking tuna, in order to achieve a 5-log reduction of the most prolific histamine-forming bacterium, *M. morgani*.
- The thermal death time values used in a General Method calculation employed the Trapezoidal rule, where $D_{60^{\circ}\text{C}}$ of 0.26m and $z = 4.1^{\circ}\text{C}$.

Nolte, Fred, D. Glenn Black, John DeBeer, Elena Enache. 2014. 'Use of end point internal product temperature to control histamine formation in tuna at pre-cooking step'. Food Protection Trends. 03/2014. 34:94-100

Measuring Heat Resistance

- Bacterial heat resistance is measured in D and z values and is specific to an organism
- The D value is the number of minutes at a specific temperature which reduces a population of a specific bacterial organism by 90%, or one log cycle
- The z-value is the number of degrees change which will result in a 10-fold difference in the D value
- Enache et al's results of the heat resistance studies of *M. morganii*...

$D_{60^{\circ}\text{C}}$ of *M. morganii* = 0.26 min

z value = 4.1°C

5-Log Reduction

- A 5 log reduction of *M. morgani* has been proposed as an effective control of histamine formation, similar to controls employed for control of Salmonella and in regulation for juices (21CFR120), F. Vogl studies.
- Multiple papers have studied initial populations of histamine-forming bacteria acceptable for tuna processing. The worst-case scenario was Garcia-Tapia (2013), who estimated the maximum number of histamine-forming bacteria at 10^4 CFU per gram.

Nolte, Fred, D. Glenn Black, John DeBeer, Elena Enache. 2014. 'Use of end point internal product temperature to control histamine formation in tuna at pre-cooking step'. Food Protection Trends. 03/2014. 34:94-100

García-Tapia, G., Barba-Quintero, G., Gallegos-Infante, J. A., Aguilar, R. P., Ruíz-Cortés, J. A., & Ramírez, J. A. (2013). Influence of physical damage and freezing on histamine concentration and microbiological quality of yellowfin tuna... Food Science and Technology (Campinas), 33(3), 463-467.

Author - year	Species	Max CFU/gm	Brief summary
198 – Taylor and Sprekles	Skipjack tuna (Katsuwonus pelamis)	Not measured	Only 3 out of 10 fish had any histamine forming bacteria on them
1994 - Lopez-Sabater	Bluefin (Thunnus thynnus)	1.1×10^3 CFU/gm,	Histamine-producing bacteria counts between 4 CFU/g and 1.1×10^3 CFU/g were only found in three samples from the last step of the canning process before heat sterilization. In fact, post-catching contamination has been considered Spain, fish from the Pacific Ocean
1996 - Lopez-Sabater	Bluefin (Thunnus thynnus)	1.1×10^1 CFU/gm	Tuna was gutted and chopped up. Very low numbers on HFB. Enterobacteriaceae counts < 10^3 CFU /gm Fish from Retail markets in Spain
2011 - Koohdar, et al	Skipjack tuna (Katsuwonus pelamis)	10^3 CFU/gm, Hi-Histamine 10^2 CFU/gm, low histamines	Oman Sea, Histamines near 200 ppm, but HFB at 10^3 /CFU/gm – The authors did not even use log numbers on the Y-axis for CFU/gm count. Histamines under 50 ppm, HFB at almost 10^2 levels.
2013 - Garcia-Tapia	Yellowfin (Thunnus albacares)	10^4 CFU/gm - adjusted	Mexico - Mesophilic HFB – 10^4 , Histamine @ 40 ppm HFB CFU/gm – 5×10^3 , (SD - 2.3×10^3)
2012 - Koohdar, et al	Longtail tuna (Thunnus tonggol)	3×10^3 CFU/gm, Table 2	Histamines over 50 ppm, but HFB at 10^3 /CFU/gm – The authors did not even use log numbers on the Y-axis for CFU/gm count. Histamines under 50 ppm, HFB at almost 200 CFU/gm levels.
2015 – Hongpattaraket et al.	Longtail tuna (Thunnus tonggol)	1×10^3 CFU/gm	Thailand – Fresh fish Max Initial viable count @ 10^3 CFU/gm Histamine max @ 11ppm

Chart – Summary of tuna histamine studies

Calculating Log Lethality of *M. morganii*

- At 2° C heating rate the formulas are...
 - Lethal Rate = $10^{((\text{deg C} - 60)/z)}$
 - Log Reduction = Lethal Rate ÷ D
 - Accumulated D = Σ Log Reductions

