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**U. S. Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Seafood  
January, 1999**

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# **HACCP REGULATION FOR FISH AND FISHERY PRODUCTS**

## **QUESTIONS AND ANSWERS**

for guidance to facilitate the implementation of a HACCP system in seafood processing

Issue Three

January, 1999

### **PREFACE**

On December 18, 1995, The Food and Drug Administration (FDA) published as a final rule 21 CFR 123, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products" that requires processors of fish and fishery products to develop and implement Hazard Analysis Critical Control Point (HACCP) systems for their operations. The regulation became effective December 18, 1997.

The agency also published the "Fish and Fishery Products Hazards and Controls Guide" ("the Guide") in September, 1996, to assist processors in the development of their HACCP plans, and to provide information to help them identify hazards that may be associated with their products and formulate control strategies for those hazards. The guide was developed to coincide with the issuance of the final regulation.

A large number of questions have been raised by the seafood industry, regulators, consumers, and others about interpretation of the regulation. Recognizing this, FDA has developed "HACCP Regulation for Fish and Fishery Products: Questions and Answers" to provide answers to some of the more common questions. Future issues will be printed as other questions are received.

Seafood processors that are in the process of developing or revising HACCP systems to be in compliance with the new regulation, should first review the regulation to determine its requirements. Secondly, they should review the Guide for help to identify hazards and formulate control strategies. After reviewing the regulation and the Guide, if processors have remaining questions on the development of a HACCP system, they should refer to "HACCP Regulation for Fish and Fishery Products: Questions and Answers" for guidance. If processors still have further questions, they may contact:

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To the extent that it can, the office will provide responses to such inquiries.

"HACCP Regulation for Fish and Fishery Products: Questions and Answers" is intended only to be guidance to facilitate compliance with the new regulation. It does not bind the agency nor does it create or confer any rights, privileges, or benefits for or on any person. While "HACCP Regulation for Fish and Fishery Products: Questions and Answers" represents the best advice of the agency, it does not have the force and effect of law. The interpretations presented herein are obviously subject to the requirements of law both in the statute and in the regulations.

**This revision includes new questions and answers and changes to HACCP Regulations for Fish and Fishery Products: Questions and Answers - Issue 2. New material, including changes, is printed in bold text; unchanged material from Issue Two is in regular text. The following changes and additions are particularly noteworthy:**

### **Section III. Hazard Analysis**

- **Lobster unlikely to contain toxic quantities of PSP -Q. 7|**

### **Section IV. HACCP Plan**

- **Cook step ordinarily considered CCP for cooked-ready-to eat products, without a final heat treatment - Q. 13|**
- **Alternative time/temperature critical limits for histamine control during processing -Q. 15|**
- **Alternative sample sizes may be applicable for histamine analysis at receipt of scombroid species under specific circumstances -Q. 16|**

### **Section IX. Sanitation Control**

- **Sanitation monitoring not a substitute for HACCP controls for time/temperature abuse -Q. 5|**

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### **I. Definitions §123.3 (21 CFR)**

1. **Question:** If a firm owns a seafood product but is not involved in its processing, is the firm required to comply with the regulation?

**Answer:** No, but conversely the processor is required to comply with the regulation regardless of who owns the product.

2. **Question:** If a custom seafood processor, such as a contract manufacturer, processes fish owned by another entity is the custom processor required to comply with the regulation?

**Answer:** Yes, if the custom processor is performing activities defined in the regulation as "processing", the processor is required to have and implement a HACCP plan to control those hazards that are reasonably likely to occur in the product. The processor is required to comply with the regulation regardless of who owns the product.

3. **Question:** How does the Seafood HACCP Regulation affect food service distributors? How does the regulation affect food service providers, hospitals, restaurants, and supermarkets?

**Answer:** Food service distributors that store fish and fishery products meet the definition of "processing" contained in the regulation, and are, therefore, covered if they are engaged in interstate commerce. However, food service providers, including hospitals, restaurants, and supermarkets, are retail establishments, and are, therefore, exempt.

A food service distributor must perform a hazard analysis and develop and implement a HACCP plan if the analysis identifies a hazard that is reasonably likely to occur. If a distributor stores only frozen or canned fish and does not otherwise engage in processing, it is not likely that a HACCP plan would be required. In either case, the distributor would still be required to comply with the sanitation provisions of the regulations.

4. **Question:** Is a firm that manufactures tuna sandwiches from canned tuna and distributes (sells) the product to sandwich vendors covered by the Seafood HACCP Regulation?

**Answer:** Yes. The vendors themselves sell the product retail, and are, therefore, exempt. However, the manufacturer sells the product wholesale and is, therefore, covered. The manufacturer must also be engaged in interstate commerce in order to be covered by the regulation, but, with canned tuna, that is highly likely.

5. **Question:** Is a firm that distributes seafood sandwiches in its own vending machines subject to the regulation?

**Answer:** No, such a firm is a retail entity and is exempt from the regulation.

6. **Question:** If a firm sells their product intrastate to another processor, such as a warehouse which distributes interstate, is the original firm covered?

**Answer:** Yes, firms that sell their product intrastate to another processor with knowledge that the product will then be introduced into interstate commerce, or with good reason to believe that the product will be introduced into interstate commerce, are subject to the requirements of the seafood HACCP regulation.

However, a processor that distributes only to intrastate retailers or distributors with full expectation that the product will be ultimately distributed within that state, is not subject to the regulation. Situations such as these require careful consideration on a case-by-case basis.

7. **Question:** If a firm receives raw materials from outside the state and distributes the finished seafood product inside the state, is the firm subject to the HACCP regulation provisions for this product?

**Answer:** Yes, this scenario constitutes interstate commerce, and subjects the product to the provisions of the regulation.

8. **Question:** How is interstate commerce defined?

**Answer:** Interstate commerce is defined in the Food, Drug, and Cosmetic Act (FD&C) section 201(b) as "(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body". A product is in interstate commerce if a component originated from another state, territory, or country, or if the finished product itself moves to another state, territory, or country.

9. **Question:** Are domestic firms that produce seafood for export considered to be "processors" under §123?

**Answer:** Yes, exportation is a form of "interstate commerce", and therefore those who process (manufacture) seafood products for export meet the definition of "processor" and must comply with the seafood HACCP regulation. However, the Import/Export section (Section 801(e)(1)) of the Federal Food, Drug and Cosmetic Act (the Act) exempts export products, including food, from the adulteration provisions of the Act if they meet the following criteria:-

- (A) accords to specifications of the foreign purchaser
- (B) is not in conflict with the laws of the country to which it is intended for export,
- (C) is labeled on the outside of the shipping package that it is intended for export, and
- (D) is not sold or offered for sale in domestic commerce.

Thus, seafood products to be exported that meet these criteria would be exempt from the seafood HACCP regulation provisions.

10. **Question:** Is a firm that stores imported frozen fish and distributes it to local fast food restaurants subject to the Seafood HACCP Regulation?

**Answer:** Yes. Storage meets the definition of "processing" in the regulation. The fact that the firm handles imported product indicates that they are engaged in interstate commerce. If the firm is also the

importer of the product, as defined by the regulation, it would also be responsible for meeting the importer verification requirements of the regulation.

11. **Question:** Are public cold storage facilities exempt from the Seafood HACCP Regulation?

**Answer:** No, they are covered by the regulation. They are defined as "processors" for purposes of the regulation. See 21 CFR 123.3(l).

12. **Question:** Are cash and carry distributors covered by the Seafood HACCP Regulation?

**Answer:** Cash and carry distributors often sell both retail and wholesale. To the extent that they sell wholesale, they are covered by the regulation.

13. **Question:** Are central kitchens covered by the Seafood HACCP Regulation?

**Answer:** Central kitchens are processing centers that ship only to their own outlets, usually grocery stores or retail chains. They are considered a retail entity and are, therefore, exempt from the regulation even if they ship in interstate commerce, provided they ship only to their own retail outlets. However, if they ship to another company's outlet, they are considered processors, as defined by 21 CFR 123.3, and therefore subject to the regulation.

14. **Question:** Are central warehouses for grocery store chains required to comply with the Seafood HACCP Regulation?

**Answer:** Yes, central warehouses are subject to the seafood HACCP regulation. They store and handle fish and fishery products, and, as such, meet the definition of "processor" in 21 CFR 123.3. 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. The retail food program has not traditionally encompassed warehouses.

15. **Question:** Does the seafood HACCP regulation apply to food salvage firms that distribute reclaimed seafood to soup kitchens, shelters, and food banks?

**Answer:** Yes, a food salvage firm that stores, handles, repacks and relabels the product meets the definition of a "processor" in the seafood HACCP regulation. Such food salvage firms are not considered to be retail operations.

16. **Question:** Are airline caterers considered to be retail operations?

**Answers:** Yes, airline caterers are retail operations, under FDA's Interstate Travel Sanitation (I.T.S.) program, and therefore are exempt from the regulation.

17. **Question:** Since the regulation excludes retail, is a retail seafood market that processes some products (e.g. smoked fish) for the wholesale market covered?

**Answer:** Any products that are sold wholesale must be processed in accordance with the regulation, provided that the product is in interstate commerce. This is true even if the firm's primary business is retail.

18. **Question:** Must a retailer who imports products comply with the Seafood HACCP Regulation?

**Answer:** Retailers are exempt from processor provisions of the regulation. However, if a retailer is also an importer, as defined in the regulation, the retailer must perform the importer verification functions

described by the regulations. There is no retail exemption from the importer provisions of the regulations.

19. **Question:** Is the "Importer of Record" the same as the "importer", i.e., the individual responsible for verifying that a foreign processor has processed the seafood product in compliance with the seafood HACCP regulation?

**Answer:** No, the terms refer to separate responsibilities, under different regulations. The "Importer of Record" is a term used under U.S. Customs regulations to mean the holder of a redelivery bond at the time an entry is presented. For U.S. Customs purposes, someone (company or individual) is required to post a bond for a formal entry before the entry is allowed to move from Customs control. before the entry is allowed to move from Customs control.

