

Seafood HACCP and the FDA Food Safety Modernization Act: Guidance for Industry

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Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(tel) 240-402-1700
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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

August 2017

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Seafood HACCP and the FDA Food Safety Modernization Act: Guidance for Industry¹

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I. Introduction

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) enables the FDA to better protect public health by helping to ensure the safety and security of the food supply. It requires FDA to promulgate food safety rules that focus on preventing food safety issues rather than relying on detecting issues and reacting to them after they occur. FSMA recognizes that FDA has previously established a preventive control type regulation for fish and fishery products (Title 21, Code of Federal Regulations (21 CFR) part 123, the seafood HACCP regulation) based on the Hazard Analysis and Critical Control Point (HACCP) concept. See FSMA §§ 103(a), 103(f), 105(d), and 301 (§§ 418(j) and 805(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 350g(j), 350g note, 350h note, and 384a(e))). The seafood HACCP regulation requires seafood processors to identify food safety hazards that are reasonably likely to occur and to develop plans for the control of those hazards.

In addition, the seafood HACCP regulation requires importers of certain seafood products to comply with requirements designed to help ensure that these imported products are processed in accordance with the seafood HACCP regulation.

Importantly, several of the regulations that FDA has issued under FSMA provide exemptions related to the seafood HACCP regulation. This guidance addresses those exemptions, and also provides information about the seafood HACCP regulation in connection with the FSMA regulations.

Though not the subject of this guidance, we also note that some seafood products are also subject to 21 CFR part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically

¹ This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

Sealed Containers). Certain FSMA regulations provide additional exemptions related to part 113.

This guidance summarizes how the following FSMA regulations affect processors and importers subject to the seafood HACCP regulation:

- 21 CFR part 117, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods (CGMP & PC Regulation)
- 21 CFR 1, subpart L, Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (the FSVP Regulation)
- 21 CFR 1, subpart M, Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications (Accredited Third-Party Certification Regulation)
- 21 CFR part 121, Mitigation Strategies To Protect Food Against Intentional Adulteration (the IA Regulation)
- 21 CFR 1, subpart O, Sanitary Transportation of Human and Animal Food (the ST Regulation)

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

The CGMP & PC regulation contains 7 subparts which address key areas associated with a comprehensive food safety program. Below is a brief summary of the content of each subpart:

Subpart A: General Provisions

This subpart provides definitions, identifies exemptions, defines applicability of subparts, and specifies training requirements.

Subpart B: Current Good Manufacturing Practice

Subpart B contains most of the provisions previously in 21 CFR part 110. The changes include modifications that either delete or make previously recommended practices into requirements and provide explicit regulatory text to address allergen cross-contact.

Subpart C: Hazard Analysis and Risk-Based Preventive Controls

Subpart C describes the requirements for a food safety plan, including hazard analyses and preventive controls for facilities subject to this subpart.

Subpart D: Modified Requirements

Subpart D describes the modified requirements for qualified facilities and facilities solely engaged in the storage of unexposed packaged food (for food that requires time/temperature control for safety).

Subpart E: Withdrawal of a Qualified Facility Exemption

Subpart E addresses the withdrawal of a qualified facility exemption and the appeal and reinstatement procedures.

Subpart F: Requirements Applying to Records that must be Established and Maintained

Subpart F establishes the requirements that apply to all subparts for the records required to be kept.

Subpart G: Supply-Chain Program

Subpart G requires the establishment of written risk-based supply-chain programs for receiving facilities (manufacturers/processors) for raw materials and other ingredients when a hazard associated with the raw material or other ingredient has been controlled before receipt. It further describes the requirements for supply-chain programs, supplier verification activities, and recordkeeping for those programs.

Subpart A – General Provisions

1. Are seafood processors subject to the Current Good Manufacturing Practice and Preventive Controls Regulation (21 CFR part 117)?

Seafood processors must meet the requirements of specific subparts of the CGMP & PC Regulation. The exemption in 21 CFR 117.5(b) applies to the activities that are subject to part 123 (21 CFR 123). 21 CFR 117.5(b) specifically exempts the processing activities of seafood processors from the requirements of subpart C, *Hazard Analysis and Risk-Based Preventive Controls*, and subpart G, *Supply-Chain Program*, if the seafood processor is in compliance with the seafood HACCP regulation with respect to the activities that are subject to part 123. Seafood processors still must meet the requirements of subparts A, B, and F (for the records required by subpart A) of part 117.