Min	Deg C	L Rate	Log	Σ Log
00:00	50	0.004	-	-
00:01	52	0.011	0.043	0.043
00:02	54	0.034	0.132	0.175
00:03	56	0.106	0.407	0.582
00:04	58	0.325	1.251	1.833
00:05	60	1.000	3.846	5.679
00:06	62	3.075	11.826	17.505

- At 60°C after 5 minutes the accumulated log-lethality is > 5.6

Calculating Log Lethality of *M. morganii*

Minutes	Deg C	L Rate	Log	Σ Log
00:00	< 50	0.000	0.000	-
00:01	< 50	0.000	0.000	-
00:02	< 50	0.000	0.000	-
00:03	< 50	0.000	0.000	-
00:04	< 50	0.000	0.000	-
00:05	50	0.004	0.014	0.014
00:06	52	0.011	0.043	0.057
00:07	54	0.034	0.132	0.189
00:08	56	0.106	0.407	0.596
00:09	58	0.325	1.251	1.847
00:10	60	1.000	3.846	5.693

- So, if the core temperature is 60°C at the time of 1st temperature measurement (T0), the accumulated log-lethality is already > 5.6

Calculating Log Lethality of *M. morganii*

T0	Min	Deg C	L Rate	Log	Σ Log
	00:00	50	0.004	0.014	-
	00:01	52	0.011	0.043	0.043
	00:02	54	0.034	0.132	0.175
	00:03	56	0.106	0.407	0.582
00:00	00:04	58	0.325	1.251	1.833
00:01	00:05	58	0.325	1.251	3.084
00:02	00:06	58	0.325	1.251	4.335
00:03	00:07	58	0.325	1.251	5.586

- If the core temperature is 58°C at the time of 1st temperature measurement (T0), and remains at 58°C, after 3 more minutes the accumulated log-lethality is > 5.5

Calculating Log Lethality of *M. morganii*

If the core temperature is 56°C at the time of 1st temperature measurement (T0), and remains at 56°C, after 12 more minutes the accumulated log-lethality is > 5.4

Log lethality holding the fish at a fixed core temperature, after a 2°C heating rate, is summarized in the following table

T0	Min	Deg C	L Rate	Log	Σ Log
	00:00	50	0.004	0.014	-
	00:01	52	0.011	0.043	0.043
	00:02	54	0.034	0.132	0.175
00:00	00:03	56	0.106	0.407	0.582
00:01	00:04	56	0.106	0.407	0.989
00:02	00:05	56	0.106	0.407	1.396
00:03	00:06	56	0.106	0.407	1.803
00:04	00:07	56	0.106	0.407	2.210
00:05	00:08	56	0.106	0.407	2.616
00:06	00:09	56	0.106	0.407	3.023
00:07	00:10	56	0.106	0.407	3.430
00:08	00:11	56	0.106	0.407	3.837
00:09	00:12	56	0.106	0.407	4.244
00:10	00:13	56	0.106	0.407	4.651
00:11	00:14	56	0.106	0.407	5.057
00:12	00:15	56	0.106	0.407	5.464

Times and temperatures required to achieve a 5-log reduction in *M. organii*

Log lethality after holding the fish at a fixed core temperature Degrees C - Fixed after a 2°C/Min Heating Rate								
Min	62°C	61°C	60°C	59°C	58°C	57°C	56°C	55°C
0	17.5	9.9	5.7	3.2	1.8	1.0	0.6	0.3
1	29.3	16.7	9.5	5.4	3.1	1.7	1.0	0.5
2	41.1	23.4	13.3	7.6	4.3	2.4	1.4	0.8
3	52.9	30.2	17.2	9.8	5.6	3.1	1.8	1.0
4	64.8	36.9	21.0	12.0	6.8	3.9	2.2	1.2
5	76.6	43.6	24.9	14.2	8.1	4.6	2.6	1.5
6	88.4	50.4	28.7	16.3	9.3	5.3	3.0	1.7
7	100.2	57.1	32.5	18.5	10.6	6.0	3.4	1.9
8	112.0	63.9	36.4	20.7	11.8	6.7	3.8	2.1
9	123.9	70.6	40.2	22.9	13.1	7.4	4.2	2.4
10	135.7	77.3	44.1	25.1	14.3	8.1	4.6	2.6
11	147.5	84.1	47.9	27.3	15.6	8.8	5.0	2.8
12	159.3	90.8	51.7	29.5	16.8	9.5	5.4	3.1
13	171.1	97.6	55.6	31.7	18.1	10.2	5.8	3.3
14	183.0	104.3	59.4	33.9	19.3	11.0	6.2	3.5
15	194.8	111.0	63.3	36.1	20.6	11.7	6.6	3.8

Times and temperatures required to achieve a 5-log reduction in *M. morganii*

- What happens if core temperatures increase during the time from initial measurement to re-measurement?

