

Table 4: HACCP "Prerequisites" Side-By-Side

FSIS	FDA	NACMCF	CODEX
<p>9 CFR ' 416; Food Safety and Inspection Service (FSIS).</p> <p align="center">*****</p> <p>NOTE: No attempt was made to match this column to another.</p> <p align="center">*****</p>	<p>21 CFR ' 123; Food and Drug Administration (FDA).</p> <p align="center">*****</p> <p>NOTE: No attempt was made to match this column to another.</p> <p align="center">*****</p>	<p>Adopted August 14, 1997, by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) as a revision of their 1992 adopted HACCP System document. From the Journal of Food Protection, Volume 61, Number 9, 1998, pages 1246-1259, and as noted in the article, this article may reproduced without permission. Tables, figures, appendixes, references, and some introductory text portions are not included in this comparison document.</p> <p align="center">*****</p> <p>NOTE: No attempt was made to match this column to another.</p> <p align="center">*****</p>	<p>Adopted June 1997; Codex Alimentarius Commission and the FAO/WHO Food Standards Programme, annex to CAC/RCP 1-1969, Rev. 3.</p> <p align="center">*****</p> <p>NOTE: No attempt was made to match this column to another.</p> <p align="center">*****</p>
<p>[FSIS stated its views regarding the association of sanitation procedures and HACCP n the preamble to the Pathogen Reduction/HACCP final regulation (i.e., "[i]n a sense, the Sanitation SOP's are a prerequisite for HACCP"). FSIS further stated that "[a] sanitation procedure that is incorporated into a validated HACCP plan need not be duplicated in the Sanitation SOP's" (61 FR 38834, July 25, 1996). The following information is the</p>	<p>[The FDA seafood HACCP regulations cross-reference the FDA Current Good Manufacturing Practice (cGMP) regulations contained in 21 CFR ' 110, as well as specify sanitation requirements. Below, the cGMP requirement found in the seafood HACCP regulations is restated, along with the sanitation requirements].</p> <p align="center">*****</p> <p>' 123.5 Current Good</p>	<p>(Realigned from page 1248, Guidelines for Application of HACCP Principles, Introduction): HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. For successful implementation of a HACCP plan, management must be</p>	<p><u>Guidelines for the application of the HACCP system.</u> Prior to application of HACCP to any sector of the food chain, that sector should be operating according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety legislation. Management commitment is necessary for implementation of an effective HACCP system. During hazard</p>

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<p>FSIS Sanitation SOP's.]</p> <p>*****</p> <p>§ 416 Sanitation standard operating procedures.</p> <p>§ 416.11 General rules.</p> <p>Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.</p> <p>§ 416.12 Development of Sanitation SOP's.</p> <p>(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).</p> <p>(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall</p>	<p>Manufacturing Practice.</p> <p>(a) Part 110 of this chapter applies 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.</p> <p>(b) The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.</p> <p>' 123.6(f) Sanitation.</p> <p>Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Sec. 123.11(b) they need not be included in the HACCP plan, and vice versa.</p> <p>(g) Legal basis. Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through</p>	<p>strongly committed to the HACCP concept. A firm commitment to HACCP by top management provides company employees with a sense of the importance of producing safe food. HACCP is designed for use in all segments of the food industry from growing, harvesting, processing, manufacturing, distributing, and merchandising to preparing food for consumption. Prerequisite programs such as current Good Manufacturing Practices (cGMPs) are an essential foundation for the development and implementation of successful HACCP plans. Food safety systems based on the HACCP principles have been successfully applied in food processing plants, retail food stores, and food service operations. The seven principles of HACCP have been universally accepted by government agencies, trade associations and the food industry around the world. The following guidelines will facilitate the development and implementation of effective HACCP plans. While the specific application of HACCP to manufacturing facilities is emphasized here, these guidelines should be applied as appropriate to each segment of the food industry under</p>	<p>identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety. The intent of the HACCP system is to focus control at CCPs. Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found. HACCP should be applied to each specific operation separately. CCPs Identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step. It is important when applying HACCP to be flexible where appropriate, given the context of the application taking into account the nature and the size of the operation.</p>