2. What if the facility is not in compliance with 21 CFR part 123?

We expect that situations in which enforcement actions to ensure compliance with the seafood HACCP regulation in 21 CFR part 123 are insufficient to correct problems and lead to a facility losing its exemption from the requirements of subparts C and G of part 117 will be rare and will depend on very specific circumstances. The extent of non-compliance with part 123 that will result in the loss of exemption will be considered on a

case-by-case basis by FDA. We do not expect loss of exemption to be commonplace; however, FDA may use this regulatory tool when adequate control cannot be achieved through the implementation of an effective HACCP program by a processor.

3. Which definitions in part 117 apply to my facility and process?

The terms defined in 21 CFR 117.3 apply to seafood processors, except the definitions for “processor,” “food safety hazard,” and “processing” listed in 21 CFR 123.3 apply within the context of the application of the seafood HACCP regulation instead of the terms “facility,” “hazard,” and “manufacturing/processing.”

4. What additional training requirements apply to seafood processors under 21 CFR part 117?

In addition to the training requirements listed in 21 CFR 123.10, the management of an establishment must also ensure that their employees meet the training requirements listed in subpart A of part 117. The training requirements in subpart A replace the training recommendations previously listed in part 110. The workers who are engaged in manufacturing, processing, packing, or holding seafood (including temporary and seasonal personnel) must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual’s assigned duties (“*qualified individual*”) and must receive training in the principles of food hygiene and food safety (21 CFR 117.4(b)). In addition, supervisory personnel must have the necessary education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food (21 CFR 117.4(c)).

Seafood processors must maintain records of the training of those “*qualified individuals*” and their supervisors in the principles of food hygiene and food safety, including health and personal hygiene, as appropriate to the food, the facility, and their assigned duties (21 CFR 117.4(d)). The requirements of subpart F of part 117 apply to these training records.

5. When do I need to comply with the relevant provisions in 21 CFR part 117 that apply to me, including the records requirements?

Compliance dates for businesses are staggered over several years.

- *Very small businesses*, which means, for purposes of part 117, a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee), must be compliant by September 17, 2018. (This is also the compliance date for grade “A” milk and milk products covered by the Pasteurized Milk Ordinance.)

- *Small businesses*, which means, for the purposes of part 117, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees, must be compliant by September 18, 2017.
- *All other businesses* must be compliant by September 19, 2016.

Subpart B – Current Good Manufacturing Practices

6. Are the Current Good Manufacturing Practices provisions in 21 CFR part 117 different from those in 21 CFR part 110?

The CGMP requirements in part 117 (mostly located in subpart B) generally align with the requirements of part 110, with the non-binding provisions in part 110 removed or made binding in part 117. In addition, subpart B addresses allergen cross-contact explicitly in the regulatory text. In addition, the training requirements that were recommended in 21 CFR part 110 are now mandated in 21 CFR part 117 subpart A (refer to question 4.)

7. What procedures and controls does FDA require a seafood processor to have and implement to control allergen cross-contact?

The seafood HACCP regulation requires seafood processors to address all seafood safety hazards identified by the hazard analysis in their HACCP plan and to comply with part 110 or part 117 (whichever is applicable). FDA intends to provide separate guidance regarding control of allergen cross-contact by seafood processors.

8. Does 21 CFR part 117 require seafood processors to have written sanitation procedures?

No. Subpart B of part 117 does not require written sanitation standard operating procedures (SSOPs). Seafood processors are exempt from subpart C of part 117 where the requirement for written sanitation controls is found. The seafood HACCP regulation recommends, but does not require, written SSOPs for sanitation. Seafood processors continue to be required to implement sanitation monitoring procedures and to maintain written sanitation monitoring and corrective action records as defined by 21 CFR 123.11.

9. Does the exemption from 21 CFR part 117 subpart B for establishments solely engaged in the holding of raw agricultural commodities apply to seafood processors?

Yes. A “*raw agricultural commodity*” is any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing (21 USC 321(r)). Examples of seafood products that are considered “raw agricultural commodities” are whole, raw unviscerated fish, whole raw crabs or lobsters, and raw head-on shell-on shrimp. Establishments that solely hold these types of fishery products are exempt from subpart B of part 117, but must still meet the requirements of

part 123. An exemption for “*raw agricultural commodities*” from CGMPs previously located in 21 CFR 110.19 is now located in 21 CFR 117.5(k) of subpart A.

Subpart C – Hazard Analysis and Risk-Based Preventive Controls

10. What additional 21 CFR part 117 risk-based preventive controls, if any, do seafood processors in compliance with 21 CFR part 123 need to implement for the non-seafood raw materials and ingredients they use in their fishery products?