Accumulated Log Reduction of <i>M. morganii</i>				
	Ending temp after 10 min - deg C			
Initial BB Temp	60	59	58	57
60	40.3			
59	32.5	24.1		
58	25.7	18.5	13.8	
57	20.9	14.6	10.6	7.8
56	17.5	11.9	8.4	6.0
55	15.0	10.0	6.8	
54	13.1	8.6	5.7	
53	11.7	7.5		
52	10.6	6.7		
51	9.7	6.0		
50	8.9	5.5		

Accumulated Log Reduction of <i>M. morganii</i>					
	Ending temp after 15 min - deg C				
Initial BB Temp	60	59	58	57	56
60	59.5				
59	47.2	35.1			
58	37.2	26.9	20.0		
57	30.2	21.2	15.3	11.4	
56	25.1	17.2	12.1	8.7	6.5
55	21.4	14.3	9.8	6.9	
54	18.6	12.2	8.2	5.6	
53	16.4	10.6	7.0		
52	14.7	9.4	6.0		
51	13.4	8.4	5.3		
50	12.3	7.6			

Verification

Calculating log lethality from time/temperature data collected from every cook provides verification that a 5-log reduction of the histamine-forming bacterium *Morganella morganii* has been achieved

RECORD KEEPING

“How will you document what has happened?”



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

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

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

Time 0 Calculation Click

Time - 10 Minutes - Calculation Click

Time - 15 Minutes - Calculation Click

Results 1st Test		
Time 1	12:00	
Elapsed Time (Min)		
N	36	
Mean	62.0	
StDev	2.4	
Lower Limit = Avg - (3*SD)	54.7	
Lowest ACTUAL core Temp	57.0	
R - Correl Coef	0.998	
Normal?	Yes, Normal, p>= .100	
RJ_Crit_.10 N=	36	0.975
RJ_Crit_.05 N=	36	0.969
Minimum Log Lethality	0.2	
Decision	WAIT	

Results 2nd Test		
Time 2	12:10	
Elapsed Time (Min)	00:10	
N	36	
Mean	65.0	
StDev	2.4	
Lower Limit = Avg - (3*SD)	57.7	
R - Correl Coef	0.998	
Normal?	Yes, Normal, p>= .100	
Decision Criteria		
1st Test Lower limit	54.7	
2nd Test Lower Limit	57.7	
Minimum Log Lethality	< 5	
Decision	WAIT	

Results 3rd Test		
Time 3	12:15	
Elapsed Time (Min)	00:15	
N	36	
Mean	68.0	
StDev	2.4	
Lower Limit = Avg - (3*SD)	60.7	
R - Correl Coef	0.998	
Normal?	Yes, Normal, p>= .100	
Decision Criteria		
1st Test Lower limit	54.7	
2nd Test Lower Limit	60.7	
Minimum Log Lethality	18.6	
Decision	RELEASE	

Print Work Sheet
Clear Ranges

Print Work Sheet



Record Keeping

The fish temperature data collection and calculation work sheet satisfies record keeping requirements of the HACCP program

Note: Records should include all pertinent lot and batch information and should be signed by the operator

HACCP › SUMMARY

“How does this all fit together?”



HACCP Summary

- All of the above can be summarized in a conventional HACCP table in US FDA format...
- For an example, see Table 7-4 “Control Strategy Example 2 – Histamine Testing”, Chapter 7, Page 136, of the US FDA 'Fish and Fishery Products Hazards and Controls Guidance, 4th edition.