Under the seafood HACCP regulation however, the "importer" is defined as either the U.S. owner or the U.S. consignee at the time of entry. If there is no U.S. consignee at the time of entry, then the "importer" is the U.S. agent of the foreign owner or consignee. The "importer" is responsible for ensuring that the goods are in compliance with the requirements of the seafood HACCP regulation.

Therefore, if an individual or company is solely acting in the capacity of the "importer of record" for Customs purposes, the requirements of the HACCP regulation would not necessarily apply to them. However, if the holder of the Custom's redelivery bond is also the "importer" as defined by the HACCP regulation, then both Customs and seafood HACCP requirements would apply to that person or company.

20. **Question:** Does the definition of "importer" apply to a warehouse that stores imported product and is not the "Importer of Record"? In this case both the owner and consignee are foreign. The product is stored in the warehouse under the foreign owner's account.

**Answer:** Yes, the regulation defines the "importer" as the U.S. owner at the time of entry. If there is no U.S. owner, which appears to be the case here, then the U.S. consignee is considered to be the "importer". However, if the consignee is a foreign firm, which also appears to be the case here, then the importer is the U.S. agent or representative of the foreign owner or consignee.

It is the responsibility of the foreign owner or consignee to designate a U.S. agent which may or may not be the warehouse. A U.S. agent is necessary to fulfill the importer requirements of the regulations before the product can be entered.

21. **Question:** Is an aquaculture producer a "processor" under the Seafood HACCP Regulation?

**Answer:** No, aquaculture producers are exempt from coverage. Treatment with carbon dioxide, bleeding, washing, and icing of otherwise unprocessed fish by the aquaculture producer is an integral part of the process of harvesting and getting the fish to market, and is, therefore, not considered to be processing. However, heading, gutting, or packaging of fish (e.g. retail or wholesale packages or cartons) performed by the aquaculture producer is considered processing, and would subject the producer to coverage under the regulations.

22. **Question:** Does holding lobsters in a lobster pound constitute "holding" as defined in the HACCP regulation?

**Answer:** Yes, the practice of holding live lobsters until they are marketed is a form of processing, as defined by the regulations. Consequently, lobster pounds are subject to the sanitation and HACCP requirements of the regulation. At a minimum, safety concerns to consider in the development of a HACCP plan for these operations include water quality and use of animal drugs.

23. **Question:** Which activities of a molluscan shellfish harvester are exempt from the requirements of the seafood HACCP regulation (21 CFR §123)?

**Answer:** A person is exempt from all provisions of 21 CFR, §123 if they engage in the activity of harvesting molluscan shellfish without otherwise processing the shellfish. The following harvesting activities are not considered to be "processing":

- temporarily holding shellstock in bulk, or in containers, in a part of the same natural shellfish growing waters where harvested, where such holding is an integral part of the operation of getting the harvested product to market
- placing shellstock in containers as they are harvested
- placing shellfish shipping tags on containers of shellstock
- sorting or washing shellstock in the harvest area
- transporting by the harvester of shellstock in a boat or truck to a processing facility

24. **Question:** Are molluscan shellfish wet storage facilities covered by the Seafood HACCP Regulation?

**Answer:** Yes, if the shellfish are harvested from the growing water and moved to another body of water (natural or artificial) in which they are then held awaiting marketing, the wet storage would be considered processing, as defined by the regulation, in that it constitutes "holding" or "storage." However, if, for example, aquacultured shellfish are harvested and then temporarily resuspended in a container in the same area during the remainder of the harvesting operation, the temporary storage would not be considered "holding," but rather a necessary part of the harvesting operation.

25. **Question:** Does the exemption for transportation include company trucks, contract haulers, drayage firms and **middlemen i.e., firms that buy products from various harvesters at the dock, load product directly into their trucks, ice the product, and transport the product to market?**

**Answer:** The Seafood HACCP Regulation specifically exempts common carriers from coverage. Furthermore, it is not FDA's intent to seek compliance with the regulation for any form of transportation, regardless of who is performing the transportation, who owns the product, or who owns the vehicle. Control of hazards that may be introduced during transport should be addressed through a receiving CCP by the firm receiving the product.

26. **Question:** Which activities of a harvest vessel are exempt from the regulation, under the definition of processing in 21 CFR 123.3(k), and which are not?

**Answer:** Specific examples of activities of fishing vessels that are exempt are:

- **A fishing vessel that simply catches the fish or that catches, heads, eviscerates, or freezes the fish onboard the vessel, and then delivers the product to market, whether retail or wholesale, is exempt from the regulation.**
- **A fishing vessel that catches the fish and then processes the fish in any manner (e.g., cuts steaks and/or fillets or cooks), and then sells the product at retail (i.e., to the consumer or end user) is exempt from the regulation.**

**However, the following activities are not exempt from the regulation:**

- **A fishing vessel that catches the fish and then processes the fish in a manner that is beyond the scope of "heading, eviscerating, or freezing intended solely to prepare –it| for holding on board –the| harvest vessel" (e.g., steaking, filleting, cooking) and then sells the product, or a portion of the product at wholesale (i.e., with the intent that it will be resold to the consumer or end user), is subject to the requirements of the regulation.**

**Such an entity meets neither the fishing vessel exemption nor the retail exemption.**

27. **Question:** Do vessels that process fish or fishery products on board (i.e. factory vessels) meet the definition of "processor" in the regulation?

**Answer:** Yes, a processing vessel meets the definition of "processor" in the regulation.

28. **Question:** Fish are frozen, bagged, and boxed on a harvest vessel, are sold upon docking, and are unloaded into the buyer's dockside storage. Is the vessel a "processor" and, therefore, covered by the regulations?

**Answer:** If the packaging is only what is minimally necessary in order to facilitate transport to the shore and subsequent unloading (e.g. totes or bulk bins), the operations onboard the harvest vessel would not subject it to the regulation. However, if the harvester places the product in packaging designed for marketing purposes (e.g. wholesale or retail packages or cases), then the operations onboard the vessel constitute "processing", and the vessel is covered by the seafood HACCP regulation.

29. **Question:** Since fishing vessels and carriers can have a marked influence on the safety of seafood products and yet are exempt from the Seafood HACCP Regulation, what can a processor do to minimize hazards that may be introduced at these points?

**Answer:** When a food safety hazard can be introduced or made worse by a harvester or carrier (e.g. histamine development in scombroid species of fish on the harvest vessel or pathogen growth in cooked, ready-to-eat fishery products during transportation) the processor should include controls in his HACCP plan that require, as a condition of receipt, demonstration that the hazard has been controlled by the harvester or carrier. For example, the processor may require documentation from the harvest vessel that shows that the scombroid species of fish were handled properly (e.g. cooling or icing log). Or, the processor may require documentation from the carrier that shows that the cooked, ready-to-eat fishery products were held at proper temperatures (e.g. temperature recorder chart). Such control options are covered in greater detail in FDA's "Fish and Fishery Products Hazards and Controls Guide."

30. **Question:** If scallopers treat scallops with sodium tripolyphosphate onboard the harvest vessels, are they still exempt from the regulation?

**Answer:** Yes. This is a customary practice associated with the onboard scallop eviscerating process, and is, therefore covered by the harvest vessel exemption of the regulation. It is similar in that respect to the onboard treatment of shrimp with sulfiting agents, which is also covered by the harvest vessel exemption.

31. **Question:** When does temporary storage by a fisherman become "processing" as defined in the HACCP regulation?

**Answer:** Holding or storage by a fisherman is not covered by the regulation when the temporary storage is a necessary component of harvesting and getting the product to market. However, such holding is covered if it is performed while a marketing decision is being made.

The following activities are temporary storage that are not covered by the regulation:

- A fisherman holds his catch in port until he can deliver it to market, or until it can be picked up for delivery to market.

The following activities constitute "holding" and are covered by the regulation:

- A crab fisherman unloads live crabs and stores them for several days until he has enough to sell.
- A crab fisherman stores his and others' crabs in his cooler, until they are picked up by a truck or sold elsewhere.
- A wholesale dealer buys crabs from fishermen and holds them for pick up by a common carrier.

32. **Question:** Are sea cucumbers considered "fish" under the Seafood HACCP Regulation?

**Answer:** Yes, sea cucumbers are included in the definition of "fish", 21 CFR part 123.3(d).

## **II. Current Good Manufacturing Practice §123.5 (21 CFR)**

1. **Question:** Does the Seafood HACCP Regulation replace the Current Good Manufacturing Practice Regulations (21 CFR 110) for fish and fishery products?

**Answer:** No, the requirements of Part 123 are in addition to the requirements of other FDA regulations, including Part 110. Section 123.5(a) of the Seafood HACCP Regulation states that the GMPs continue to be applicable to seafood processors in determining whether their facilities, methods, practices, and controls are safe and whether those products have been processed under sanitary conditions.

## **III. Hazard Analysis §123.6(a) (21 CFR)**

1. **Question:** Are all **processors** of raw fish species that have a parasite hazard required to control that hazard regardless of the intended use of the product (e.g., consumed raw, or cooked)?

**Answer:** No, a processor only needs to control the parasite hazard under the following conditions:

- the processor has reason to know that the fish will be consumed raw, OR
- the processor markets the fish for raw consumption, i.e., represents, labels, or promotes the product to be consumed raw

–**Note:** This question was previously q. 13 in Section IV of Qs and As, Issue 2|

2. **Question:** **Is the hazard of parasites reasonably likely to occur in the processing of fish roe during which the eggs are removed from the scein and then processed in brine?**

**Answer:** **No, ordinarily under these circumstances, the brine would serve to separate the parasite larvae from the fish eggs, i.e., the parasite larvae would sink and the fish eggs would float.**

3. **Question:** With respect to changes that require processors to reassess their hazard analyses and HACCP plans [§123.8(a)(1) and (c)], what do the terms "sources of raw material" and "consumers of finished product" refer to?

