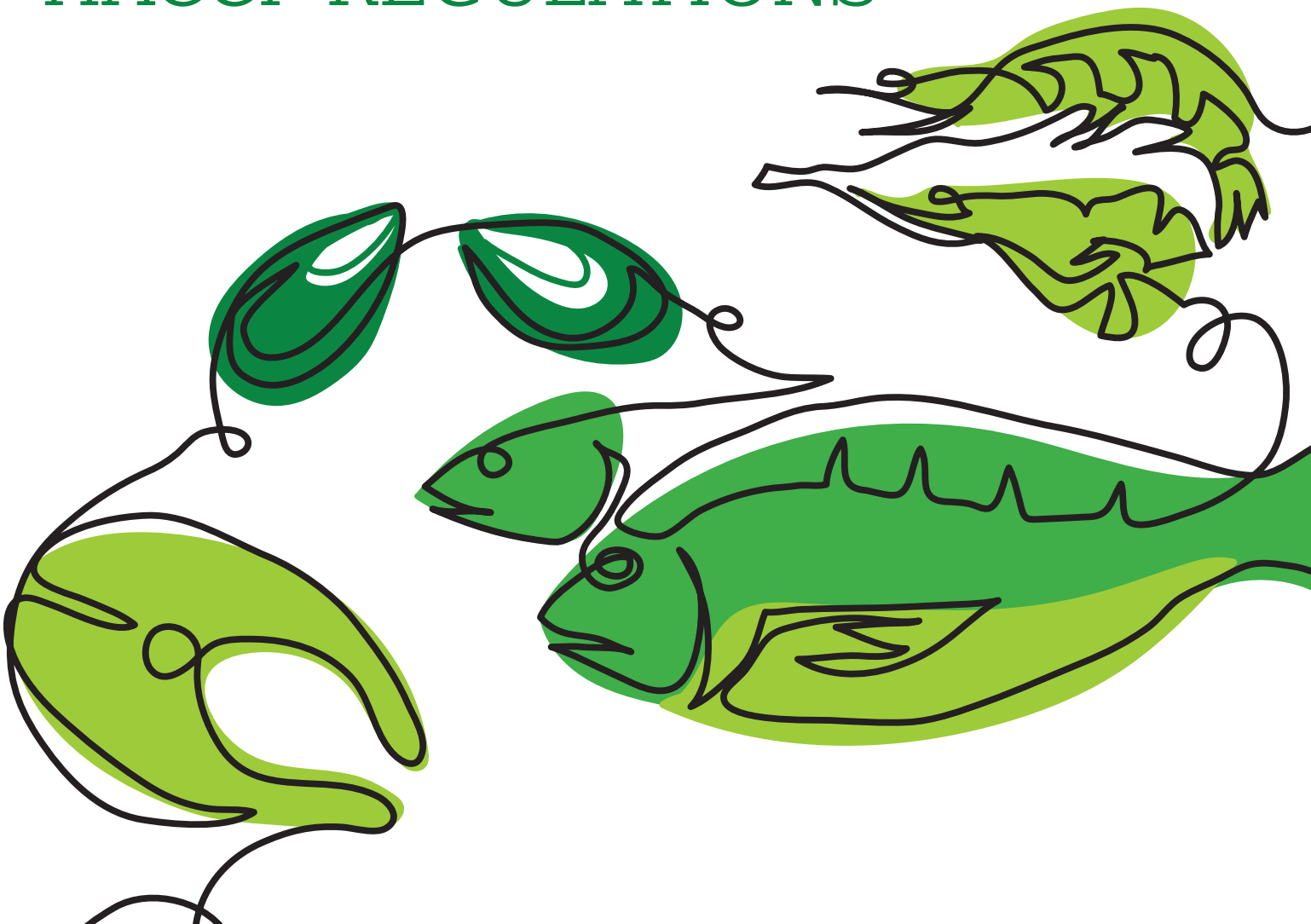
FMI THE FOOD INDUSTRY ASSOCIATION

RETAIL PRODUCT WAREHOUSING AND TRANSIT CONTROLS IN COMPLIANCE WITH CURRENT SEAFOOD HACCP REGULATIONS



Retail Product Warehousing and Transit Controls
in compliance with
Current Seafood HACCP Regulations