Control Strategy at Precooking

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	HAZARD	CRITICAL LIMIT	MONITORING				CORRECTIVE ACTIONS	RECORDS	VERIFICATION
			WHAT?	HOW?	FREQUENCY?	WHO?			
Precooking	Histamine (scombrototoxin) formation	All core temperatures and the calculated lower limit $\geq 60^{\circ}\text{C}$ after precooking	Fish core temperatures after precooking	<p>Insert thermometers as the fish exit the cooker. Read and record core temperatures.</p> <p>Test the sample distribution for normality with the Ryan-Joiner (R-J) test</p>	<p>36 fish from every batch</p> <p>Each set of temperature measurements from every batch</p>	<p>Trained Precook personnel</p> <p>Trained Precook personnel</p>	<p>At T0...</p> <ul style="list-style-type: none"> - If the core temperature of any sample is below 56°C, return the batch to the cooker for further cooking. - If all core temperatures are $\geq 56^{\circ}\text{C}$, but any are below 60°C, WAIT 10 minutes and re-measure. - If all core temperatures are $\geq 60^{\circ}\text{C}$ but the calculated lower limit is below 60°C, WAIT 10 minutes and re-measure. <p>At T10...</p> <ul style="list-style-type: none"> - If the core temperature of any sample is below 60°C, WAIT 5 minutes and re-measure. - If all core temperatures are $\geq 60^{\circ}\text{C}$ but the calculated lower limit is below 60°C, WAIT 5 minutes and re-measure. <p>At T15...</p> <ul style="list-style-type: none"> - If the core temperature of any sample is below 60°C, return the batch for further cooking. - If all core temperatures are $\geq 60^{\circ}\text{C}$ but the calculated lower limit is below 60°C, return the batch for further cooking. 	<p>Data collection worksheet</p> <p>Training Record</p> <p>Thermometer Calibration record</p>	<p>Confirm calculated log lethality of <i>M. organii</i> ≥ 5.0 for every batch</p> <p>Review monitoring, corrective action, and verification records within one week of preparation</p> <p>Train pertinent Precook personnel at least annually</p> <p>Calibrate thermometers at least once per quarter.</p> <p>Check thermometers for damage before use and for accuracy by immersing in boiling water (100°C)</p>

EXECUTIVE SUMMARY

“Have you achieved what you intended?”



Prerequisites

Make sure all equipment is functioning as intended...

- ★ Calibrate temperature measuring equipment
- ★ Survey equipment at cooking & thawing
- ★ Conduct temperature-distribution testing of cooking & thawing equipment

Ensure consistent segregation of fish by size...

- ★ Develop size categories to match production activities
- ★ Sort fish sizes at receiving
- ★ Segregate fish by size in the cold store

Establish formal thawing & cooking schedules...

- ★ Conduct heat penetration testing at cooking and thawing for each size category of tuna
- ★ Develop formal thaw & cook schedules from heat penetration data
- ★ Before cooking: Verify critical factors (initial temperature and size) are within the parameters used to establish the cooking schedule

In-Process

Schedule fish for a smooth process flow...

- ★ Schedule fish by size through thawing and butchering to ensure a direct flow to cooking
- ★ Avoid unscheduled delays

Make sure measuring does not impact results...

- ★ After cooking: Collect temperature quickly and accurately and evaluate the data
- ★ Have enough thermometers on hand to do the job
- ★ Verify thermometer accuracy at least daily

Verify that you have achieved what you intended...

- ★ Evaluate temperature data to verify minimum 5-log lethality of *M. morganii* has been achieved

Keep records of your results...

- ★ Document lot identification details
- ★ Record processing data (times, temperatures, weights, etc.)

DISCUSSION

“What are some of the most common problems encountered?”