**Answer:** "Sources of raw materials" refers to the harvester or supplier of the raw material. If, for example, a processor expands or changes the area from which he purchases a species of fish to include an area in which a harvest closure based on chemical contaminants exists, the processor should reassess whether it is necessary to change his plan to accommodate the new hazard.

"Consumers of product" refers to the ultimate consumer, who buys the product at a retail establishment or consumes it at a food service establishment. If, for example, a processor changes his marketing for a product to specifically target persons in hospitals and nursing homes, or other high risk populations, he should reassess whether it changes the significance of potential hazards in the product.

4. **Question:** What are the factors that make *Clostridium botulinum* a hazard that is reasonably likely to occur in a fishery product?

**Answer:** Some factors which contribute to the likelihood of a *Clostridium botulinum* hazard include packing the product under vacuum, in a modified atmosphere, in a hermetically sealed container or in oil, and/or applying a moderate heat treatment in combination with salt at less than 10%. For additional information consult FDA's "Fish and Fishery Products: Hazards and Controls Guide" (Guide), Edition Two, p. 154.

5. **Question:** Is *Clostridium botulinum* (*C. bot.*) a hazard in vacuum packaged raw seafood products that are stored and distributed refrigerated?

**Answer:** Yes, the Guide states that FDA is not aware of any suitable controls for *C. bot.* in vacuum packaged raw fish, i.e. such a product would not contain any known barriers to the growth of *C. bot.* Refrigeration alone is not a suitable barrier without adequate temperature control (monitoring) from processor to consumer. If a processor intends to pack raw fish in a vacuum package, he will need to establish adequate safety controls. The most likely procedure would be to carry out inoculated pack studies.

6. **Question:** Would a processor of a vacuum packaged salmon product made from smoked salmon and cream cheese need to control the percent water-phase salt (wps)?

**Answer:** In some cases, yes. The processor would need to exercise sufficient control to prevent the growth and toxin formation of *Clostridium botulinum* in the finished salmon and cream cheese product. Such controls could include the incorporation of barriers to its growth, such as water phase salt, water activity, pH, or a combination of these. If the barriers used do not match the levels presented in the Guide, the firm would be required to establish the safety of the product through trials, such as inoculated pack studies.

7. **Question:** Is the hazard of PSP reasonably likely to occur in lobster?

**Answer:** No, based on current information, it is not reasonably likely that lobster meat or lobster tomalley will contain a toxic quantity of PSP. This is in part because the amount of toxin in lobster meat and tomalley, even from lobsters caught in the same suspect location, is highly variable. This change in the current FDA recommendation will be reflected in the next edition of the Guide (Edition Three).

8. **Question:** A firm that obtains shellfish from federal waters performs a hazard analysis in which the potential for PSP in these waters is considered. The firm concludes that this hazard is not reasonably likely to occur. In its analysis, the firm recognizes that while no state or federal agency has conducted an actual study of the federal waters for the incidence of PSP, the agencies expressed opinions that the hazard is not reasonably likely to occur. Additionally, the firm notes that there is no notice from federal or state agencies that these waters are occasionally closed due to a PSP hazard. Is this information sufficient from which to draw a conclusion that the hazard is not reasonably likely to occur, or would the firm need to perform a study?

**Answer:** The scenario describes a responsible hazard analysis. FDA would not ask that the processor perform a study of the federal waters for the incidence of PSP in such a case.

9. **Question:** If a state regulatory authority has issued a "Consumption Advisory" for fish, including paddlefish roe, taken from a specified body of water, must a processor of the fish consider or address that advisory in his hazard analysis?

**Answer:** Yes, any fish processor should consider the consumption advisory. The processor should not accept fish from an area that is "closed" to harvest. However, consumption advisories are not closures. Thus, the processor should first ask the state if the consumption advisory is based on a state decision that fish coming from the area are reasonably likely to contain contaminants above the FDA/EPA action levels. If the advisory is based on those levels, the processor must test every lot of the fish before accepting it.

However, most consumption advisories are not based on such levels. The level of safety in most consumption advisories is usually stricter than the federal action levels, i.e. they are set at a smaller amount of the contaminant based on locally high consumption patterns. In this case, the processor can accept the fish with no further action.

10. **Question:** Is it true that no HACCP plans are required for raw shrimp and non-scombroid fresh fish?

**Answer:** All processors must conduct, or have conducted for them, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur in their product. This hazard analysis must be conducted for each location, each process and each kind of product processed. If no safety hazards are determined, then no HACCP plans are required.

Raw shrimp and non-scombroid fresh fish may not need a HACCP plan, but this must be determined in each individual processor's situation. For example, if the raw shrimp comes from aquaculture farms, then the use of animal drugs is a hazard that must be addressed **by the primary processor**. Also, parasites may be a hazard in some non-scombroid fresh fish that are marketed for raw consumption.

11. **Question:** Must sulfites be identified as a significant hazard in a HACCP plan for shrimp?

**Answer:** In all cases, sulfites should be considered in the hazard analysis for shrimp, and in most cases sulfites will be a hazard that must be controlled in a HACCP plan. However, in geographical areas where sulfites are not used in shrimp, the hazard may not be reasonably likely to occur. Another example in which the hazard may not be reasonably likely to occur is shrimp from a harvester that immediately freezes shrimp on board the harvest vessel without using sulfites.

#### IV. Hazard Analysis Critical Control Point (HACCP) Plan, §123.6(b-g) (21 CFR)

1. **Question:** Will FDA approve HACCP plans?

**Answer:** No, FDA will not formally "approve" HACCP plans, domestic or foreign.

2. **Question:** Without pre-approval of the HACCP plan, isn't the processor in jeopardy of being off the mark, and in violation of the regulation during the initial inspection?

**Answer:** There is the possibility that a processor's HACCP plan will be found to be unacceptable at the time of the first FDA HACCP-based inspection, despite reasonable efforts by the processor to be in compliance with the regulation. However, processors can minimize this risk by attending training that is at least equivalent to the Seafood HACCP Alliance training program and by consulting FDA's "Fish and Fishery Products Hazards and Controls Guide" (Guide). These sources of information will provide processors with a good understanding of hazards that are reasonably likely to occur in seafood products and the kinds of controls that would be acceptable to FDA.

While preapproval of HACCP plans might have been desirable to further minimize this risk, such a system would unduly burden the agency's resources, and would likely slow down the plan modification process that many processors will find necessary. Additionally, FDA believes that the effectiveness of a plan is best evaluated under actual operating conditions.

3. **Question:** Will FDA develop a unique numbering system for HACCP plans (like a Food Canning Establishment (FCE) number)?

**Answer:** No, HACCP plans are neither submitted to nor preapproved by FDA. Thus, an ID numbering system would be impractical.

4. **Question:** Are HACCP Plans for manufacturers and warehouses location specific?

**Answer:** Yes, as stated in 123.6(b)(1), a HACCP plan shall be specific to each location where fish and fishery products are processed by that processor.

5. **Question:** Will HACCP plans developed for the Department of Commerce (DOC) HACCP program meet FDA HACCP requirements?

**Answer:** FDA will need to independently evaluate HACCP plans for compliance with 21 CFR 123, despite their prior status in the DOC program. However, the two agencies are working closely to minimize the potential that an acceptable plan under the DOC program would be found unacceptable by FDA.

6. **Question:** What procedure will FDA follow when a processor's HACCP plan contains fewer Critical Control Points (CCPs) than FDA would expect for such a product?

**Answer:** FDA investigators are instructed to evaluate a processor's HACCP plan against the recommendations of the Guide and their own personal knowledge of the product and the process. Where differences arise, they are instructed to discuss their concerns with the processor and attempt to reach agreement. If, at the end of the discussion, the investigator is convinced that the processor deviated from the recommended control for sound, scientifically supported reasons, he is to accept the plan and evaluate whether it is being properly implemented.

If, at the end of the discussion, the investigator is unconvinced, he is to collect whatever supporting statements and data that may be available from the processor and refer the issue to agency experts for resolution. Depending upon his degree of conviction, the investigator will either formally object to the apparent deficiency (i.e. list it on the form FDA-483) or simply report it verbally, pending review, to the firm's management.

7. **Question:** What would a typical HACCP plan look like for a wholesaler who buys product from a processor? For a retailer that buys directly from watermen? For watermen who sell directly to retailers? For a small seafood company?

**Answer:** All seafood processors, as defined by the regulation, must perform a hazard analysis, and must develop and implement a HACCP plan that addresses all of the hazards that the hazard analysis identifies as reasonably likely to occur. For example, hazards such as pathogen growth in cooked, ready-to-eat seafood or histamine development in scombroid species of fish as a result of temperature abuse during storage must be addressed in the wholesaler's plan if they are reasonably likely to occur.

However, certain environmental hazards, such as pesticides or natural toxins from the harvest area need not be covered by the wholesaler if he is purchasing the product from a processor that is also subject to the regulation. Those hazards should be fully controlled by the primary processor, and are no

longer reasonably likely to occur by the time the wholesaler has received them.

Neither retailers nor watermen are subject to the seafood HACCP regulation. However, if the waterman processes further than heading, gutting, or freezing onboard the harvest vessel, he would be covered by the regulation. FDA has made certain recommendations to State agencies that regulate retail foods related to appropriate controls for retailers that purchase seafood directly from watermen. These are contained in the FDA Food Code. In general, in states where these recommendations are adopted, such retailers would be required by state regulation to develop a HACCP plan.

There are no special features of a HACCP plan for a small processor as opposed to a plan for a large processor. The plan is not dependent upon the size of the firm, but rather by the number and nature of the hazards.

8. **Question:** Can a single HACCP plan cover frozen, raw, breaded shrimp and frozen, parfried **breaded** shrimp?

