AUDIT STANDARDS COMPARISON TO THE FDA HAZARD ANALYSIS AND CRITICAL POINT (SEAFOOD HACCP) SYSTEMS REGULATION

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TITLE 21—FOOD AND DRUGS **CHAPTER 1 - SUBCHAPTER B** **PART 123—FISH AND FISHERY PRODUCTS [SEAFOOD HACCP]**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
Subpart A—General Provisions				
§123.5 Current good manufacturing practice.				
(a) Except as provided by §117.5(b), 21 CFR part 110 and 21 CFR part 117 apply in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions. (b) The purpose is to set forth requirements specific to the processing of fish and fishery products.				The exemption in 21 CFR 117.5(b) exempts the processing activities of seafood processors from the requirements of subpart C, Hazard Analysis and RiskBased 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 must meet the requirements of subparts A, B, and F (for the records required by subpart A) of 21 CFR 117.
§123.6 Hazard analysis and Hazard Analysis Critical Control Point (HACCP) plan.				

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(a) *Hazard analysis.* Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.				

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(b) *The HACCP plan.* Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to:				
(1) Each location where fish and fishery products are processed by that processor; and				
(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.				
(c) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:				

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(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:				
(i) Natural toxins;				
(ii) Microbiological contamination;				
(iii) Chemical contamination;				
(iv) Pesticides;				
(v) Drug residues;				
(vi) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;				

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(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;				
(viii) Unapproved use of direct or indirect food or color additives; and				
(ix) Physical hazards;				
(2) List the critical control points for each of the identified food safety hazards, including as appropriate:				
(i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and				
(ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;				
(3) List the critical limits that must be met at each of the critical control points;				

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(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;				
(5) Include any corrective action plans that have been developed in accordance with §123.7(b), to be followed in response to deviations from critical limits at critical control points;				
(6) List the verification procedures, and frequency thereof, that the processor will use in accordance with §123.8(a);				
(5) Include any corrective action plans that have been developed in accordance with §120.10(a), and that are to be followed in response to deviations from critical limits at critical control points;				
(6) List the validation and verification procedures, and the frequency with which they are to be performed, that the processor will use in accordance with §120.11; and				

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(7) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.				
(d) *Signing and dating the HACCP plan.* (1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.				
(2) The HACCP plan shall be dated and signed:				
(i) Upon initial acceptance;				
(ii) Upon any modification; and				
(iii) Upon verification of the plan in accordance with §123.8(a)(1).				

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(e) *Products subject to other regulations.* For fish and fishery products that are subject to the requirements of part 113 or 114, the HACCP plan need not list the food safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.				
(f) *Sanitation.* Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with §123.11(b) they need not be included in the HACCP plan, and vice versa.				
§123.7 Corrective actions.				
(a) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:				
(1) Following a corrective action plan that is appropriate for the particular deviation, or				
(2) Following the procedures in paragraph (c) of this section.				

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(b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with §123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:				
(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and				
(2) The cause of the deviation is corrected.				
(c) When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:				
(1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;				

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(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with §123.10;				
(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;				
(4) Take corrective action, when necessary, to correct the cause of the deviation;				
(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with §123.10, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.				

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(d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with §123.8(a)(3)(ii) and the recordkeeping requirements of §123.9.				
§123.8 Verification.				
(a) *Overall verification.* Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:				

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(1) *Reassessment of the HACCP plan.* A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with §123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of §123.6(c).				
(2) *Ongoing verification activities.* Ongoing verification activities including:				

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(i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;				
(ii) The calibration of process-monitoring instruments; and,				
(iii) At the option of the processor, the performing of periodic end-product or in-process testing.				
(3) *Records review.* A review, including signing and dating, by an individual who has been trained in accordance with §123.10, of the records that document:				
(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;				

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(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with §123.7. This review shall occur within 1 week of the day that the records are made; and				
(iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.				
(b) *Corrective actions.* Processors shall immediately follow the procedures in §123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.				

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(c) *Reassessment of the hazard analysis.* Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with §123.10.				
(d) *Recordkeeping.* The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the recordkeeping requirements of §123.9.				

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§123.9 Records.				
(a) *General requirements.* All records required by this part shall include:				
(1) The name and location of the processor or importer;				
(2) The date and time of the activity that the record reflects;				
(3) The signature or initials of the person performing the operation; and				
(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.				
(b) *Record retention.* (1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.				

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(2) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.				
(3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.				
(e) *Tags.* Tags as defined in §123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of §123.28(c).				

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(f) *Records maintained on computers.* The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.				
§123.10 Training.				
At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.				
(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of §123.6(b);				

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(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in §123.7(c)(5), the HACCP plan in accordance with the verification activities specified in §123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in §123.8(c); and				
(c) Performing the record review required by §123.8(a)(3); The trained individual need not be an employee of the processor.				
§123.11 Sanitation control procedures.				
(a) *Sanitation SOP.* Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.				