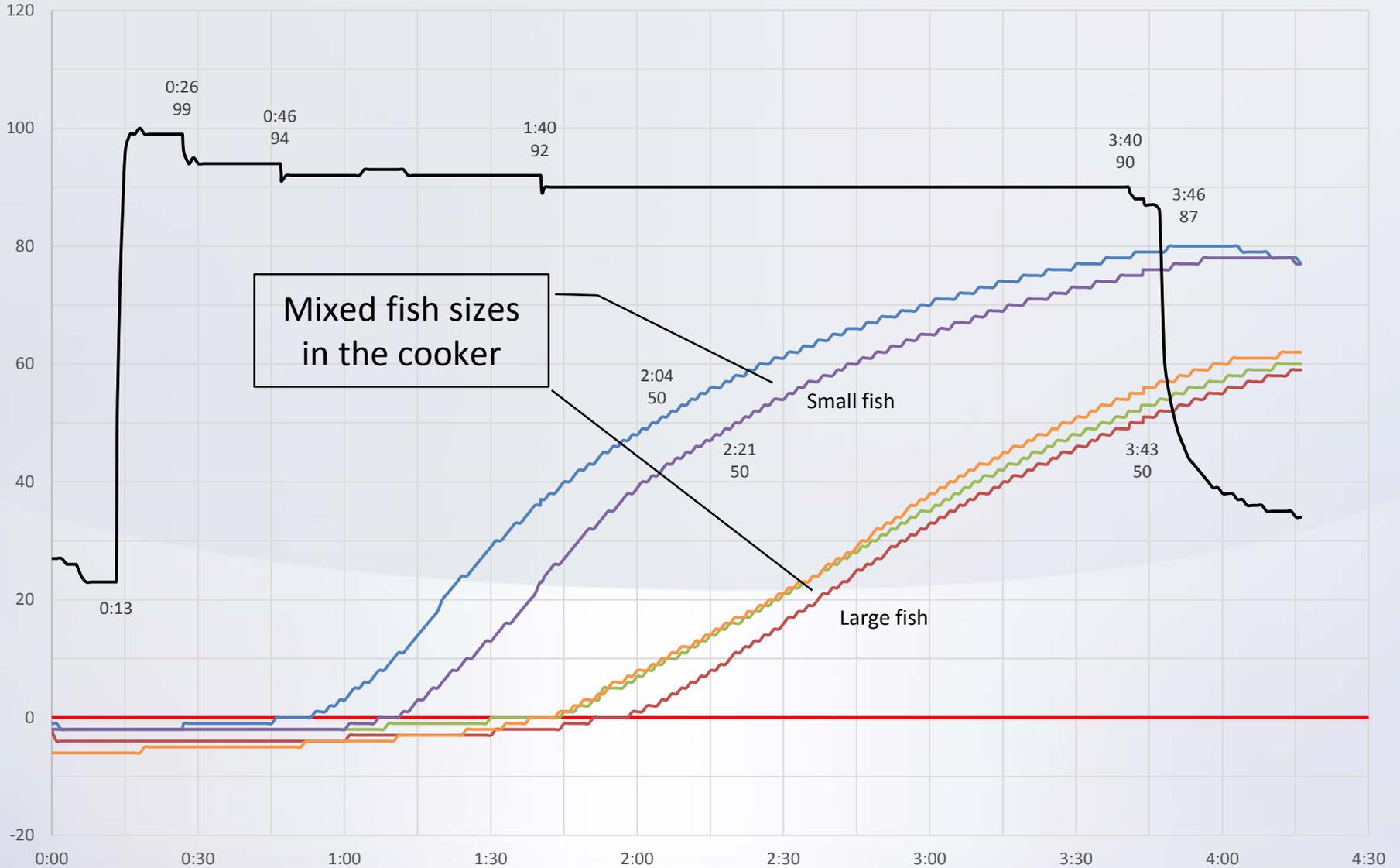
Temperature Variation

There are two common reasons why some fish may not reach the critical limit of 60° C, or for excessive variation of fish core temperatures after cooking...

- There are mixed fish sizes in the cooker. The temperature of small fish increases in temperature faster than large fish.
- There are fish still frozen at the core at the start of cooking. These fish 'lag' until the ice in the core has been melted, while other fish are increasing in temperature.
- Sizing and thawing are prerequisites (OPRP) to precooking. It is essential that they are controlled in order for the CCP (precooking) to be properly controlled.