**Answer:** Yes, one plan could ordinarily be used for both products, because the same hazards ordinarily apply to both products. Both are battered and breaded. Neither product is ready-to-eat, e.g., parfry does not result in a cooked shrimp product. For both products the hazard of *Staphylococcus aureus* toxin formation in the batter is reasonably likely to occur and is of concern because the toxin could survive frying by the consumer.

9. **Question:** Must a firm have a separate HACCP plan for each different size shrimp it processes, when the only differences are the cooking times (e.g., the critical limits)?

**Answer:** No, FDA would not object to grouping products [in one HACCP plan] that have the same hazards and controls, (e.g., monitoring, corrective action and verification procedures, and records), other than the critical limits.

10. **Question:** Does the seafood HACCP regulation apply to low acid canned seafood (LACF) or acidified seafood?

**Answer:** Yes, the HACCP regulation does apply to LACF and acidified foods. However, as explained in section 123.6(e), it is not necessary for an LACF processor, domestic or foreign, to address the hazard of *Clostridium botulinum* toxin in their HACCP plans. This hazard is already addressed under the LACF regulations, 21 CFR part 113 or 114, with which they must already comply.

However, hazards, other than *C. Botulinum* that are associated with these canned foods (e.g., histamine in canned tuna) must be controlled by the processor's HACCP plan. The seafood HACCP regulations supplement other regulations enforced by the FDA, including the LACF regulations.

11. **Question:** Is control of the thawing process critical to ensuring the adequacy of the subsequent cook step?

**Answer:** Each processor should establish the Critical Limits (CL) of the cook step in their process by a scientific study. The possibility of partially thawed product and its possible effect on the cooking process should be considered in the study. The study will establish whether the thawing process is critical, based on the processor's normal operating procedures.

12. **Question:** Must blue crab processors conduct heat penetration studies on their products and temperature distribution studies on their retorts, even if they have recording devices to show that they are cooking for a minimum of 4.5 minutes at 240° F?

**Answer:** Not necessarily, but under ordinary circumstances, every crab processor should have information that scientifically establishes the adequacy of their cooking process. This information should be referenced in their HACCP plan. It is not necessary for every crab processor to perform their own heat penetration study, provided they process with the parameters of an existing study.

In addition to scientifically establishing the adequacy of their cooking process, every crab processor should have information that scientifically establishes the adequacy of their cooking equipment. This information should also be referenced in their HACCP plan. But again, it may not be necessary for each processor to independently perform temperature distribution studies in their cooking equipment. They may be able to rely on studies that establish that equipment of a particular design and operated in a particular manner will provide adequate temperature distribution. Some such studies may already exist in the literature.

13. **Question:** Is the cook step a CCP for the control of pathogens in crab?

**Answer:** Yes, ordinarily the cook step should be considered to be a CCP for cooked-ready-to-eat products to eliminate pathogens on the raw material, unless the product receives a final heat treatment, such as pasteurization. To date, FDA is unaware of any studies that conclusively demonstrate that the cook step can be eliminated as a CCP for the processing of unpasteurized crabs.

14. **Question:** The recommendations in the Guide for cooling extremely large tuna (600-1200 pound fish) to 50° F within 6 hours of death are impractical. What alternatives do the industry have?

**Answer:** If the guidance contained in the Guide is not practical, the processor has the option of scientifically establishing other limits that provide an equivalent level of control.

15. **Questions:** Because of the slow development of histamine at low temperatures, the recommendations in the Guide (Edition Two, p. 79) for time/temperature critical limits during processing, seem unduly restrictive. Are there suitable alternatives?

**Answer:** Yes, the next edition of the Guide will be modified to provide the following alternatives:

○ For fish that have not been previously frozen -

A) The fish should not be exposed to temperatures above 70°F for more than four hours, cumulatively, before cooking (e.g., canned tuna "precook") or final freezing;

B) The fish should not be exposed to temperatures above 40°F but below 70°F for more than eight hours, cumulatively, before cooking (e.g., canned tuna "precook") or final freezing;

○ For fish that have been previously frozen -

A) The fish should not be exposed to temperatures above 70°F for more than twelve hours, cumulatively, before cooking (e.g., canned tuna "precook") or final freezing;

B) The fish should not be exposed to temperatures above 40°F but below 70°F for more than twenty-four hours, cumulatively, before cooking (e.g., canned tuna "precook") or final freezing.

These recommended critical limits are designed to prevent the development of dangerous levels of histamine and are not necessarily appropriate for the production of high quality fish. They are only suitable for fish that have been properly handled prior to receipt by the processor, i.e., those that have met the recommended receiving critical limits.

**However, for all fish (i.e., frozen or unfrozen) that were subjected to a corrective action as a result of a receiving critical limit deviation, the fish should not be exposed to temperatures above 40°F for more than four hours, cumulatively, before cooking (e.g., canned tuna "precook") or final freezing.**

16. **Question:** In industries like the canned tuna industry, where large quantities of fish (i.e., hundreds of tons) are received at a time from a single vessel, suppliers are usually quite stable, and there is a long history of histamine analysis with a low incidence of positive findings, the sample size for histamine analysis recommended in the Guide, (Edition Two, p. 81) seems excessive. Are there any alternatives?

**Answer:** Yes, there may be. The sample size recommended in the Guide is designed to provide a reasonable level of statistical assurance that a lot will not contain fish with histamine in excess of 50 ppm. However, there are several approaches that may be used to reduce the sample size from that which is recommended in the Guide. For example, the sample size could be safely reduced if the critical limit was also reduced (e.g., to 30 ppm). The sample size could also be safely reduced if the processor could demonstrate that there was a substantial history of compliance (i.e., low incidence of histamine findings above 50 ppm) from a stable group of suppliers. The principle of more intensive initial screening at receiving (i.e., with new suppliers), followed by less intensive screening as a pattern of compliance emerges with a particular supplier or group of suppliers is reasonable and is applied elsewhere in the Guide.

17. **Question:** Does a subsequent processor need to ensure that a previous processor has actually controlled hazards in his product?

**Answer:** No, a subsequent processor need not verify that a previous processor is fulfilling the requirements of the regulation. It is FDA's role to verify compliance. Some processors have chosen to obtain written guarantees of compliance from their suppliers. These letters are not required by the seafood HACCP regulation.

18. **Question:** In the case of fish that have a parasite hazard that are intended for raw consumption, is a label statement that the product should be cooked or frozen before consumption an acceptable control?

**Answer:** No, labeling is not an appropriate control measure for a hazard that affects the general population, as is the case with parasites. Freezing a fish by the processor is the only control measure of which FDA is aware that is both practical and effective for fish that are intended to be consumed raw and that are identified as having a parasite problem.

Processors that distribute a species of fish in the frozen state for raw consumption and the same species fresh for cooked consumption, are certainly free to identify the fish intended for cooked consumption with labeling indicating that it is not intended for raw consumption. However, a retailer using a product for raw consumption that is labeled for cooked consumption, could be placing himself in regulatory jeopardy with local food control ordinances.

19. **Question:** Must HACCP plans have controls to address all of the hazards contained in Appendix 5 of the Guide?

**Answer:** No, HACCP plans only need to have controls for those guidance levels that relate to hazards that are reasonably likely to occur as determined by the hazard analysis.

## **V. Corrective Actions §123.7 (21 CFR)**

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## VI. Verification §123.8 (21 CFR)

1. **Question:** What does the requirement for a yearly reassessment of the HACCP plan in Part 123.8(a)(1) mean?

**Answer:** At a minimum the HACCP plan must be reassessed annually to determine whether the hazard analysis is still appropriate and whether the plan effectively controls the identified hazard(s). The processor must consider how or if any changes in the firm's operations could affect the adequacy of the hazard analysis or the HACCP plan. (For example, changes in the kinds of raw materials used in the product, the suppliers of the raw materials, the product formulation, the equipment or operations used to process the product, the way in which the product will be used by the consumer, or the types of consumers likely to use the product could have major impact.) If the reassessment indicates a deficiency in the plan, the plan must be immediately revised.

Processors are free to perform the reassessment in any manner that works for them. For example, a "HACCP team" could discuss changes in the firm's operations since the last reassessment. Or, reassessment could also include a review of consumer or trade complaints, finished product or in-line samples, or of monitoring or corrective action records. FDA will judge the adequacy of the reassessment process by the adequacy of the HACCP plan.

2. **Question:** How should a processor measure the performance of a HACCP plan?

**Answer:** Measuring the performance of a HACCP program is termed "verification." Processors are required by 21 CFR 123.8 to verify their HACCP plan. Certain verification steps are mandatory, such as process instrument calibration, and review of processing, calibration, and corrective action records. Others are left at the option of the processor, such as finished product testing. Still others are required, but are intentionally left broad, such as the requirement to reassess the plan under certain conditions, and at least annually. This mix of requirements should allow the processor ample flexibility to design a verification program that meets his needs.

FDA will verify the performance of the industry-wide HACCP program by evaluating the results of reports of HACCP-based inspections performed by FDA investigators and by cooperating state and local agencies. Additionally, FDA will collect and analyze samples of product from processors that are operating under compliant HACCP programs, in an effort to determine whether safety defects are occurring in such products. Traditional program evaluation methods, such as reviews of consumer and trade complaints and regulatory actions, will also be used.

3. **Question:** Are there specific instances where a firm must provide sampling results when the sampling is not part of their HACCP program or Sanitation Standard Operating Procedures (SSOPs)?

**Answer:** No, the results of analytical testing are not ordinarily required to be shown to FDA investigators. However, if a firm chooses to use product testing as a part of their HACCP plan's monitoring or verification procedures, or as a part of their formal sanitation monitoring program, the analytical results would be subject to FDA review and copying.

4. **Question:** Does a processor have to show an FDA investigator sampling results that were generated under a HACCP program prior to the effective date of the HACCP regulation, December 18, 1997?