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<p>be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.</p> <p>(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.</p> <p>(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).</p> <p>§ 416.13 Implementation of SOP's.</p> <p>(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.</p> <p>(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.</p> <p>(c) Each official establishment shall monitor</p>	<p>an evaluation of the processors overall implementation of its HACCP plan, if one is required.</p> <p>' 123.11 Sanitation control procedures.</p> <p>(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.</p> <p>(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 part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:</p> <p>(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;</p>	<p>consideration.</p> <p>Prerequisite Programs</p> <p>The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. Examples of common prerequisite programs are listed in Appendix A. Each segment of the food industry must provide the conditions necessary to protect food while it is under their control. This has traditionally been accomplished through the application of cGMPs. These conditions and practices are now considered to be prerequisite to the development and implementation of effective HACCP plans. Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food. Many of the conditions and practices are specified in federal, state and local regulations and guidelines (e.g., cGMPs and Food Code). The Codex Alimentarius General Principles of Food Hygiene describe the basic conditions and practices expected for foods intended for international trade. In addition to the requirements specified in regulations, industry often adopts</p>	

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<p>daily the implementation of the procedures in the Sanitation SOP's.</p> <p>§ 416.14 Maintenance of Sanitation SOP's.</p> <p>Each official establishment shall routinely evaluate the Effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.</p> <p>§ 416.15 Corrective Actions.</p> <p>(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).</p> <p>(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be</p>	<p>(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;</p> <p>(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;</p> <p>(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;</p> <p>(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;</p> <p>(6) Proper labeling, storage, and use of toxic compounds;</p> <p>(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and</p> <p>(8) Exclusion of pests from</p>	<p>policies and procedures that are specific to their operations. Many of these are proprietary. While prerequisite programs may impact upon the safety of a food, they also are concerned with ensuring that foods are wholesome and suitable for consumption (Appendix A). HACCP plans are narrower in scope, being limited to ensuring food is safe to consume. The existence and effectiveness of prerequisite programs should be assessed during the design and implementation of each HACCP plan. All prerequisite programs should be documented and regularly audited. Prerequisite programs are established and managed separately from the HACCP plan. Certain aspects, however, of a prerequisite program may be incorporated into a HACCP plan. For example, many establishments have preventive maintenance procedures for processing equipment to avoid unexpected equipment failure and loss of production. During the development of a HACCP plan, the HACCP team may decide that the routine maintenance and calibration of an oven should be included in the plan as an activity of verification. This would further ensure that all the food in the</p>	

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<p>contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.</p> <p>§ 416.16 Recordkeeping requirements.</p> <p>(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.</p> <p>(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.</p>	<p>the food plant. The processor shall correct in a timely manner, those conditions and practices that are not met.</p> <p>(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 Sec. 123.9.</p> <p>(d) Relationship to HACCP plan. Sanitation controls may be included in the HACCP plan, required by Sec. 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.</p> <p>' 123.12 Special requirements for imported products.</p> <p>This section sets forth specific requirements for imported fish and fishery products.</p> <p>(a) Importer verification. Every importer of fish or fishery products shall either:</p> <p>(1) Obtain the fish or fishery product from a</p>	<p>oven is cooked to the minimum internal temperature that is necessary for food safety.</p> <p>Realigned from page 1254, Appendix A: Examples of Common Prerequisite Programs</p> <p>The production of safe food products requires that the HACCP system be built on a solid foundation of prerequisite programs. Each segment of the food industry must provide the conditions necessary to protect food while it is under their control. This has traditionally been accomplished through the application of cGMPs. These conditions and practices are now considered to be prerequisite to the development and implementation of effective HACCP plans. Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food. Common prerequisite programs may include but are not limited to:</p> <p>Facilities.</p> <p>The establishment should be located, constructed, and maintained according to sanitary design principles. There should be linear product flow and traffic</p>	