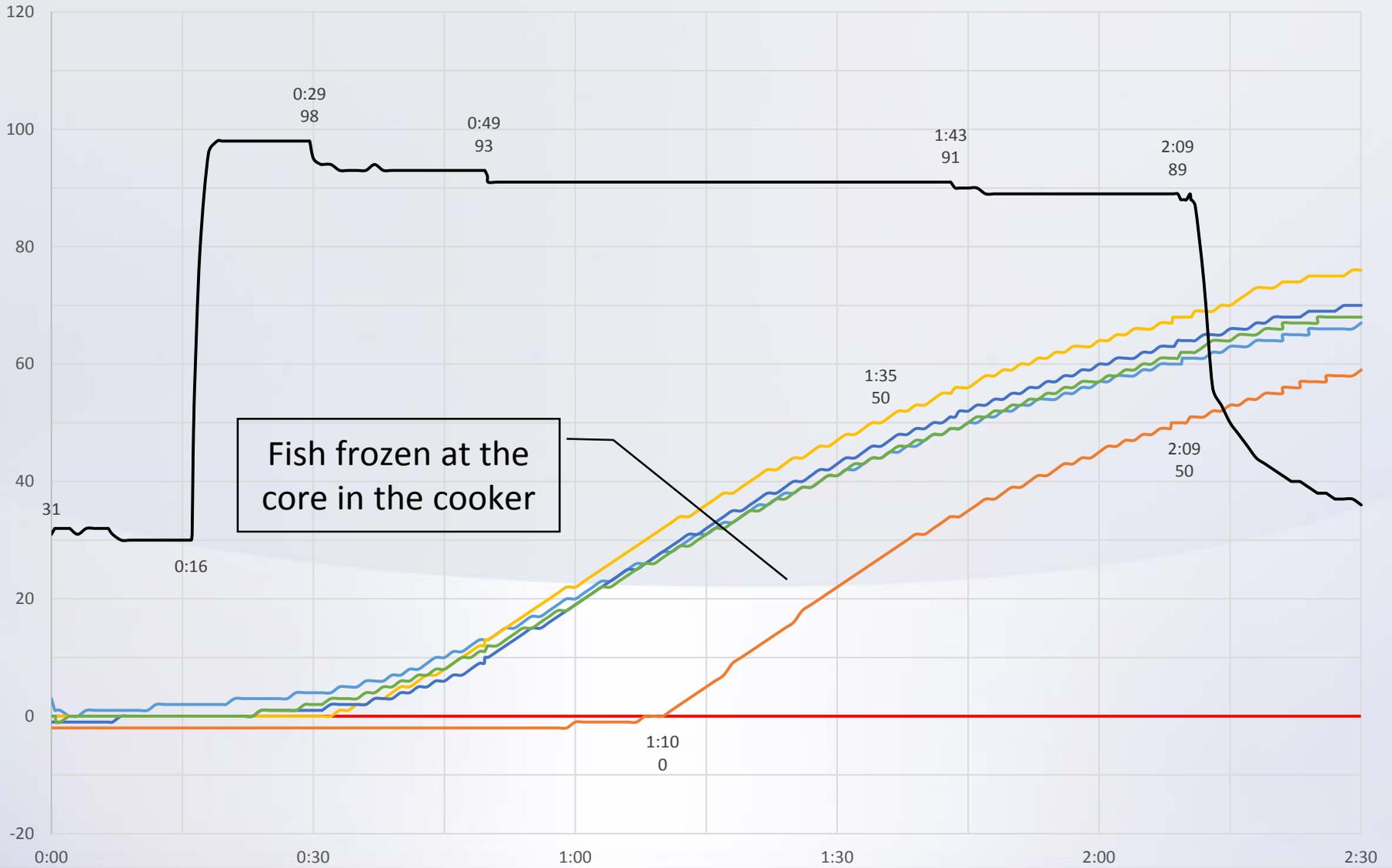
SJ

9 to 12 Lbs



SJ

9 to 12 Lbs



Fish frozen at the core in the cooker

OPRP: Sizing

- Observation:
 - Excessive core temperature variation after cooking
- Question:
 - Why is temperature variation excessive?
- Hypothesis:
 - There are mixed fish sizes in the cooker batch. It is required to wait until the last fish (probably the one of the largest fish) reaches 60° C to achieve the critical limit.
- Action:
 - Calibrate fish size classifications to match the number of fish per cooking tray
- Prediction:
 - This will eliminate mixed fish sizes at cooking, so there will be only one size of fish in each cooker batch. The result will be uniform cooking times with less temperature variation after cooking.

OPRP: Thawing

- Observation:
 - Excessive core temperature variation after cooking
- Question:
 - Why is temperature variation excessive?
- Hypothesis:
 - The design and application of thawing equipment is insufficient to achieve temperature uniformity (i.e., not enough water flow or agitation). As a result, there are still fish frozen at the core at the start of the cooking process. These fish 'lag' until all the ice has been melted, while other fish are increasing in temperature.
- Action:
 - Complete a comprehensive survey of thawing equipment—conduct temperature distribution testing to validate that it is functioning as intended.
- Prediction:
 - Making corrections to equipment design and thawing procedures will eliminate frozen fish before cooking. The result will be uniform cooking times with less temperature variation after cooking.

Temperature Variation

Sometimes the reasons why some fish may not reach the critical limit of 60° C, or why there is excessive variation of fish core temperatures after cooking, originate from the precooking step...

- The cooking schedule selected was inappropriate for the size and initial temperature of the fish in the batch.
- Procedures before cooking failed to identify the coldest and/or largest fish for monitoring during the cooking process (there were bigger colder/fish that were not selected).
- Temperature measuring after cooking was too slow. The fish are in the continued heating phase and core temperatures are rising. The temperature of the last fish may be as much as 10° to 15° C higher than the first fish measured and recorded. This is probably the most common reason for the standard deviation being too high.

CCP: Cooking

- Observation:
 - Core temperatures sometimes do not reach 60° C after cooking.
- Question:
 - Why do core temperatures sometimes not reach 60° C?
- Hypothesis:
 - The cooking schedule selected was inappropriate for the size and initial temperature of the fish in the batch.
- Action:
 - Conduct formal heat penetration testing to develop cooking schedules by fish size and initial temperature.
- Prediction:
 - Cooking schedules established by formal heat penetration testing will eliminate core temperatures not reaching 60° C after cooking.