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(b) *Sanitation monitoring.* Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in 21 CFR part 110 or subpart B of part 117 that are both appropriate to the plant and the food being processed and relate to the following:				
(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;				
(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;				
(3) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;				
(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;				

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(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;				
(6) Proper labeling, storage, and use of toxic compounds;				
(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and				
(8) Exclusion of pests from the food plant.				
The processor shall correct in a timely manner, those conditions and practices that are not met.				
(c) *Sanitation control records.* Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of §123.9.				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 123 (e.g., definitions). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures. In addition to meeting the applicable requirements of 21 CFR Part 123, processors of fish and fishery products intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., current good manufacturing requirements in 21 CFR Part 117 subpart B).

TITLE 21—FOOD AND DRUGS **CHAPTER 1 - SUBCHAPTER B** **PART 123—FISH AND FISHERY PRODUCTS [SEAFOOD HACCP]**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
d) *Relationship to HACCP plan.* Sanitation controls may be included in the HACCP plan, required by 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section they need not be included in the HACCP plan, and vice versa.				
Subpart B—Smoked and Smoke-Flavored Fishery Products				
§123.16 Process controls.				
In order to meet the requirements of subpart A, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of 21 CFR part 113 or 114, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.				
Subpart C—Raw Molluscan Shellfish				
§123.28 Source controls.				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 123 (e.g., definitions). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures. In addition to meeting the applicable requirements of 21 CFR Part 123, processors of fish and fishery products intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., current good manufacturing requirements in 21 CFR Part 117 subpart B).

TITLE 21—FOOD AND DRUGS **CHAPTER 1 - SUBCHAPTER B** **PART 123—FISH AND FISHERY PRODUCTS [SEAFOOD HACCP]**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(a) In order to meet the requirements of subpart A as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.				
(b) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. Federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the Federal government.				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 123 (e.g., definitions). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures. In addition to meeting the applicable requirements of 21 CFR Part 123, processors of fish and fishery products intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., current good manufacturing requirements in 21 CFR Part 117 subpart B).

TITLE 21—FOOD AND DRUGS **CHAPTER 1 - SUBCHAPTER B** **PART 123—FISH AND FISHERY PRODUCTS [SEAFOOD HACCP]**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(c) To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in §1240.60(b). In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in §1240.60(b). Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:				
(1) The date of harvest;				
(2) The location of harvest by State and site;				
(3) The quantity and type of shellfish;				
(4) The date of receipt by the processor; and				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 123 (e.g., definitions). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures. In addition to meeting the applicable requirements of 21 CFR Part 123, processors of fish and fishery products intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., current good manufacturing requirements in 21 CFR Part 117 subpart B).

TITLE 21—FOOD AND DRUGS **CHAPTER 1 - SUBCHAPTER B** **PART 123—FISH AND FISHERY PRODUCTS [SEAFOOD HACCP]**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.				
(d) To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with §1240.60(c). Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:				
(1) The date of receipt;				
(2) The quantity and type of shellfish; and				
(3) The name and certification number of the packer or repacker of the product.				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 123 (e.g., definitions). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures. In addition to meeting the applicable requirements of 21 CFR Part 123, processors of fish and fishery products intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., current good manufacturing requirements in 21 CFR Part 117 subpart B).

TITLE 21—FOOD AND DRUGS CHAPTER 21 PART 1240—CONTROL OF COMMUNICABLE DISEASES	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
Subpart D--Specific Administrative Decisions Regarding Interstate Shipments				
§ 1240.60 Molluscan shellfish.				
(a) A person shall not offer for transportation, or transport, in interstate traffic any molluscan shellfish handled or stored in such an insanitary manner, or grown in an area so contaminated, as to render such molluscan shellfish likely to become agents in, and their transportation likely to contribute to the spread of communicable disease from one State or possession to another.				
(b) All shellstock shall bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority, where applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information.				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 123 (e.g., definitions). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures. In addition to meeting the applicable requirements of 21 CFR Part 123, processors of fish and fishery products intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., current good manufacturing requirements in 21 CFR Part 117 subpart B).

TITLE 21—FOOD AND DRUGS **CHAPTER 21** **PART 1240—CONTROL OF COMMUNICABLE DISEASES**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(c) All containers of shucked molluscan shellfish shall bear a label that identifies the name, address, and certification number of the packer or repacker of the molluscan shellfish.				
(d) Any molluscan shellfish without such a tag, shipping document, or label, or with a tag, shipping document, or label that does not bear all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.				