There are no additional requirements when seafood processors are in compliance with part 123. Seafood processors must consider all raw materials and ingredients, including both fish and non-fish raw materials and ingredients, during their hazard analyses (21 CFR 123.6(a)). When reasonably likely food safety hazards are identified, they must be addressed in the seafood HACCP plan (21 CFR 123.6(c)). For example, as with fish and fishery products, if temperature controls are necessary to ensure the safety of a refrigerated non-fish raw material, FDA will expect the necessary critical control points for those raw materials or ingredients to be identified and included in the seafood HACCP plan. Seafood processors may need to refer to additional guidances for appropriate preventive controls when conducting their hazard analyses to identify the hazards associated with non-seafood raw materials or ingredients and recommended controls.

11. What controls are required if a facility is producing both seafood products and non-seafood products?

The portion of the operation that manufactures, processes, packs, or holds products and their raw materials or ingredients that are not subject to the seafood HACCP regulation must meet the requirements of subparts C and G of part 117 unless an exemption applies. The raw materials and activities associated with the processing of the seafood products must meet the requirements of part 123 and subparts A, B, and F (for the training requirements of subpart A) of part 117.

12. Are radiological hazards relevant to my hazard analysis?

Yes. Radiological hazards are a type of chemical hazard. Although radiological contamination of foods is a rare event, radiological hazards might need to be considered under some circumstances, such as contamination arising from accidental release from a nuclear facility or from damage to a nuclear facility from a natural disaster. A seafood processor’s HACCP plan must list the necessary critical control points and controls to prevent the radiological hazard associated with the fish or fish they process if that hazard is identified as reasonably likely in the hazard analysis (21 CFR 123.6(a), (c)(1)(iii)).

Subparts D and E – Modified Requirements and Withdrawal of a Qualified Facility Exemption

13. Do the requirements applicable to a qualified facility in subparts D and E apply to seafood processors??

No. A “*qualified facility*” is eligible for an exemption that enables very small businesses to comply with modified requirements. A qualified facility is exempt from the requirements of subparts C and G, but is subject to the provisions of 21 CFR 117.201 in subpart D, *Modified Requirements*, which requires those very small facilities to submit specific attestations to FDA as part of their responsibilities as a qualified facility and could be subject to subpart E, *Withdrawal of a Qualified Facility Exemption*. However, since subpart A exempts the activities subject to part 123 of all seafood processors (not just very small businesses) from subparts C and G of part 117 when the processor meets the requirements of part 123, the seafood processor does not have to comply with modified requirements, nor is there a provision to withdraw the exemption that applies to seafood processors.

However, if a facility also conducts activities that are not covered under the seafood HACCP regulations, then that portion of the operations may be subject to subparts D and E of part 117 if the business meets the definition of a “*qualified facility*” as defined in 21 CFR 117.3.

Subpart F - Requirements Applying to Records that must be Established and Maintained

14. Do the records requirements listed in subpart F apply to my seafood HACCP program?

No. The record keeping requirements in subpart F only apply to the training records required by 21 CFR 117.4(d). Records that are intended to meet the requirements of the seafood HACCP regulation must comply with the requirements in 21 CFR 123.9.

Subpart G – Supply-Chain Program

15. Does subpart G apply to seafood products?

No. Activities that are subject to part 123 are exempt from subpart G of part 117. Seafood processors who are in compliance with part 123 are not required to have and implement the supply-chain controls required by subpart G.

III. Foreign Supplier Verification Program (FSVP)

The Foreign Supplier Verification Programs for Food Importers of Food for Humans and Animals (FSVP) is in part 1, subpart L, of FDA’s regulations (21 CFR 1.500-1.514). The FSVP regulation requires importers to create and follow procedures to ensure the safety of the food they import.

16. Does the definition of importer in 21 CFR 123.3(g) of the seafood HACCP regulation still apply to seafood importers?

Yes. Since the FSVP regulation does not apply to fish and fishery products that are imported from foreign suppliers that are subject to the seafood HACCP regulation and in compliance with the seafood HACCP regulation, importers of fish and fishery products that are subject to the seafood HACCP regulation must comply with the requirements applicable to importers of those products under 21 CFR 123.12. Consequently, the definition of an importer in 21 CFR 123.3(g) applies to such importers, and the definition of importer in 21 CFR 1.500 (FSVP) does not apply.