CCP: Cooking

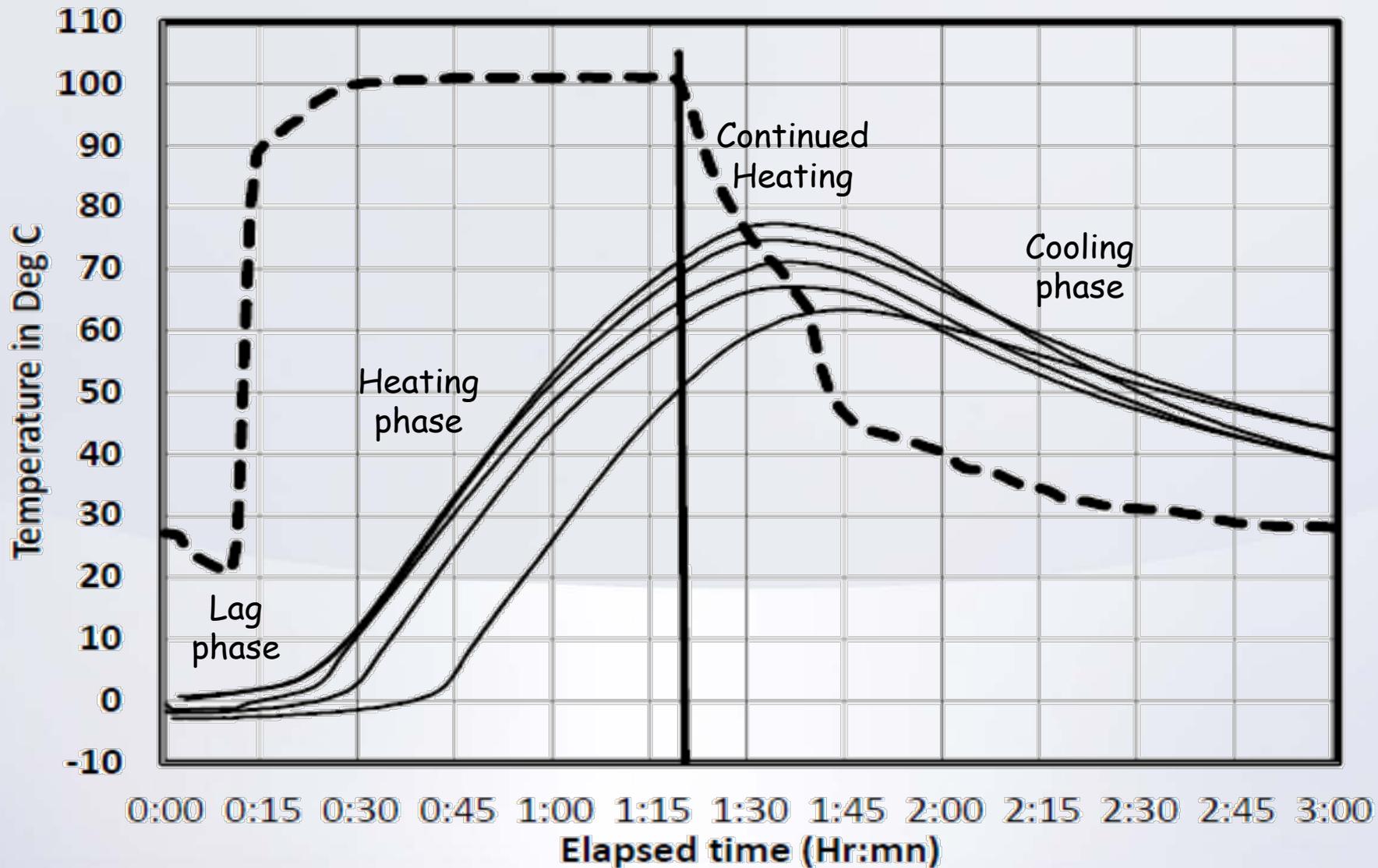
- Observation:
 - Core temperatures sometimes do not reach 60° C after cooking.
- Question:
 - Why do core temperatures sometimes not reach 60° C?
- Hypothesis:
 - Procedures before cooking failed to identify the coldest and/or largest fish for monitoring during the cooking process (i.e., there were bigger colder/fish that were not selected).
- Action:
 - Apply the same variable acceptance plan before cooking (36 fish) for sampling weights and temperatures. Select the biggest coldest fish from the sample for monitoring.
- Prediction:
 - Identifying the coldest/largest fish for monitoring during cooking will ensure proper schedule selection and eliminate core temperatures after cooking that do not reach 60° C.