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Disclaimer: *This guidance is provided by the Food Marketing Institute as a service to its members and does not constitute legal advice. This document is designed to support retailer and wholesaler efforts to comply with the Seafood HACCP Regulations through clarification of existing recommendations or use of alternative approaches. As legal advice must be tailored to the specific circumstances of each case and laws and regulations are frequently changing, nothing provided herein should be used as a substitute for the advice of competent counsel.*

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Introduction and Overview

This information is provided as guidance to retail operations in assessing and adjusting their current seafood safety controls as mandated by the U.S. Food and Drug Administration (FDA) and the respective state-based authorities. This guidance is based on the most recent recommendations published by FDA in the fourth edition of the *Fish and Fishery Products Hazards and Controls Guidance* (FDA Guidance) issued in April 2011. FMI's guidance references existing FDA recommendations and recent interpretations based on FMI membership experience and training programs provided through the National Seafood HACCP Alliance (SHA). This document features issues that may still require further clarification from retailers and the respective authorities and will be updated as the issues are clarified. The intent is to assure consistent regulatory practices and commercial compliance for necessary and effective food safety controls.

Current Recommendations

This information is organized in alignment with the Hazard Analysis and Critical Control Point (HACCP) recommendations that represent FDA's current *thinking* as outlined in their 4th edition of the Fish and Fishery Products Hazards and Controls Guidance posted April 2011 http://www.fda.gov/food/foodsafety/hazardanalysiscriticalcontrolpointshaccp/seafoodhaccp/default.htm. FDA clearly state that their recommendations offer approaches that can satisfy the prevailing seafood HACCP requirements specified in federal statutes and regulations (*Seafood HACCP Regulation* -21CFR123). They also state **alternative approaches** are possible if they also satisfy the most current statutes and regulations. In some situations the interpretation of practices that satisfy FDA's expectations are not readily evident or obvious and may require clarification. FDA has provided the following contact information:

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Phone – (240) 402-2300

Retailer Requirements

According to FDA, most retail operations with central warehousing, (including supermarkets with central warehousing), are considered seafood 'processors' if they handle, store, package, label or hold fish [seafood] and fishery products. Since the company owned warehouse stores and handles fish and fishery products, and, as such, meet the definition of "processor" in 21 CFR 123.3. These procedures usually involve retail warehouse receiving, handling and storage of the seafood products. According to FDA mandates, all seafood processors participating in commerce for consumption in the USA must have and implement a written HACCP program. Retailers must also maintain an accompanying sanitation control records for the involved retail operations. FDA has not sought to redefine "retail" for purposes of this regulation, but rather has relied upon the historical definition provided in its retail food protection program therefore it does not apply to retail store operations.

In most situations (except those that by definition are a primary processor) the retail warehousing and storage facilities are considered **secondary processing** operations which receive their seafood from **primary processors** that are distinguished by initial procurement from producers (i.e., harvesters, fishing vessels or dockside unloading) and/or production facilities (i.e., fish farmers, aquaculture farms or a collection of farm raised products). This distinction is very important relative to the responsibility to prevent potential seafood borne hazards. Most prevention procedures or control steps occur during primary processing, but some are shared with or required by the secondary processor.

General Changes in the FDA Guidance

One of the more significant changes to the 4th edition of the FDA Guidance is how it is formatted. Instead of listing each control strategy followed by critical limits, monitoring, corrective actions and other interests, all elements of a control strategy are now consolidated, and in most cases an example of a HACCP plan follows each control strategy.
Whereas the previous guide outlines how to complete a HACCP plan in each chapter, the mechanics of completing a HACCP plan are now outlined only in Chapter 2.

There are some overarching changes in critical limits, monitoring and verification procedures. These changes are repeated in many chapters that include critical limits for product handling, distribution and storage, i.e., Chapter 7 - Histamine Formation, Chapter 12 – Pathogen growth, and Chapter 13 – *Clostridium botulinum* toxin formation. However the overall control strategies have not changed from the previous edition of the Guide, but they are arranged for more clarity and include some additional emphasis in details for monitoring, corrective actions, records and verifications. Based on your current HACCP Plan, some modifications may be needed.