**Answer:** No, HACCP records generated prior to the implementation of the HACCP rule are not required to be shown to the investigator.

5. **Question:** How often should a firm test for sulfites in frozen shrimp they receive, if they have a certificate that states the shrimp is sulfite-free?

**Answer:** It is reasonable to assume that this processor is not the primary processor because the product is frozen. The sulfite hazard should be controlled by the primary processor, and therefore need not be addressed by the secondary processor. Guidance contained in FDA's "Fish and Fishery Products - Hazards and Controls Guide" recommends that the primary processor should collect at least one representative sample per quarter, randomly selected from its suppliers, and analyze for sulfiting agents. Additionally, the processor should collect at least one representative sample for each new supplier, and analyze for sulfiting agents.

6. **Question:** The hazard analysis need not be written. Must the reassessment of a hazard analysis be written?

**Answer:** No, whether conducted as part of an annual review or because a reassessment is required by a process change that might affect a product's safety, reassessment of a hazard analysis need not be written.

7. **Question:** What is an acceptable calibration procedure for indicating thermometers?

**Answer:** Calibration of indicating thermometers may differ with: 1) the type of thermometer; e.g., mercury-in-glass thermometer, dial thermometer, or electronic thermometer, 2) the degree of accuracy needed, or 3) the temperature range over which the thermometer will operate.

For most common processing applications (other than retorting, aseptic processing or other pressurized high temperature processing), accuracy within 1-2°F is usually sufficient.

For temperature ranges near the freezing point (e.g., refrigeration units), testing in a fresh water ice slurry (32°F) is normally sufficient for calibration.

For temperature ranges near 212°F, testing in boiling fresh water is normally sufficient.

For temperature ranges at or near room temperature, it may be appropriate to test both in an ice slurry and in boiling water, to ensure the accuracy of the instrument between the two testing points.

## **VII. Records §123.9 (21 CFR)**

1. **Question:** How long must sanitation records be held if sanitation is not part of the HACCP plan?

**Answer:** 21 CFR 123.9(b) states that all records required by the regulation, including sanitation records, must be retained for one year for refrigerated products and two years for frozen, preserved or shelf stable products.

2. **Question:** If a firm includes quality and economic fraud hazards in its HACCP plan, and identifies control steps relating to these hazards as CCPs, will FDA have access to records maintained relative to these hazards?

**Answer:** No, processors are not required to provide monitoring information or records that are outside the scope of the Seafood HACCP Regulation, for example information or records related to non-safety hazards. FDA has access only to records specifically required by the regulation.

3. **Question:** Is there a standard form to help the industry keep proper HACCP records?

**Answer:** There are no standard monitoring, verification, corrective action, or sanitation records that FDA is advocating for use by seafood processors for HACCP recordkeeping purposes. To the extent possible, FDA encourages processors to utilize existing forms for this purpose or to modify such forms,

where necessary, in order to minimize the cost and operational disruption that the regulation may cause.

However, standard forms are included in the Fish and Fishery Products Hazards and Controls Guide for the hazard analysis and the HACCP plan. FDA encourages, but does not require, processors to use these forms, to reduce the processors' risk of leaving out important information and to reduce the time necessary for FDA investigators to review the information.

4. **Question:** Do all these records have to be in English?

**Answer:** Yes, all records required by 21 CFR 123 must be in English.

5. **Question:** Are processors required to keep letters of guarantee from their raw material suppliers, to demonstrate that the previous processor operates in compliance with the regulation?

**Answer:** No, processors need not keep such letters.

6. **Question:** Do the HACCP records need to be reviewed by a HACCP trained individual?

**Answer:** Yes, §123.8(a)(3) requires that review of monitoring, corrective action, and instrument calibration records is performed by an individual who has been trained in accordance with §123.10.

### **VIII. Training §123.10 (21 CFR)**

1. **Question:** Does FDA recognize the National Marine Fisheries Service (NMFS) HACCP course certificate as meeting the Seafood HACCP Regulation training requirement?

**Answer:** FDA participated in the Seafood HACCP Alliance to develop a training curriculum that meets the requirements of 21 CFR 123.10. The preamble to the final regulation stated that FDA would not "approve" or "recognize" training courses using other curricula, because, to do so would require the agency to expend its limited resources evaluating those courses.

In the preamble, FDA also explained that trainers that chose to use other training curricula should compare their curricula to the Alliance curriculum and modify them, as necessary, to ensure that they provide at least an equivalent level of understanding of the principles of HACCP, the requirements of the Seafood HACCP Regulation, and the guidance contained in FDA's "Fish and Fishery Products Hazards and Controls Guide" (Guide).

The NMFS has informed FDA that they have evaluated their course against the Alliance curriculum and have determined that by providing past and future students with a copy of the Seafood HACCP Regulation and the Guide, their existing course would be equivalent. FDA has made no independent judgement in this regard.

2. **Question:** Must a seafood processor have a HACCP-trained individual do their hazard analysis, even if their product does not require a HACCP plan?

**Answer:** Yes, a HACCP-trained individual must perform the hazard analysis initially at least annually, and whenever there is a change in the firm's operations that might affect the hazard analysis, even if the product does not need a HACCP plan. However, the trained individual need not be an employee of the processor.

3. **Question:** Is HACCP training mandatory for foreign processors?

**Answer:** Yes. All of the requirements of the Seafood HACCP Regulation apply equally to U.S.

processors and foreign processors that ship their products to the U.S.

4. **Question:** How long is the HACCP training?

**Answer:** The Seafood HACCP Alliance training course curriculum is 3 days. Other training courses may be somewhat longer or shorter. For example, the Interstate Shellfish Sanitation Conference has developed a 1 1/2 day course for shellfish shippers and reshippers only. This is a highly targeted course that covers a limited number of potential hazards for a select audience.

## **IX. Sanitation Control Procedures §123.11 (21 CFR)**

1. **Question:** Must the processor review sanitation records under the HACCP regulation?

**Answer:** No, 21 CFR 123.11(c) requires a processor to maintain sanitation monitoring and correction records, but the firm need not review those records. This differs from the requirement at 21 CFR 123.8(a)(3) that processors review HACCP monitoring, corrective action, and calibration records within certain time constraints. As a practical matter, however, it would be prudent for processors to perform such a review of sanitation records in order to ensure that they are maintaining control of sanitation in the plant.

2. **Question:** Are processors required to have a written sanitation standard operating procedure (SSOP)?

**Answer:** No, the seafood HACCP regulation does not require processors to have written SSOPs. However, a written plan is strongly recommended because an SSOP would help the processor identify the tasks necessary to meet the sanitation monitoring requirement in 21 CFR 123.11.

3. **Question:** What are the microbiological and quality criteria for water used in seafood processing?

**Answer:** In accordance with FDA's Good Manufacturing Practices (GMP) regulations, 21CFR Part 110, all food process water must be safe and suitable for its intended use. (Part 110.37(a) Facilities, Water Supply: "The water supply shall be sufficient for the operations intended and shall be derived from an adequate source." Part 110.80, (a)(1) Processes and Controls, Raw materials and other ingredients: "...Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality....")

In certain situations, "safe and suitable" water may be water that is not of potable water quality but is known to be sanitary and to pose no risk of chemical or biological contamination to the food product. Any processor using such water, however, must be able to demonstrate that the water is safe and suitable for the use. (Note: This subject is under review by FDA)

4. **Question:** Should a processor of cooked-ready-to-eat products monitor its processing water for residual chlorine?

**Answer:** In some cases, yes. Water used in contact with cooked, ready-to-eat product must be potable. If the water is from a municipal source, no controls to ensure potability will likely be needed, except where the municipal supply is occasionally contaminated. If, however, the source is private, the microbiological quality (e.g., total coliforms) should be checked periodically - ordinarily at least once or twice per year. If chlorination is needed to ensure the potability of a private source, residual chlorine should be checked frequently - ordinarily at least daily. If recirculated water is used in contact with the product, the proper controls would depend upon the water temperature, the length of time between water replacement, and the method of water filtration/treatment.

5. **Question:** Can controls for time/temperature abuse during processing or storage be included in a processor's sanitation standard operating procedure rather than its HACCP plan?

**Answer:** No, to the extent that time/temperature abuse that can lead to the development of a hazard (e.g., histamine development or pathogen growth) is reasonably likely to occur at a step in the process, time/temperature abuse must be controlled through HACCP rather than through sanitation monitoring. Monitoring of time/temperature in a HACCP plan must be at a frequency to detect loss of control that would result in the development of a hazard.

## X. Special Requirements for Imported Products §123.12 (21 CFR)

### A. General

1. **Question:** Will the FDA maintain a listing of foreign firms with acceptable or unacceptable HACCP plans?

**Answer:** No, the FDA will not maintain a listing of foreign firms. However, when HACCP equivalency agreements are reached between FDA and other governments, lists of exporters covered by these international equivalency agreements may be available.

Conversely, FDA maintains an import alert (#16-120) covering foreign processors who have been placed on detention without physical examination due to the absence or inadequacy of HACCP plans.

2. **Question:** If the foreign processor does not have a formal HACCP plan but takes all steps necessary to assure safety of products, is this sufficient?

**Answer:** No, the regulations, section 123.6(b), require every processor (domestic and foreign) to have and implement a written HACCP plan whenever a hazard analysis identifies one or more food safety hazards that are reasonably likely to occur in the product.

3. **Question:** What will be required of domestic seafood processors who buy their raw materials through import brokers?

**Answer:** A processor has the same HACCP obligation under Part 123, irrespective of the source of his raw materials, to conduct a hazard analysis to determine all food safety hazards that are reasonably likely to occur in his product. The U.S. processor, however, will not need to control certain environmental hazards which are fully controlled by the foreign processor such as ciguatera toxin or environmental pesticides. That is because those hazards should be fully controlled by the foreign processor, who is the primary processor. Those hazards are no longer reasonably likely to occur when the U.S. processor receives the product.