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<p>(c) Records required by this part shall be maintained for at least 6 months and made accessible available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.</p> <p>§ 416.17 Agency verification.</p> <p>FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:</p> <p>(a) Reviewing the Sanitation SOP's;</p> <p>(b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;</p> <p>(c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be</p>	<p>country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or</p> <p>(2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:</p> <p>(i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,</p> <p>(ii) Affirmative steps that may include any of the following:</p> <p>(A) Obtaining from the</p>	<p>control to minimize cross-contamination from raw to cooked materials.</p> <p>Supplier Control.</p> <p>Each facility should assure that its suppliers have in place effective GMP and food safety programs. These may be the subject of continuing supplier guarantee and supplier HACCP system verification.</p> <p>Specifications.</p> <p>There should be written specifications for all ingredients, products, and packaging materials.</p> <p>Production Equipment.</p> <p>All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules should be established and documented.</p> <p>Cleaning and Sanitation.</p> <p>All procedures for cleaning and sanitation of the equipment and the facility should be written and followed. A master sanitation schedule should be in place.</p> <p>Personal Hygiene.</p> <p>All employees and other</p>	

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<p>taken; and</p> <p>(d) Direct observation or testing to assess the sanitary conditions in the establishment.</p>	<p>foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;</p> <p>(B) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;</p> <p>(C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;</p> <p>(D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;</p> <p>(E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the</p>	<p>persons who enter the manufacturing plant should follow the requirements for personal hygiene.</p> <p>Training.</p> <p>All employees should receive documented training in personal hygiene, GMP, cleaning and sanitation procedures, personal safety, and their role in the HACCP program.</p> <p>Chemical Control.</p> <p>Documented procedures must be in place to ensure the segregation and proper use of nonfood chemicals in the plant. These include cleaning chemicals, fumigants, and pesticides or baits used in or around the plant.</p> <p>Receiving, Storage, and Shipping.</p> <p>All raw materials and products should be stored under sanitary conditions and the proper environmental conditions such as temperature and humidity to assure their safety and wholesomeness.</p> <p>Traceability and Recall.</p> <p>All raw materials and products should be lot-coded and a recall system should be in place so that rapid</p>	

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	<p>imported fish or fishery product is processed in accordance with the requirements of this part or,</p> <p>(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.</p> <p>(b) Competent third party. An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.</p> <p>(c) Records. The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of Sec. 123.9.</p> <p>(d) Determination of compliance. There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported</p>	<p>and complete traces and recalls can be done when a product retrieval is necessary.</p> <p>Pest Control.</p> <p>Effective pest control should be in place.</p> <p>Other examples of prerequisite programs might include quality assurance procedures; standard operating procedures for sanitation, processes, product formulations, and recipes; glass control; procedures for receiving, storage, and shipping; labeling; and employee food and ingredient handling practices.</p>	

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	<p>fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.</p> <p>' 123.15 General.</p> <p>This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery Products.</p> <p>' 123.16 Process controls.</p> <p>In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, 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.</p> <p>' 123.20 General.</p> <p>This subpart augments subpart A of this part by setting forth specific requirements for processing</p>		

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	<p>fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.</p> <p>' 123.28 Source controls.</p> <p>(a) In order to meet the requirements of subpart A of this part 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.</p> <p>(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.</p> <p>(c) To meet the requirements of paragraph (b) of this</p>		

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	<p>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 Sec. 1240.60(b) of this chapter. 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 Sec. 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:</p> <ul style="list-style-type: none"> (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 (5) The name of the harvester, the name or registration number of 		

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	<p>the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.</p> <p>(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 Sec. 1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:</p> <p>(1) The date of receipt;</p> <p>(2) The quantity and type of shellfish; and</p> <p>(3) The name and certification number of the packer or repacker of the product.</p>		