Time /Temperature:

Where time and temperature controls are required during transit to control hazards such as histamine and pathogen growth/toxin formation, there is some additional information regarding critical limits at receipt such as (pages 220 – 223):

- All lots of fish are accompanied by transport records that show either the ambient or internal temperature of the fish during transit was at 40°F or below.
- If the transit time is 4 hours or less, the time of transit does not exceed 4 hours – including all time the fish is outside a controlled environment – and not on ice, and the internal temperature of the fish at receipt is at or below 40°F. It is also recommended that a secondary processor who is using only internal temperature of the fish because the transit time is less than 4 hours, that a temperature indicating device, or thermometer be used to take the internal temperatures of product from at least 12 containers and all containers if there are less than 12 in the lot received.
- If chemical cooling media, such as gel packs are used, there must be an adequate quantity of frozen cooling media to keep the internal temperature of the fish at 40°F or below. The internal temperature of the fish must also be taken at time of delivery. Monitoring the quantity and frozen status of the cooling media is recommended in a representative number of containers.

When time and temperature controls are required during refrigerated storage to control hazards such as histamine and pathogen growth/toxin formation it should be noted that:

- Cumulative time and temperature critical limits – for example not more than 50°F for more than 6 hours – during refrigerated storage, are not ordinarily suitable

because of the difficulty of determining when and for how long specific products were taken from and then returned to the cooler storage.

Monitoring Procedures:

- If minor fluctuations in cooler temperature measurements occur due opening and closing doors or defrost cycles, place the sensor of the temperature recording device in a liquid that mimics the characteristics of the products.

- High temperature alarms are no longer recommended for monitoring temperatures in coolers or processing areas because they do not produce a positive monitoring record. An observation denoted with an accompanying signature is a positive record.

- Last, when adequacy of ice is used as a critical limit for refrigerated storage, FDA previously recommended that monitoring be performed at least twice a day – the guide now recommends that monitoring be performed with sufficient frequency to ensure control.

The guide clarifies the difference between accuracy checks and calibration of monitoring devices, i.e., thermometers. These checks are recorded as verification procedures in the HACCP plan. Updated information on how to perform an accuracy check of a temperature recording device, frequency of checks, and frequency of calibration is now provided.

Accuracy:

Accuracy checks are typically done more frequently and against one standard point. For example, immersing a thermometer in an ice slurry and checking it for accuracy against an NIST thermometer in the same ice slurry. The guide now recommends verification frequencies for checking the accuracy of temperature indicating devices as follows:

- Check accuracy before the temperature device is put into service by immersing it in a ice slush, or boiling water or a combination of both or comparing it with the temperature reading on a known accurate device

- Check accuracy daily before beginning of operation. Less frequent checks can be made based on manufacturers recommendations of if the history of checks show that the device remains consistently accurate

- The guide also recommends checking temperature sensors and attached wires for damage or kinks, as well as the operational parts of the equipment such as paper, and ink where applicable.

Calibration:

For **calibration**, the frequency of verification is at least once a year, or more frequently if needed. For example, if accuracy checks show that there are consistent temperature variations away from the actual value, then calibration may need to be done more often.

- Calibration is performed at two temperatures that bracket the temperature range at which it is used. For example, calibrating a temperature sensor used in a smoking unit at a temperature above and below the critical limit temperature.
- Calibration is done using a known reference device (NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer.

Changes in the FDA Guidance by Chapter

Chapter 1: General Information

This is a general introductory section that list changes in the FDA Hazards Guidance since prior editions. Although this listing of changes can be a helpful reference, it is best to review each chapter for details because the rearrangement in the 4th edition of the FDA Hazard Guidance has added clarifications and more emphasis on certain issues and requirements that may not have been evident in prior editions.