Also, if the U.S. processor is the "importer" as defined in the regulation, then the U.S. processor must also meet the importer verification requirements.

4. **Question:** Who is responsible for the bond of an entry, the "Importer of Record" or the Customs Broker?

**Answer:** Whoever has posted the bond is responsible. Action against a redelivery bond is a U.S. Customs Service action.

5. **Question:** How will the Custom house brokers certify that the importers and/or the foreign processors meet the requirements of the HACCP regulations?

**Answer:** The HACCP regulations do not apply to Custom house brokers, unless they are also the U.S. owner or his U.S. consignee or the U.S. agent of the foreign owner or consignee, i.e., meet the definition of "importer" in 21 CFR 123.3.

6. **Question:** How do the regulations affect international forwarders who ship seafood, but do not buy or sell the product?

**Answer:** Intermediaries, such as freight forwarders, are not normally "importers" under the definition of importer, in 123.3(g). Therefore, the regulations do not normally apply to them.

However, if an "intermediary" firm is the U.S. owner or consignee at the time of entry, or in the absence of such an entity, is the U.S. agent of the foreign owner or consignee, then the firm would be considered to be an "importer" and would need to meet the HACCP requirements for an importer.

7. **Question:** How could ISO 9000 certification be useful to a foreign processing company in order to demonstrate compliance with the HACCP regulation?

**Answer:** An ISO 9000 plan may help facilitate the verification procedure, but it does not take the place of a hazard analysis nor a HACCP plan.

8. **Question:** Has the EU accepted HACCP as a replacement for ISO when importing from companies outside the U.S.?

**Answer:** The EU does not require ISO for imported foods, although some buyers may require it. The EU does, however, require HACCP to be implemented by seafood processors who ship to the EU. The EU further requires that seafood processors shipping to the EU be on a list submitted to the member state inspection body by the competent inspection body in the third country.

9. **Question:** Does the seafood HACCP regulation apply to imported low acid canned foods (LACF) or acidified foods?

**Answer:** Yes, but only to hazards other than *Clostridium botulinum*, which is addressed by the LACF regulations, 21 CFR parts 113 and 114. (See also Chapter IV. Hazard Analysis Critical Control Point (HACCP) Plan, §123.6, question 10).

10. **Question:** Must an importer have a HACCP plan for its own operation?

**Answer:** No, the importer is not required to perform a hazard analysis or have a HACCP plan, unless it is also engaged in processing. The importer is only required to have and implement verification procedures to ensure that the foreign processor meets the requirements of Part 123.

11. **Question:** Will Agency investigators be conducting foreign seafood inspections in the near future?

**Answer:** Yes, the FDA has traditionally performed a limited number of foreign seafood inspections and anticipates continuing this effort. In particular, foreign inspections will be conducted in establishing and verifying seafood HACCP MOUs.

## **B. Importer Verification**

12. **Question:** What verification steps are needed relative to lots purchased by an importer from other importers?

**Answer:** The U.S. firm which owns the product at the time of product entry or the U.S. consignee has

to comply with the importer verification requirements. However, any entity purchasing the product after entry does not need to comply with the importer verification requirements. It would be prudent, however, to have invoices showing the importer's identification.

13. **Question:** Can the importer verification activities, i.e., performing affirmative steps, be conducted by the foreign processor?

**Answer:** No, the foreign processor cannot perform the verification affirmative steps for the importer.

14. **Question:** Is it required that an importer hire a third party to perform its verification activities?

**Answer:** No, it is not required for an importer to use a third party to perform the verification activities as outlined in the HACCP regulations. The importer may perform these steps itself.

15. **Question:** How can an importer comply with the verification requirement?

**Answer:** An importer can demonstrate verification by obtaining a fish or fishery product from a country that has an active MOU, as described in part 123.12(a)(1), or by having and implementing written verification procedures as described in part 123.12(a)(2). These procedures include having product safety specifications and following one or more of the affirmative steps specified in section 123.12(a)(2)(ii), which is also described in their verification procedures.

16. **Question:** Does the importer need verification that Sanitation Standard Operating Procedures (SSOP) are being followed and monitored by a foreign processor?

**Answer:** Yes, the importer must verify that sanitation is being monitored by the foreign processor. Section 123.12(2) states that the verification procedures must ensure that the imported products were processed in accordance with the requirements of all of part 123, which includes sanitation monitoring procedures. However, written sanitation standard operating procedures are not required of U.S. or foreign processors.

### **C. Memorandum of Understanding (MOU)**

17. **Question:** If an importer receives product from a country covered by a seafood HACCP MOU, does the importer need to maintain any HACCP verification documentation?

**Answer:** No, the existence of an MOU fulfills the importer's requirement under the seafood HACCP regulation unless the importer is also a processor, and no documentation is required. However, the importer should be in a position to demonstrate that the product came from a country covered by a seafood HACCP MOU.

18. **Question:** If a country has an MOU with FDA, is it possible for a processor that is not on that country's approved facilities list to export seafood to the United States under §123.12(a)(2)?

**Answer:** Yes, a processor that is not on the country's approved facilities list could export to the United States, if the processor can demonstrate to the importer that the processor's operation meets the requirements of the seafood HACCP regulation.

19. **Question:** What is the procedure for initiating a country-to-country HACCP equivalency agreement?

**Answer:** The country should send a formal letter to the FDA/Office of Seafood indicating its interest in pursuing an equivalency or MOU seafood agreement and requesting information to begin the process.

The FDA Office of Seafood will reply and enclose a package of information outlining the procedures to begin the process. The packet will contain forms for the country to complete in English:

- a side-by-side comparison of the country's HACCP program with 21 CFR Section 123, the seafood HACCP regulation;
- a side-by-side comparison of the country's sanitation program with FDA's Good Manufacturing Practices regulation, 21 CFR Section 110;
- a side-by-side comparison of the country's low acid canned food and acidified food program with FDA's low acid canned food and acidified food regulations, 21 CFR 108, 113 and 114; and
- a check list of the country's regulatory control system, procedures, etc., to demonstrate the control authority's authority and ability to enforce a HACCP-based control program.

FDA will evaluate these completed documents to determine if the country's seafood control program appears to be equivalent. Work will continue toward establishing an agreement, if the paper review is satisfactory. FDA will perform an on-site visit to determine if the foreign program has been implemented as it is written. Further steps toward finalizing negotiations will follow as appropriate.

The process is extensive and usually lengthy and involves a thorough exchange of information.

20. **Question:** Does a Memorandum of Understanding (MOU) signify that an acceptable HACCP program exists?

**Answer:** An active MOU applicable to fish and fishery products will signify that the country's authority for control of seafood for export has agreed to comply with Part 123 or that their seafood regulatory system is equivalent to the U.S. system. The MOUs may be product and/or processor specific and may not cover all the seafood products from the signatory country.

21. **Question:** Are any countries currently pursuing HACCP MOUs with the FDA?

**Answer:** The FDA has no HACCP MOUs to date. Countries which are in the process of developing HACCP MOUs with the FDA include Australia, Canada, Chile, the European Union, Iceland, Japan, New Zealand, Norway, the People's Republic of China, and Thailand. These are in varying stages of the process, and only one or two are close to completion.

However, the existing Molluscan shellfish MOUs will be accepted as fulfilling the HACCP requirements of a Molluscan Shellfish importer. Countries with active molluscan shellfish MOUs are Canada, Chile, Mexico, South Korea, and New Zealand.

22. **Question:** Once an MOU is established with a new country, will those importers of that country's products, who are subject to detention without physical examination because their importer verification documents were inadequate, be automatically removed from the Import Alert?

**Answer:** Yes, when the MOU is signed the importers will be removed from the import alert if the MOU covers the product and processor that are listed in the import alert. The country's agreement to take responsibility to verify processor compliance with the HACCP regulation requirements will fully satisfy the importer's verification requirements.

#### **D. Product Safety Specifications**

23. **Question:** Can one product safety specification be used by several importers of the same product?

**Answer:** Yes, the product safety specification can be used by any importer for which it is applicable. This is likely if the product is the same with similar product methods, ingredients, etc, such that the food safety hazards are the same.

24. **Question:** Will importers be required to test entries against their product specifications?

**Answer:** No, Part 123.12(a)(2)(i) does not require that importers test product to see if their product safety specifications are met.

25. **Question:** Is it necessary for importers to insist that their product specifications be signed by the foreign processor or that the foreign processors write a letter guaranteeing adherence to the specifications?

**Answer:** No, it is not necessary. However, the importer may wish to have the foreign processors indicate in some manner an intent to meet the specifications.

26. **Question:** Do product specifications need to address non-safety issues such as filth and decomposition?

**Answer:** No, the product specification requirement is for safety only. Specifications such as water activity, pH, histamine content and pathogen limits, are examples of specifications that importers might set in their efforts to ensure product safety. It is important to note that an importer's specifications are not necessarily the same as a processor's HACCP critical limits. For example, an importer may include a specification that salmonella not be detectable in the product, even though the seafood will be cooked by the consumer. This standard is consistent with FDA's policy that seafood is adulterated if it contains this pathogen. However, the presence of salmonella would not be expected to be a critical limit in a HACCP plan for the same product.

### **E. Affirmative Steps**

27. **Question:** What will represent adequate affirmative step documentation for product exported by shippers who do not process the product shipped to the U.S. (i.e., foreign companies that purchase and consolidate products for export)?

**Answer:** The regulations require that the importer verify that the seafood products that it imports into the U.S. were processed in accordance with the regulation. The importer must have documentation in its file that one of the six affirmative steps was taken to verify this fact. The documentation needs only to cover processors. Shippers that do not also meet the definition of processor need not be covered by the importer's documentation. It is FDA's intent to concentrate on ensuring that documentation exists relative to the manufacturer of the final product form, as shipped to the U.S.