17. Will the FSVP regulation impact my importation of fish and fishery products?

The FSVP regulation (21 CFR 1.501(b)(1)) exempts fish and fishery products that are imported from a foreign supplier that is subject to and in compliance with part 123. However, in accordance with 21 CFR 123.12, importers of fish and fishery products subject to the HACCP regulation must still comply with the requirements for importer verification under the seafood HACCP regulation.

It is important to note that the FSVP regulation requires all importers subject to that rule to identify themselves as the FSVP importer upon entry. As a consequence, all food imports will be prompted for an additional data code at entry. Because importers of fish and fishery products are exempt from the FSVP regulation, they should transmit the Affirmation of Compliance code, “FSX” (designating that the food is exempt from the FSVP regulation or that compliance with the FSVP regulation is not required), for each entry. Without a code, the entry will be rejected. An incorrect code could result in the importer being listed in the FSVP inventory for inspection. The *Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation* provides information on how importers exempt from FSVP may comply with FDA’s requirements for entries. See: <https://www.fda.gov/food/guidanceregulation/fsma/ucm556661.htm> .

18. How does FSVP affect my importation of other raw materials or ingredients used in fish and fishery products?

If an importer imports raw materials or other ingredients that are only used by the importer in the manufacturing or processing of fish and fishery products subject to part 123, FSVP does not apply to those raw materials or ingredients, provided the importer complies with part 123 with regards to manufacturing or processing of the fish or fishery product manufactured from the imported raw materials or other ingredients (see 21 CFR 1.501(b)(2)).

For example, an importer imports frozen fish blocks, breading, batter mix, and oil that the same importer then uses to manufacture breaded fish portions. As an importer of a fish or fishery product (e.g., frozen fish blocks), the firm must follow verification requirements under the seafood HACCP regulation for the frozen fish blocks in accordance with 21 CFR 123.12. With regards to the breading, batter mix, and oil, the importer is not required to implement verification procedures defined in 21 CFR 123.12 (because such products are not fish or fish or fishery products). In addition, the importer is not required to meet the requirements of FSVP for the breading, batter mix, and oil, provided that the firm manufactures the breaded fish portions in accordance with the seafood HACCP regulation.

IV. Accreditation of Third-Party Certification Bodies

19. Does a seafood importer need to have and implement written verification procedures in accordance with 21 CFR 123.12(a)(2) if the importer obtains a certification from an accredited Third-Party Certification Body under the requirements of the Third-Party Certification Program (21 CFR part 1, subpart M)?

Yes. Certifications from third-party certification bodies, including those under the Third-Party Certification Program, do not meet the requirements of 21 CFR 123.12(a)(1). Therefore, seafood importers are required to comply with 21 CFR 123.12(a)(2).

V. Mitigation Strategies To Protect Food Against Intentional Adulteration (IA)

23. Must a seafood processor also comply with 21 CFR part 121 – Mitigation Strategies to Protect Food against Intentional Adulteration?

Domestic and foreign seafood processors required to register with FDA (21 USC 350d) must comply with 21 CFR part 121 unless an exemption applies to the facility. Facilities must be in compliance by the dates established by the IA final regulation.

- The IA regulation does not apply to a very small business (i.e., a business, including any subsidiaries or affiliates, averaging less than \$10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in both sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, e.g., held for a fee), except that the facility is required to provide for official review, upon request, documentation sufficient to show that the facility qualifies for this exemption.
- This regulation does not apply to the holding of food, except the holding of food in liquid storage tanks.
- This regulation does not apply to the packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact.

- This regulation does not apply to activities of a farm that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).
- This regulation does not apply to the manufacturing, processing, packing, or holding of food for animals.

See 21 CFR 121.5 for exemptions.

VI. Sanitary Transportation of Human and Animal Food

24. Is the shipment of seafood covered under 21 CFR 1 subpart O – Sanitary Transportation of Human and Animal Food?

Seafood processors are subject to this regulation when they are engaged in transportation operations for food that is not excluded from the definition of transportation operations in 21 CFR 1.904. For example, the transportation of seafood that requires temperature control for safety is subject to the regulation. The transportation of a shelf stable seafood product completely enclosed by a container is not. Note that businesses subject to the requirements of part 1, subpart O, that are appropriately certified and are inspected under the requirements established by the Interstate Shellfish Sanitation Conference's National Shellfish Sanitation Program (NSSP), are waived from the requirements of the ST regulation, only when engaged in transportation operations involving molluscan shellfish in vehicles that are permitted by the State NSSP certification authority.