Chapter 2: Conducting a Hazard Analysis and Developing a HACCP Plan

This chapter provides some directions for conducting the required hazard analysis and development of a HACP plan. This approach is covered with an enclosed model, "*Wholesale/Distribution/Warehouse Facilities*" prepared as part of the Seafood HACCP Alliance training program. Additional models are posted at the Florida Sea Grant website (http://www.flseagrant.org/component/content/article?catid=45:seafood-production-and-safety&id=279:seafood-haccp-alliance-publications)

Chapter 3: Potential Species-Related & Process-Related Hazards

Potential seafood safety hazards that are 'reasonably likely to occur' or should be considered for certain products or processes are outlined in three main tables;
The new Table 3-1 provides examples for how illegal product substitution or misbranding could lead to a potential food safety problem. For example, potential natural toxins could be involved if puffer fish were sold as monkfish.

The tables used in the 3rd edition of the Fish and Fishery Products Hazards and Controls Guidance for potential hazards associated with certain seafood species (Table 3-2 for fish and other vertebrates, and Table 3-3 the invertebrates that include shellfish and crustaceans), and the accompanying Table 3-4 for potential hazards during processing have been updated with additions and changes based on experience and developments through the past 10 years. Examples:

- Added more aquaculture species
- Changed some species per hazards and some hazards per species
- Distinguishes individual species of catfish rather than one market name for all catfish
- All crabs noted for potential environmental chemicals and pesticide hazards

Chapter 4: Pathogens from the Harvest Area

Strategies for the control of pathogens introduces and recognizes the use of validated post-harvest processing (PHP) methods to reduce or eliminate certain potential bacterial pathogens associated with the harvest of certain shellfish, primarily oysters destine for raw consumption. These processing methods can involve special procedures that have been officially validated for use of freezing, high pressures, partial heating and irradiation. The PHP recommendations are outlined in Chapter 17.

Microbial pathogens can be present in harvest waters for certain seafood products. Pathogens can be present and associated with the seafood due to natural occurrence or contamination of the harvest waters.

Chapter 5: Parasites

The recommended controls are similar to the original guidelines based on thorough cooking or prior freezing for a certain period of time at certain temperatures.
Application of these controls can occur during primary or secondary processing, or possibly during the final retail or restaurant operations depending on evidence that assures the controls are applied

Some additional parasites and seafood species with potential parasites have been included in Hazard Table 3-2

Likewise, the Guide includes specific language for processors trying to eliminate parasites as a significant hazard when they are unsure of the product's intended use. The Guidance indicates they should obtain documented assurances from the subsequent processor (retailer), restaurateur, or institutional user that the fish will be processed in a way that will kill the parasites (FDA Guidance page 93)

Chapter 6: Natural Toxins

Some new additions include: Molluscan shellfish exposed to natural marine algal toxins (phytoplankton; domestic & imported) Puffer fish (added PSP- paralytic shellfish poisoning,

along with T- tetrodotoxin) Ciguatera Fish Poisoning – new action levels and harvest areas of concern (page 101)
FDA advices against importation and interstate commerce for escolar and oilfish due to gempylotoxin (page 102). Although this advice is not an established limitation or restriction, it represents a significant deterrent to commerce of these fish

Chapter 7: Scombrotoxin (Histamine) Formation

- This chapter contains the first introduction of common temperature controls from harvest through processing, and during product transit and storage. The recommended critical controls points and temperature monitoring, plus the associated corrective actions, records and verifications that are introduced in Chapter 7 are repeated through many chapters addressing hazards that require temperature controls. However the overall control strategies have not changed from the previous edition of the Guide, but they are arranged for more clarity and include some additional emphasis in details for monitoring, corrective actions, records and verifications. Based on your current HACCP Plan, some modifications may be needed.

Harvest controls are best monitored at receiving by the primary processor. Depending on the processor's knowledge and confidence in harvesting practices, the receiving controls may involve histamine testing. Further time and temperature controls during processing, storage and transit can involve both the primary and secondary processors

The recommendations are similar as in prior editions of the Guide. To determine which option to use, processors should decide on a control strategy that relies on either:

1. **Using delivery truck refrigeration** to keep all products below 40°F during transit. With this option it is likely that a continuous time temperature record of either product or delivery truck temperature will be needed when the product is received.