28. **Question:** What should be the frequency of affirmative step procedures (i.e., How often should on-site audit visits be made or how often should a product be tested)?

**Answer:** The regulation does not specify frequency of the affirmative steps. Frequency should be as often as necessary to provide the importer confidence that the foreign processor is meeting the requirements of the seafood HACCP regulation. Frequency will vary with circumstances such as: the number and type of hazards associated with the product, the importer's familiarity with and confidence in the foreign processor, the particular affirmative step being undertaken, etc. It may be prudent to check more frequently initially and reduce the frequency over time, if initial results are satisfactory.

Under ordinary circumstances, reasonable affirmative step frequencies could be:

(A) monitoring records - every shipment

(B) continuing lot certification - once a year

lot-by-lot certification - every lot

(C) foreign on-site inspection - once a year

(D) processor's HACCP plan/guarantee - once a year

(E) periodic tests/guarantee - test first three entries, if satisfactory - quarterly (Guarantee once a year)

29. **Question:** How many of the six affirmative steps found in the regulation must be conducted by importers?

**Answer:** Importers need only conduct one of the listed affirmative steps. An importer can use a variety of affirmative steps for different suppliers and/or products.

30. **Question:** Do HACCP plans and all sanitation and HACCP monitoring records held by importers as part of their verification program need to be in English?

**Answer:** Yes, part 123.12(c) states that importer verification records must be maintained in English.

31. **Question:** Part 123.12 (2)(ii)(A), monitoring records, and (B), lot-by-lot certificates, refer to verification procedures documentation for individual lots. How does the FDA define a lot?

**Answer:** How a lot is defined is largely up to the processor and the importer. FDA characterizes a lot as an entry, group of entries, or a portion of an entry of merchandise that can be clearly defined as a shipment for FDA sampling and examination purposes. An amount of a product produced during a period of time indicated by a specific code.

32. **Question:** If importers elect to follow affirmative step (E) (periodically test the product and maintain on file a written guarantee the foreign processors are following the provisions of the HACCP rule), what sampling plans and methods should be followed? For example, is it sufficient to sample and test a product using the same sampling plans and methods used for import entries by the FDA?

**Answer:** Using a sample plan and analytical methods utilized by the FDA would be sufficient. The importer **should** utilize a sampling plan that will give it assurance that its foreign processors are meeting the requirements of the seafood HACCP regulation.

33. **Question:** Do importer verification records (i.e., affirmative action step documents) need to be originals? For instance, the original HACCP plans or monitoring records received by importers may have been in a foreign language, and the importer may have had them translated into English; or, for the sake of timeliness, the monitoring records, HACCP plans, guarantee letters and certificates may be sent via fax.

**Answer:** No, the verification records held by the importer need not be originals. However, the copies need to be accurate and legible and the Agency reserves the right to obtain the originals if necessary.

34. **Question:** If the importer chooses to visit the shipper or foreign manufacturer as a verification affirmative step, does the person visiting need to be HACCP certified?

**Answer:** No, there is no requirement that a person performing an on-site inspection for importer verification purposes be HACCP certified. However, the person should be competent to perform that

task. Competency could include a through knowledge of the seafood industry sector, the principles of HACCP, the HACCP regulation, and Current Good Manufacturing Practices (GMPs).

### **F. Competent Third Party**

35. **Question:** When a third party certificate is used to demonstrate the foreign processor's adherence to the HACCP rule, what documentation is necessary? Is the third party's audit report necessary?

**Answer:** For third party certification complying with 123.12(a)(2)(ii)(B), the importer need only maintain on file either a lot-by-lot certificate of compliance or a certificate attesting to continuing compliance. However, the Agency reserves the right to request additional supporting documents, such as a copy of the full inspection report and documentation of the competency of the third party, if necessary.

36. **Question:** Does the FDA have a standard form for a certificate? At a minimum, what should continuing and lot-by-lot certificates indicate?

**Answer:** FDA does not have a standard certification form. However, an acceptable statement for a lot-by-lot certificate could state for example, "This certificate is to verify that inspectors of (third party name or title) have determined that (name and address of foreign processor firm) have processed the (type and amount of product in a specific lot - identify the lot #) under sanitation and HACCP procedures that comply with the requirements of Title 21, United States Code of Federal Regulations, part 123." (Note: The statement could be appropriately modified for continuing lot certification.)

For continuing certificates, in addition to the above information, the certificate should include the expiration date of the certificate. Certificates should be signed. The regulations do not indicate how long a continuing certificate can remain in effect, but a maximum of one year would be reasonable.

37. **Question:** Does the use of a third party by an importer for verification provide greater confidence to the FDA over an importer's on-site inspection or a foreign government's certification?

**Answer:** No, the FDA does not consider the importer's use of a competent third party to be superior to any of the other five affirmative step options.

### **G. Importer Records**

38. **Question:** Under the seafood HACCP regulation, will FDA investigators now inspect importers directly?

**Answer:** Yes, FDA will inspect importers to review their written verification procedures and documentation of affirmative steps.

39. **Question:** Will FDA review importer verification documents only during the HACCP inspection of an importer at his place of business?

**Answer:** No. Importer verification documents will be reviewed primarily at the importer's place of business. However, when a shipment is detained at entry because of the finding of a safety defect, a reconditioning request will not be approved by FDA without proper importer verification documents. At some later date, FDA may also require importer verification documents at the time of entry as a condition of entry, for some percentage of entries.

40. **Question:** Are invoices considered mandatory records subject to review?

**Answer:** Yes, at time of entry, invoices have always been considered to be part of entry documentation and must be provided to FDA upon request.

41. **Question:** Must the importer's HACCP records accompany the product at entry?

**Answer:** No, an importer's HACCP records are not required to accompany the product upon entry. The importer will be alerted by the FDA if verification documents are needed.

42. **Question:** If a foreign processor has determined that there are no safety hazards in its product, should the importer maintain a copy of the processor's hazard analysis?

**Answer:** The regulation does not require that a processor have a written hazard analysis. However, in the event that an importer had selected option §123.12(a)(2)(ii)(D) (maintaining a copy of the foreign processor's HACCP plan and a written guarantee of compliance with the HACCP regulation) or option §123.12(a)(2)(ii)(A) (obtaining HACCP and sanitation monitoring records) and there is no HACCP plan because the processor has determined that there are no hazards that are reasonably likely to occur, it would be prudent of the importer to be prepared to demonstrate that fact.

43. **Question:** Should the importer maintain copies of the foreign processor's Sanitation Standard Operating Procedures (SSOPs)?

**Answer:** No, written sanitation standard operating procedures are recommended, but not required, by the regulation. In the event that an importer selects option §123.12(a)(2)(ii)(D) (maintaining a copy of the foreign processor's HACCP plan and a written guarantee of compliance with the regulation), the written guarantee serves to document the foreign processor's compliance with the sanitation monitoring requirements of the regulation.

## **H. Determination of Compliance**

44. **Question:** What action will the FDA take when it finds that an importer has not met his/her verification requirements?

**Answer:** The FDA may place the importer/product/foreign processor combination on detention without physical examination. Section 123.12(d) states that a product not complying with the regulation "will appear to be adulterated and will be denied entry."

45. **Question:** Is it possible that an importer could follow proper verification procedures and still enter violative products? If so, what will be the FDA's response?

**Answer:** Yes, it is possible. HACCP is designed to prevent, eliminate or reduce food safety hazards to an acceptable level, but does not specifically address U.S. economic and wholesomeness standards. Moreover, the FDA recognizes that HACCP, while effective at minimizing hazards, is not a zero risk system. Thus, a product could be produced that was in compliance with the seafood regulation and still be otherwise violative under the Act. In this case, FDA will likely prevent entry of the shipment with the usual options of reconditioning, relabeling, exportating, destroying, or appealing the lot. Administrative remedies, such as detention without physical examination, will continue to apply.

46. **Question:** If, during an inspection of an importer, an importer's affirmative steps appear to be inadequate to the FDA, could the appearance of inadequacy be overcome by taking additional affirmative steps, thus avoiding placement on Import Alert 16-119?

**Answer:** Yes, the importer could take additional affirmative steps to fulfill the verification requirement. This would avoid placement on Import Alert 16-119.

47. **Question:** Will inadequacies in importer's verification procedures or a foreign processor's HACCP program always result in placement on import alert?

**Answer:** No, inadequacies will be reviewed on a case-by-case basis. If it is felt that the inadequacy is minor, the inadequacy may be pointed out to the importer with no official action taken. However, if a serious inadequacy is noted in the importer's verification procedure, the importer/product/foreign processor combination may be placed on Import Alert. If there is a serious inadequacy in the foreign processor's HACCP program, then the foreign processor/product combination, may be placed on an import alert.

48. **Question:** If a foreign processor has an adequate HACCP program, sends the same product to two importers, and one performs adequate verification and one does not, which products will be placed on detention without physical examination?

**Answer:** The importer that does not perform adequate verification will be placed on detention without physical examination for that product from that foreign processor.

49. **Question:** If a foreign processor is adhering to the seafood HACCP regulation, but the importer has failed to meet its verification obligations under the regulation, will the foreign processor and the importer both be placed on import alert, or just the importer?

**Answer:** Violation of the importer verification requirements by the importer will result in an Import Alert for that specific importer, receiving that specific product, from that specific foreign processor. The foreign processor could still ship that product to the U.S. through other importers that are in compliance with the seafood HACCP regulation, without being affected by the Import Alert.

50. **Question:** What will be the appeals process if an importer believes an inspector has erred in his/her evaluation of its verification procedures or a foreign processor's HACCP program?

**Answer:** The importer should first discuss its disagreement with the inspector during the inspection. If the disagreement cannot be resolved favorably in this manner the importer may seek consultation with district personnel and, in some circumstances, FDA headquarters staff.

51. **Question:** Does the FDA foresee an increase in microbiological testing at the point of entry to evaluate the sanitation practices of foreign processors?

