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### General

#### Scope - FDA Seafood HACCP Guide

Provides FDA's most current thinking on the topics to help processors compile with controls for seafood safety

- Assists processors in the development of a HACCP Plan
- Assists regulators in evaluating HACCP Plans
- Provides consistency
- Alternative procedures that are science based and can show they provide an equivalent level of control

The new 4<sup>th</sup> edition is issued with expectation that it can be maintained in a more current manner with progressive additions as necessary

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### General

#### Format and Organization

- Control strategies consolidated
  - Critical Limits
  - Monitoring
  - Corrective Action
  - Verification
  - Record Keeping
- Completing a HACCP Plan
  - outlined in Chapter 2

Control Strategy Examples

Hazard	Control Strategy
Microbial	Critical Limits, Monitoring, Corrective Action, Verification, Record Keeping
Chemical	Critical Limits, Monitoring, Corrective Action, Verification, Record Keeping
Physical	Critical Limits, Monitoring, Corrective Action, Verification, Record Keeping
Biological	Critical Limits, Monitoring, Corrective Action, Verification, Record Keeping

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**General Changes & Clarifications**

Critical Limits – During transit

- Time/Temperature controls during transit
  - Transportation records showing product was held at 40°F or less during transit
- On ice
- Adequate quantity of frozen cooling media
  - IT of fish
- Transit time of 4 hours or less
  - Document of transit time
  - IT of fish



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**General Changes & Clarifications**

Critical Limits - during refrigerated storage

- Time/temperature controls during storage
  - The product was held at 40°F or less during storage
- On ice
- Recommendation on avoiding minor temperature fluctuations – submerging sensor in liquid
- Cumulative time/temperature CL's not recommended for storage



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**General Changes & Clarifications**

Monitoring procedures – during refrigerated storage

- High temperature alarms no longer recommended
- Adequacy of ice checks – sufficient frequency to ensure CL is met



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### General Changes & Clarifications

- Verification procedures
  - Updated information on accuracy and calibration requirements
  - Updated information on frequency of checks



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### Accuracy Checks

#### Accuracy checks

- Done at one temperature point
  - Example: Immersing in ice slurry
- Frequency:
  - before use
  - daily at beginning of operations or as recommended by manufacturer
  - Check to ensure it is operational
    - Example: Visual exam of sensor and wires for damage or kinks and if applicable sufficient paper and ink



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### Calibration

#### Calibration

- Done at two temperature points that reflect the temperatures that the device is being used at.
- Calibrate to NIST traceable thermometer
- Frequency: At least once a year or more often if recommended by manufacturer



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### Chapter 3. Species and Process Related Hazards

Tables listing potential hazards for various seafood species and processes have all been updated with numerous changes and additions

- Table 3-2. Potential Vertebrate Species-Related Hazards
- Table 3-3. Potential Invertebrate Species-Related Hazards
- Table 3-4. Potential Process-Related Hazards

**TABLE 3-3**  
**POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS**

Note: The hazard level is based on the hazard level of a potential species-related hazard if the hazard is from marine origin. The hazard level is based on the hazard level of a potential species-related hazard if the hazard is from non-marine origin. See Chapter 4 for general information on hazard levels.

Hazard Category	Hazard Name	Hazard Level		Control Strategy	
		Marine	Non-Marine	Primary Processor	Secondary Processor
Parasites	Parasites	1	1	1	1
	Parasites (Freezing)	1	1	1	1
Shellfish	Shellfish	1	1	1	1
	Shellfish (Freezing)	1	1	1	1

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### Chapter 5. Parasites

One control strategy – freezing

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Freezing	✓	✓

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### Chapter 5. Parasites

Intended use:

- If the consumer intends to cook, then hazard is not significant even if the species table lists it as having a potential hazard
- If you are unsure of the products intended use, you should obtain documented assurance from the subsequent processor, restaurateur, or institutional user that the fish will be processed in a way that will kill the parasites

(addressed at bottom of Hazard Tables 3-2/page 61 and Chapter 5/page 93)

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**Chapter 7. Scombrototoxin (Histamine) Formation**

Some changes and clarifications for controlling histamine formation at:

- Harvest
- Primary and Secondary Processing
- Possible Histamine Analysis
- Transit
- Processing Steps
- Storage

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**Chapter 7. Scombrototoxin (Histamine) Formation**

Control Strategy	May apply to primary processor	May apply to secondary processor
Harvest Vessel Controls	✓	
Histamine testing	✓	
Processing Controls (time/temperature)	✓	✓
Storage Controls	✓	✓
Transit controls	✓	✓

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**Chapter 7. Scombrototoxin (Histamine) Formation**

Harvest Vessel Control

3 Components:

- Harvest Vessel Records
- Sensory Examination
- Internal Temperature Measurements

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### Component 1: Harvest Vessel Records

Information on record will depend on:

- method of capture
- harvest water and air temperature
- eviscerated vs. uneviscerated fish
- time to chilling after death
- chilling rates
- harvest vessel storage temperature



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### Recommended maximum time to get fish into chilling medium on board vessel:

When:		Maximum time to get fish into chilling medium (≤40°F; ice, RSW, brine) from the ...	
Water Temp (°F)	Air Temp (°F)	Estimated death time of fish...	Onboard landing is...
<b>For Uneviscerated Fish:</b>			
> 65	> 83	6 hrs	---
> 83	Any	6 hrs	---
> 65, but ≤ 65 *	≤ 83	9 hrs	---
≤ 65 *	> 83	---	6 hrs
≤ 65 *	≤ 83	---	9 hrs
<b>For Fish Eviscerated Onboard Before Chilling:</b>			
> 65	Any	12 hrs	---
≤ 65 *	Any	---	12 hrs

\* Provided exposure in 65°F water or less is ≤ 24 hours



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### Component 2: Sensory Examination

- Sensory exam of representative sample shows less than 2.5% decomposition
  - Example: 118 fish no more than 2 (not 3)
  - Must be same specie caught in similar manner
  - Reminder: Decomposed fish are deemed adulterated
- If suspect high variability in a fish lot, increase number of fish for sensory exam
- Verification: Requires sensory training with periodic refresher training



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**Component 3: Internal Temperature**

- IT for iced or refrigerated fish only – not frozen
  - Time/temperature recommendations to indicate that since harvest, fish has been chilled and temperature of fish continues to go down
- IT checks must be done on largest fish and concentrated on fish that may appear to be mishandled
  - Example: inadequately iced



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**Chapter 7. Scombrototoxin (Histamine) Formation**

**Histamine Testing Control**

- Recommended control strategy if the primary processor is not familiar with the operator of the harvest vessel

3 Components:

- Histamine Testing – refer to guide on “how to”
- Sensory Examination
- Internal Temperature Measurements



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**Transit, Processing, Storage controls**

Transit Controls


- Must document transport time and temperature showing that fish was not temperature abused during transit

Processing Controls

- Critical limits based on time/temperature and whether or not the fish was previously frozen
- Tuna salad made from canned tuna can still develop histamine as a result of recontamination and addition of other raw ingredients

Storage Controls

- Storage at 40°F or less or on ice
- Same recommendations to control minor temperature fluctuations and time/temp critical limits



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### Chapter 12. Bacterial Growth & Toxin Formation

Transit Controls (example 1)

- Must document transport time and temperature showing that fish was not temperature abused during transit

Storage Controls (example 2)

- Storage at 40°F or less or on ice
- Same recommendations to control minor temperature fluctuations and time/temp critical limits

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### Cooling After Cooking Controls (example 3)

- This control strategy should be applied to a cooling step where there is **NO** significant handling **AND** there is a need to control **sporeforming pathogenic bacteria**
  - Sporeformers: *Bacillus cereus* or *Clostridium perfringens*
    - Note: . These pathogens are not likely to be found in seafood, but controls may be needed in some cases
  - Examples: Fresh soups
- Critical limit choices:
  - Product is cooled from 135°F to 70°F within 2 hours AND further cooled to 40°F within an additional 4 hours

**OR**

- The minimum or maximum values for the critical factors that affect the rate of cooling as established by a cooling rate validation study.