2. **Using ice** to keep all products below 40°F during transit. Processors should determine if all products covered by the HACCP Plan can be completely surrounded with ice during delivery.

3. **Using gel packs** to keep all products below 40°F during transit. Note that gel packs may not be as efficient as ice and this critical limit option requires checking both the adequacy of gel packs similar to icing as well as checking for 'frozen' condition of the gel packs and product internal temperature.

4. **Transit time is 4 hours or less and delivered in refrigerated truck.** Describe that in this option time is the limiting factor but there must be positive documentation in a receiving record that shows that the delivery time is 4 hours or less. This option also requires a check of product internal temperature to verify that the product is 40°F or less at the time of receipt.

One significant change is the required transport control records and proof of transit times and internal temperature if transit time is less than 4 hours. The most important change in the latter is that somehow the processor will need to evaluate and cumulative exposures outside temperature control as part of the 4 hours – this could be difficult to document.
Processors receiving product with less than 4 hour transit times may want to use controls for longer transit times because this approach is easier for monitoring records.

The new Guide recommendations remain similar to past editions featuring monitoring to maintain a critical limit for product storage below 40F; **or,** use adequate icing (continuously surrounded by ice). Recommendations for monitoring emphasize:

- Use of continuous temperature recording devices and visual checks at least once per day, or
- When using ice, check and record results for a 'representative number of containers' per approximate number of containers in the cooler

When setting critical limits for refrigeration at 40F, the allowance for use of a thermometer or temperature sensor submerged in a liquid to better mimic the thermal characteristics of the stored food will help account for the routine fluctuations in storage room temperature during routine defrost cycles.

Recall from the general overview, all temperature and time recording devices should be verified for **accuracy** prior to use and once daily during use, plus **calibrated** annually or as needed.
This is the first time in the new Guide that the difference between verification through accuracy and calibration checks is mentioned. The critical limit chosen by the processor to ensure safety will only be as good as the monitoring devices – thermometers, pH meters, water activity meters etc. Safety control will only be as good as the monitoring.

Chapter 8: Other Decomposition Hazards

Changes are addressed in other chapters, primarily Chapter 7 and 9.

Chapter 9: Environmental Chemical Contaminants and Pesticides

Discusses the source controls at receiving raw molluscan shellfish (also see Chapter 4)

Chapter 10: Methylmercury

FDA Guide implies source controls

Chapter 11: Aquaculture Drugs

Only required if drugs are used during holding of live (submersed) products

Chapter 12: Pathogen Growth & Toxin Formation

Scientific Basis for Control Strategies (Appendix 4; page 421):

- For products that may not be cooked before they are eaten, pathogen growth must be prevented or minimized.
- These pathogens do not grow below 40°F
- Growth is very slow between 40°F and 50°F
- Growth is somewhat faster between 50°F and 70°F
- Growth is fast above 70°F
- Growth stops above 135°F and they are killed at higher temperatures

The new Guide has examples of four different control strategies for the general hazard of pathogen growth.

1. Transit temperature controls at a receiving CCP (doesn't apply to primary processors)
2. Temperature controls at refrigerated storage and refrigerated processing CCPs
3. Temperature controls at a cooling after cooking CCP
4. Time and temperature controls at unrefrigerated processing CCPs
5. The first two control strategies, **Transit and Storage** are similar as previously discussed during Chapter 7 for histamine controls

Chapter 13: Clostridium botulinum Toxin Formation

The new Guide recognizes the use of Time-Temperature Indicators or integrators (TTI's) for monitoring refrigerated seafood in reduced oxygen packaging (ROP), but the recommendations include specific details and encourage detailed integration of the TTI's within the HACCP plans.

The details regarding the possible use of TTI's are to assure proper monitoring of thermal consequences during handling, transport and storage of ROP seafood when refrigeration is the sole barrier to growth of non-proteolytic *C. botulinum.*

If freezing is the sole barrier to prevent toxin formation in a reduced oxygen package (ROP), the product must be properly labeled similar to *"Important, keep frozen until used, thaw under refrigeration immediately before use"* (FDA Guidance page 254).