**Answer:** Within actual resource allocations, FDA anticipates that microbiological testing at entry will continue at its present level.

52. **Question:** Will testing at entry of products from MOU countries be less frequent?

**Answer:** It is expected that testing of products covered by MOUs for safety attributes will be less frequent than for other products. Diverting these resources to products with a history of noncompliance is one of the benefits of MOU development.

53. **Question:** What charge would the FDA bring against a product manufactured without a HACCP Plan - (801(a)(1) or 801(a)(3))?

**Answer:** The charge for an imported product that is manufactured without a HACCP plan will be 801(a)(3) in that such article is adulterated.

54. **Question:** What will be the nature of the FDA sampling program at entry as a result of the seafood HACCP regulation?

**Answer:** The FDA sampling program at entry will not change as a result of the seafood HACCP regulation. Examination will be based on the risk associated with the product and its compliance history.

## **XI. Raw Molluscan Shellfish §§123.20 and 123.28 (21 CFR)**

1. **Question:** Does the seafood HACCP Regulation supersede the National Shellfish Sanitation Program (NSSP)?

**Answer:** No, state shellfish control agencies implement the NSSP by adopting and enforcing regulations that are consistent with the NSSP. Processors of raw molluscan shellfish are required to comply with those state regulations. They will also be required to be in conformance with the provisions of the seafood HACCP regulation. The NSSP has recently been revised to incorporate the requirements of the seafood HACCP regulation, and changes in state implementing regulations and guidelines will soon follow, as needed.

2. **Question:** Is it necessary for a shellfish dealer who removes the tags from containers of molluscan shellfish during processing, to save each individual tag, or can the dealer save a tag from each lot and the invoice to demonstrate how much of the product was purchased and from whom? Currently this practice is allowed by the NSSP.

**Answer:** No, this practice would also be acceptable under the provisions of the seafood HACCP regulation. In fact, the regulation does not specifically require that processors retain any tags, although that remains a requirement of the NSSP. Under the regulation, processors may transcribe the relevant information from the tags onto a more traditional record.

3. **Question:** Does the seafood HACCP regulation apply to all shellfish shippers, or only to those involved in interstate commerce?

**Answer:** Only processors involved in interstate commerce are covered by the regulation. See "Definitions" section for further information on interstate commerce.

4. **Question:** Is a processor in a state, which is not a participant in the NSSP, precluded by the seafood HACCP regulation from re-shipping shellstock interstate?

**Answer:** No, the regulation only requires that a processor receive shellfish from a licensed harvester or certified dealer. It does not require the processor to be certified in order to ship in interstate commerce. However, in most cases it would be a violation of state or local code for a retailer to receive product from such a processor, because the processor is an uncertified source, i.e., not certified through the NSSP.

5. **Question:** Does the Seafood HACCP Regulation permit the heat treatment of molluscan shellfish harvested from unapproved growing waters?

**Answer:** Yes, under certain conditions. The seafood HACCP regulation contains specific receiving controls for raw, molluscan shellfish that are mandatory unless the shellfish are processed in a way that "ensures the destruction of vegetative cells of microorganisms of public health concern." In other words, the processor is required by the HACCP regulation to obtain shellfish from approved growing waters unless he intends to heat treat them sufficiently to eliminate the pathogens of concern. Under those conditions, the processor may obtain the shellfish from unapproved waters. However, the processor must also ensure that any chemical or natural toxin hazards are controlled.

Additionally, State statutes do not, at present, allow harvesting from unapproved waters, unless the

molluscan shellfish are going to be relayed or depurated, and then only if subjected to certain controls.

6. **Question:** Is participation in the National Shellfish Sanitation Program (NSSP) by a foreign country sufficient evidence that shellfish harvested for canning in that country comes from approved waters?

**Answer:** No, canned shellfish are not covered by the NSSP. The NSSP applies only to fresh and fresh frozen molluscan shellfish. Under provisions of the NSSP imported fresh or frozen molluscan shellfish must originate from a country with an active shellfish Memorandum of Understanding (MOU) with FDA and the foreign processor must be certified by the foreign government and listed on the Interstate Certified Shellfish Shippers List.

Canned shellfish product must be processed according to requirements of the LACF regulation 21 CFR §113 including having an LACF registration number, and also the product must be processed in accordance with the seafood HACCP regulation, 21 CFR §123, to ensure the product is safe for hazards other than *Clostridium botulinum*.

7. **Question:** Is a foreign firm which ships raw molluscan shellstock to the United States subject to the seafood HACCP regulation?

**Answer:** Yes, fresh and frozen molluscan shellfish must comply with the requirements of the seafood HACCP regulation as well as the requirements of the NSSP.

## XII. Miscellaneous

1. **Question:** Are there any specific cooking temperatures required for a fishery product to be considered to be "fully cooked" or "ready-to-eat"?

**Answer:** No, if the protein is coagulated throughout the product, the processor should consider it likely that some consumers will consume the product without further cooking. In this case, the cooking process should be designed to eliminate vegetative pathogens of public health concern. FDA's Fish and Fishery Products Hazards and Controls Guide provides further information on the control of pathogens in cooked, ready-to-eat products.

2. **Question:** What is the purpose of the pages preceding the actual seafood HACCP regulation?

**Answer:** The text preceding the regulation discusses each provision of the regulation and responds to public comments on proposed regulation. This section is referred to as the "preamble" to the regulation. The HACCP regulation, promulgated under the Federal Food, Drug, and Cosmetic (FD&C) and the Public Health Service (PHS) Acts, become part of Title 21 of the Code of Federal Regulations (CFR), as new part 123 and amendments to part 1240.

3. **Question:** Will there be a HACCP logo for products?

**Answer:** No, FDA has no current plans for an approved HACCP logo for seafood products.

4. **Question:** Which HACCP program should a processor follow, the FDA seafood HACCP regulation or the Department of Commerce's HACCP program?

**Answer:** The FDA regulation is mandatory for all seafood processors engaged in interstate commerce. The HACCP program administered by the Department of Commerce is a voluntary, fee-for-service agreement between the processor and NMFS.

5. **Question:** Will FDA publish a list of processors who are in compliance with the seafood HACCP

regulation, similar to the Interstate Certified Shellfish Shippers List (ICSSL)?

**Answer:** No, FDA has no plans to publish such a list.

6. **Question:** What percentage of seafood, in a mixed food product, will be used to determine whether a product is covered by the seafood HACCP regulations?

**Answer:** There is no minimum percentage of fish that causes a food to be subject to the provisions of the seafood HACCP regulation. A product is subject to the regulations, if "fish" is a characterizing ingredient. For example, fish is a characterizing ingredient in "fish stew," but not in Worcestershire sauce, which contains anchovy paste.

7. **Question:** Is a fermented soy product, which is labeled as tuna-flavored and contains tuna, subject to the provisions of the regulation?

**Answer:** Yes, the use of a fish name on the label of a product clearly indicates that the fish is the characterizing ingredient. The product is therefore a fishery product as defined by the regulation and is subject to the regulation.

8. **Question:** Are FDA or NMFS certificates still necessary for shipment of seafood products to the EU?

**Answer:** Yes both FDA and NMFS will continue issuing EU health certificates until an agreement can be reached in which this is no longer needed. At this time, it is premature to say how long certificates will be needed.

### XIII. Inspections Under HACCP

1. **Question:** How will an inspection under the FDA HACCP program differ from an inspection before implementation of the HACCP regulation?

**Answer:** Previously FDA inspections of seafood processors concentrated on the sanitation conditions and practices of the processor, as well as the quality of the product. There was also considerable emphasis on end-product testing for microbiological and other defects. Under the HACCP program, these efforts will continue. However, the focus of the inspection will be on the adequacy of the processor's controls to prevent the occurrence of food safety hazards. In particular, the inspector will assess the adequacy of the processor's HACCP plan, observe the degree to which the plan is implemented in the plant, and review records of critical control point monitoring and corrective action. The inspector will also review the processor's sanitation monitoring program.

2. **Question:** Will FDA investigators be standardized in HACCP?

**Answer:** No, not in the immediate future. However, in addition to attending the AFDO/Seafood HACCP Alliance three-day course on the principles of HACCP, FDA investigators and State inspectors have been given special training and testing on how to perform HACCP-based inspections. It is expected that this training will result in inspection procedures that are as uniform as possible. Inspection certification is anticipated in the future.

3. **Question:** Will FDA be performing all HACCP inspection, or will states do some, as well?

**Answer:** As a federal regulation, the ultimate responsibility for enforcing the Seafood HACCP Regulation rests with FDA. However, a number of HACCP inspections will be performed by State agencies under contract with FDA. Additionally, FDA is in the process of entering into partnerships with state agencies, through which the state agencies would do HACCP inspections in an equivalent

manner with FDA inspections.

4. **Question:** What role does the National Marine Fisheries Service (NMFS) play in the implementation of HACCP?

**Answer:** The NMFS continues to operate a voluntary seafood HACCP program which includes not only safety but also non-safety hazards such as quality and economic fraud.

5. **Question:** The United States Department of Commerce (USDC)/National Marine Fisheries Service (NMFS) uses a checklist when performing inspections. Will FDA use a checklist?

**Answer:** No, a checklist will not be used when FDA performs seafood HACCP inspections. However, FDA investigators will complete a standardized report that summarizes their findings relative to the firm's HACCP and sanitation monitoring programs. A copy will be provided to plant management at the conclusion of the inspection along with exiting documents (e.g., FDA 483, inspectional observations).

6. **Question:** Will the FDA inspectors have guidelines to use when evaluating HACCP plans and/or verification steps?

**Answer:** Yes, the FDA investigators do have guidelines for evaluating HACCP plans and verification steps. The main sources of information will be the "Fish and Fishery Hazard & Control Guide" (Guide) and the Regulator's HACCP training manual.

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