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### Unrefrigerated Processing of Raw Ready-to-Eat Seafood (example 4)

Maximum exposure time for RAW READY-TO-EAT seafood products during Processing Steps

Aids in planning processing schedules

Text page 234  
Table page 236

If the product internal temperature is:	Then the Cumulative Exposure Time at Internal Temperatures above 50°F but below 135°F is:					
	1 Hour	2 Hours	3 Hours	5 Hours	12 Hours	Total Hours
> 70°F		X		<i>If only for Staph. aureus</i>		2 Hours
If only 2 Hours > 70°F Plus 2 Hours < 70°F but > 50°F		X				4 Hours
> 50 but < 70°F				X	<i>If only for Staph. aureus</i>	5 Hours
If internal or ambient temperature is kept < 50°F but > 40°F then time is not part of the Critical Limit for Processing Steps only.						

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**Chapter 13. *C. botulinum* Toxin Formation**

Frozen with labeling (example 3)

- If freezing is the sole barrier to prevent toxin formation (i.e., ROP), the product must be properly labeled

*“ Important, keep frozen until used, thaw under refrigeration immediately before use”*



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**Chapter 16. Pathogenic Bacteria Survival through Cooking or Pasteurization**

- Cooking and pasteurization chapters (16 & 17 in 3<sup>rd</sup> edition) combined in this edition of the guide
  - Why: Thermal process control concepts are similar, target pathogens change based on product, packaging, storage and distribution
- Includes information on End Point Internal Product Temperature (EPIPT)
  - Requires: scientific study with heat distribution and heat penetration studies



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**Chapter 16. Pathogenic Bacteria Survival through Cooking or Pasteurization**

**Lethality for Dungeness Crabmeat**

3<sup>rd</sup> Edition  
Notes that greater lethality may be required for dungeness crabmeat due to naturally occurring substances like lysozyme enhancing *C. botulinum* recovery from heat damage.

4<sup>th</sup> Edition  
Recommends process for pasteurized dungeness crabmeat to provide a minimum cumulative lethality of at least 57 minutes at 194° F (F<sub>194F</sub> of 57.0 minutes)



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**Chapter 17: Pathogenic Bacterial Survival through Processes Designed to Maintain Raw Product Characteristics**

New Chapter

- Focuses on raw products such as raw molluscan shellfish (oysters)
- Targets *Vibrio parahaemolyticus* and *Vibrio vulnificus*
- Introduces new process technologies
  - High hydrostatic pressure
  - Individual quick frozen with extend frozen storage
  - Mild heat pasteurization and
  - Irradiation



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**Chapter 19 Undeclared Major Food Allergens and Certain Food Intolerances Causing Substances and Prohibited Food and Color Additives**

- Eight major allergens: milk, egg, wheat, soybeans, peanuts, tree nuts, finfish and crustacean shellfish
  - Must be declared either:
    - in ingredient statement
    - OR
    - or a separate “Contains” statement
  - Finfish, crustacean shellfish and tree nuts must be listed (i.e., “salmon”, “shrimp”, “coconut”)



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**Chapter 19 Undeclared Major Food Allergens and Certain Food Intolerances Causing Substances and Prohibited Food and Color Additives**

- Includes information on the Food Allergen Labeling and Consumer Protection Act (FALCPA)
- Fish is an allergen and “reasonably likely to occur”
- Recommended CCP at time of labeling rather than receipt of labels



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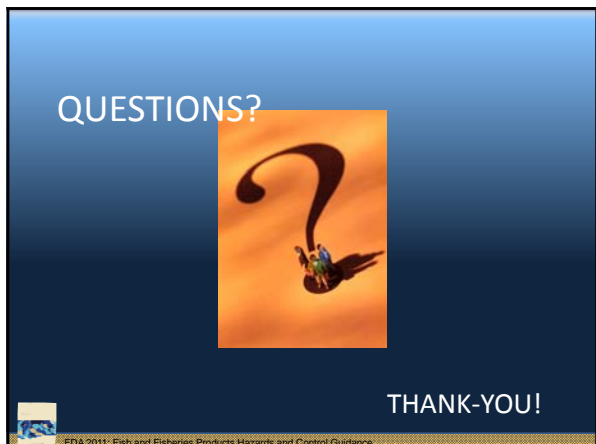
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