Chapter 14: Control of pathogenic bacteria growth and toxin formation as a result of inadequate drying:

- It is no longer recommended that consideration be given to whether the finished product will be stored and distributed frozen (*in the case of reduced oxygen packaged products*) or refrigerated (*in the case of aerobically packaged products*) when determining whether the hazard is significant. A control strategy to ensure that

refrigerated dried products are properly labeled when refrigeration is the sole barrier to toxin formation is now provided. A finished refrigerated product label must contain a statement similar to “Important, keep refrigerated until used” (FDA Guidance page 306). A control strategy to ensure that frozen products are properly labeled when freezing is the sole barrier to toxin formation is now provided in Chapter 13.

Chapter 15: Staphylococcus aureus Toxins in Wet Batter Mixes

Not applicable to retail operations.

Chapter 16: Pathogenic Bacteria Survival in Cooking or Pasteurization

This chapter discusses the primary processor requirements and transit, storage and labeling controls which can involve temperature monitoring and labeling checks for the refrigerated ready-to-eat (RTE) products.

Chapter 17: Pathogenic Bactria Survival in Processes Used to Retain Raw Product Characteristics

This chapter discusses the primary processor requirements for processing certain seafood, particularly post-harvest processing (PHP) of raw oysters, and transit, storage and labeling controls which can involve temperature monitoring and labeling checks for the refrigerated ready-to-eat (RTE) products).

Chapter 18: Introduction of Pathogenic Bacteria after Pasteurization or Specialized Cooking

This chapter discusses the primary processors requirements for specialized cooking and vacuum packaging of hot-filled soups, chowders and sauces to be held in refrigeration, and transit, storage and labeling controls which can involve temperature monitoring and labeling checks for the refrigerated ready-to-eat (RTE) products).

Chapter 19: Food Allergens

This is not applicable to retail operations unless there are requirements to assure proper labeling for seafood product identity to accompany any retail repacked items or items removed from a labeled master packaging.

Chapter 20: Metal Inclusion

This is not applicable to retail operations.

Chapter 21: Glass Inclusion

This is not applicable to retail operations unless products are repackaged in glass containers at the retail operation.

IMPORTANT NOTICE: Additional HACCP controls may be necessary if the retail operations include actual processing steps that could introduce potential seafood hazards. The following procedures could be subject to HACCP controls based on pertinent state regulations or the current FDA Food Code guidelines (http://www.fda.gov/food/foodsafety/retailfoodprotection/foodcode/default.htm) as adopted by many state authorities.

- Freezing certain fish to kill potential parasites
- Involved butchering and packaging (prolonged temperature exposure) of scombroid fish species (potential histamine formation)
- Holding live seafood submersed in waters with drugs or other medicinal controls
- Special packaging of consumer units in reduced oxygen packs (ROP) or glass containers
- Special cooking or smoking processes for products to be repackaged and stored prior to consumer purchase
- Repackaging of products to assure any necessary labeling information accompanies the repacked consumer ready units (i.e., handling instructions, storage temperatures, raw shellfish consumption advisories, and product identity for potential allergens)

Developing a Retail HACCP Plan

The latest version of the Seafood HACCP Alliance's "Wholesale/Distribution/Warehouse" model will be formatted and explained as a guide to developing a current Retail HACCP plan.

(Document under separate cover)

SUMMARY

FDA requires processors of seafood intended for the U.S. market to identify potential hazards associated with the types of seafood they process and to develop and implement a HACCP program to control those hazards that are reasonably likely to occur. Retailers can use this guidance document to help identify the changes in the Fish and Fishery Products Hazard and Control Guidance; V4 in determining the likelihood that a food safety hazard may occur in their operation and to guide them in the preparation of appropriate HACCP plans.

After review of this document and your current HACCP plan, some updates or changes may need to be made.

The following questions are outstanding issues with FDA. Once they have been answered, this guidance document will be updated.

- When measuring the internal temperatures, what is meant by adequate and sufficient (both are vague)?
- When looking at transit temperature control, does transportation apply up to the DC or from the DC to a retail store? Based on our understanding of the previous HACCP guidance document at/to retail is not required but the 2011 HACCP guidance document is vague and open to interpretation which may be applied to receipt at retail.