CCP: Cooking

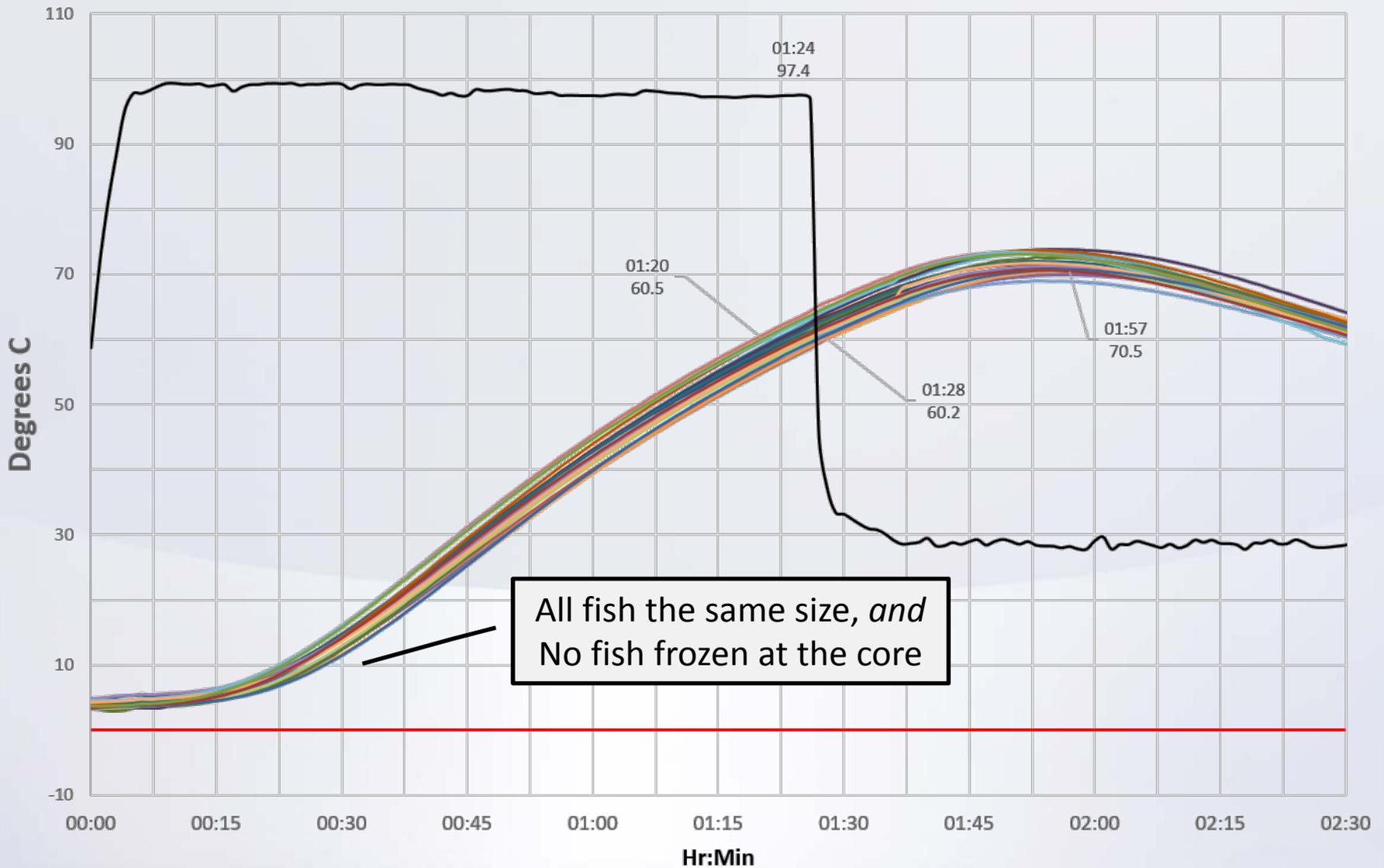
- Observation:
 - Excessive variation in core temperatures after cooking, some batches do not achieve a lower limit of 60° C, even when all 36 samples are $\geq 60^{\circ}$ C.
- Question:
 - Why is core temperature variation after cooking excessive?
- Hypothesis:
 - Temperature measuring after cooking takes too long, this contributes to excessive variation because the fish are in the continued heating phase and core temperatures are rising. This results in a falsely high standard deviation.
- Action:
 - Insert calibrated thermometers as the fish exit the cooker. Ten minutes later, read and record all temperatures as quickly as possible.
- Prediction:
 - Measuring temperatures after cooking in this manner will reduce variation, hence a lower standard deviation, so batches achieve the lower limit of 60° C.

Precooking

- Normal cooking curves follow a typical pattern...
 - Lag
 - Heating
 - Continued heating after 'steam off'
 - Cooling



SJ 2.5-3.5 kg



*“A Strategy for Controlling Histamine
Formation at Tuna Precooking”*

Thank you

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