APPENDIX A

Listing of common seafood safety hazards as outlined by chapters in FDA's 4th edition of the *Fish and Fishery Products Hazards Guidance* and the expected responsibility for HACCP processing controls.

FDA Guidance Chapters	Responsibility for HACCP Controls	
	Primary Processor	Secondary Processor
4. Pathogens from the Harvest Area (molluscan shellfish[1])	Source Controls at Receiving and Shellstock Temperature Controls	Source Controls at receiving raw molluscan shellfish
5. Parasites	If products intended to be eaten raw, must share knowledge for any necessary controls to kill certain parasites[2] in for certain species[2]	
6. Natural Toxins	Source Controls at receiving all seafood	Source Controls at receiving raw molluscan shellfish (Chapter 4)
7. Scombrotoxins (histamine formation due to prolonged temperature exposure)	Harvest Vessel ,Transit, Processing and Storage Controls; and Histamine Testing (depends)	Transit and Storage Controls (certain refrigerated fish)
8. Other Decomposition Hazards	Addressed in other chapters	
9. Environmental Chemical Contaminants and Pesticides	Source Controls for all seafood	Source Controls at receiving raw molluscan shellfish (see Chapter 4)
10. Methylmercury	FDA Guidance implies source controls	
11. Aquaculture Drugs	Source Controls and producer records	Only required if drugs used during holding of live (submersed) products
12. Pathogenic Bacteria Growth due to temperature abuse	Processing Temperature, Cooling and Refrigeration Controls	Transit and Storage Controls (refrigeration for RTE products[3])
13. *Clostridium botulinum* Toxin Formation	Process Method, Refrigeration and Labeling Controls	Transit, Storage and Labeling Controls (ROP[4] products)
14. Pathogenic Bacteria due to Inadequate Product Drying	Processing Method Controls	Transit, Storage and Labeling Controls (refrigerated and/or ROP[4])
15. *Staphylococcus aureus*	Processing Method Controls	

Toxins in Wet Batter Mixes		
16. Pathogenic Bactria Survival in Cooking or Pasteurization	Processing Method Controls	Transit, Storage and Labeling Controls (refrigerated RTE products)
17. Pathogenic Bactria Survival in Processes Used to Retain Raw Product Characteristics[5]	Processing Method Controls	Transit, Storage and Labeling Controls (refrigerated RTE products)
18. Introduction of Pathogenic Bacteria after Pasteurization or Specialized Cooking[6]	Processing Method Controls	Transit, Storage and Labeling Controls (refrigerated products)
19. Food Allergens	Share requirements for proper product labeling depending on packaged unit for sale	
20. Metal Inclusion	Process and Finished Product Controls	
21. Glass Inclusion	Process and Finished Product Controls	

[1]Molluscan shellfish include clams, oysters, mussels and scallops (if consuming the scallop viscera)
[2]Certain fish species may contain parasites that should be killed prior to raw consumption (see FDA Guidance Tables 3-2 and 3-3)
[3] RTE means ready-to-eat seafood products that are not cooked (raw or special processes) nor further cooked before consumption
[4] ROP means reduced oxygen packaging
[5]Post-Harvset Processing (PHP) methods for raw molluscan shellfish
[6]Specialized cooking can include vacuum packed hot-filled soups, chowders and sauces held in refrigeration

Overall, Appendix A can be reduced to a limited list of necessary HACCP controls for most retail operations:

- **Transit and Storage Controls** for product receiving and holding to assure proper temperature of refrigeration ready-to eat seafood, i.e.,
    - raw molluscan shellfish or special PHP molluscan shellfish
    - raw sushi items
    - pasteurized crab and other seafood
    - smoked fish and other smoked seafood items
    - products in reduced oxygen packaging

- **Labeling Controls** for certain products, i.e.,
    - receiving of raw molluscan shellfish
    - product identity for potential seafood allergens
    - storage and handling instructions for consumer ready units of refrigerated or frozen ROP seafood [ROP denotes seafood packaged in reduced oxygen packaging]