Status

This is the third edition of the Food and Drug Administrations's (FDA) "Fish and Fishery Products Hazards and Controls Guidance." This Guide relates to FDA's final regulations (21 CFR 123) that require processors of fish and fishery products to develop and implement Hazard Analysis Critical Control Point (HACCP) systems for their operations. Those final regulations were published in the *Federal Register* on December 18, 1995 and became effective on December 18, 1997. The codified portion of the regulations is included in Appendix 8.

FDA intends to revise and reissue this guidance every two to three years as the state of knowledge advances relative to fish and fishery products hazards and controls. The agency will accept public comment on this third edition of the guidance for consideration in drafting the fourth edition. Comments should be submitted to:

U.S. Food and Drug Administration
Dockets Management Branch (HFA-305)
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Comments should be identified with Docket Number 93N-0195.

This guidance is being issued as a companion document to "HACCP: Hazard Analysis Critical Control Point Training Curriculum," which was developed by the Seafood HACCP Alliance for Training and Education. The Alliance is an organization of federal and state regulators, including FDA, academia, and the seafood industry. FDA encourages processors of fish and fishery products to use the two documents together in the development of a HACCP system. Copies of the training document may be obtained from:

Florida Sea Grant
IFAS - Extension Bookstore
University of Florida
P.O. Box 110011
Gainesville, FL 32611-0011
1-800-226-1764

Purpose

The primary purpose of this guidance is to assist processors of fish and fishery products in the development of their HACCP plans. Processors of fish and fishery products will find information in this guidance that will help them identify hazards that are associated with their products, and help them formulate control strategies.

Another purpose of this guidance is to help consumers and the public generally to understand commercial seafood safety in terms of hazards and their controls. This guidance does not specifically address safe handling practices by consumers or by retail establishments, although many of the concepts contained in this guidance are applicable to both.

This guidance is also intended to serve as a tool to be used by federal and State regulatory officials in the evaluation of HACCP plans for fish and fishery products.

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Scope & Limitations

The controls and practices provided in this guidance are recommendations and guidance to the fish and fishery products industry. This guidance provides information that would likely result in a HACCP plan that is acceptable to FDA. However, it is not a binding set of requirements. Processors may choose to use other control measures, as long as they provide an equivalent level of assurance of safety for the product. However, processors that chose to use other control measures (e.g. critical limits) are responsible for scientifically establishing their adequacy.

The information contained in the tables in Chapter 3 and in Steps #10 and 11 in Chapters 4-21 provide guidance for determining which hazards are "reasonably likely to occur" in particular fish and fishery products under ordinary circumstances. The tables should not be used separately for this purpose. The tables list potential hazards for specific species and finished product types. This information must be combined with the information in the subsequent chapters to determine the likelihood of occurrence.

This guidance is not a substitute for the performance of a Hazard Analysis by a processor of fish and fishery products, as required by FDA's regulations. Hazards not covered by this guidance may be relevant to certain products under certain circumstances. In particular, processors should be alert to new or emerging problems (e.g., the occurrence of natural toxins in fish not previously associated with that toxin).

This guidance covers safety hazards associated with fish and fishery products only. It does not cover most hazards associated with non-fishery ingredients (e.g., *Salmonella enteritidis* in raw eggs). However, where such hazards are presented by a fishery product that contains non-fishery ingredients, control must be included in the HACCP plan. Processors may use the principles included in this guide for assistance in developing appropriate controls for these hazards. For example, the hazard of food allergens and food intolerance substances that are part of or directly added to the food can be controlled using the principles described in Chapter #19. As a further assistance in this regard, Appendix 6 provides a list of the most common food allergens that can pose a health risk to certain sensitive individuals.

This guidance does not cover the hazard associated with the formation of *Clostridium botulinum* toxin in low acid canned foods (LACF) or shelf-stable acidified foods. Mandatory controls for this hazard are contained in the LACF regulation (21 CFR 113) and the acidified foods regulation (21 CFR 114). Such controls need not be included in HACCP plans for these products.

This guidance does not cover the sanitation controls required by the Seafood HACCP regulation. However, the maintenance of a sanitation monitoring program is an essential prerequisite to the development of a HACCP program. If necessary sanitation controls are not included in a prerequisite sanitation monitoring program, they must be included in the HACCP plan. It is the agency's intent to provide guidance on the development of sanitation standard operating processes and sanitation monitoring programs in the future.

This guidance does not describe corrective action or verification records, because these records are not required to be listed in the HACCP plan. Nonetheless, such records must be maintained, where applicable. Likewise, it does not recount the specific requirements for the content of records that are set out in § 123.9(a).

This guidance does not cover verification activities such as reassessment of the HACCP plan and/or the hazard analysis and review of consumer complaints, that are mandated by § 123.8.

The guidance also does not provide specific guidance to importers of fish and fishery products for the development of required importer verification procedures. However, the information contained in the text, and, in particular, in Appendix 5, should prove useful for this purpose. Additionally, it is the agency's intent to provide more specific guidance for importers, either in future editions of this guidance, or in a separate guidance document.

Changes in this Edition

Following is a summary of the most significant changes in this edition of the guidance.

The information contained in Table 3-1 (Potential Vertebrate Species Related Hazards) is modified as follows:

- Dace (*Rhinichthys* spp.) is now listed as having a potential pesticides and environmental contaminants hazard;
- Alewife or river herring (*Alosa pseudoharengus*) is now listed as having a potential scombrotoxin (histamine) hazard;
- Wild-caught freshwater salmon (*Oncorhynchus* spp., *Salmo salar*) is no longer listed as having a potential aquaculture drug hazard, an error in the Second Edition;
- Mackerel (*Scomber scombrus*) is no longer listed as having a potential natural toxin (PSP) hazard.

The information contained in Table 3-3 (Potential Process Related Hazards) is modified as follows:

- Smoked fish is now listed as having a potential *C. botulinum* hazard only when it is reduced oxygen packaged and distributed or stored refrigerated;
- A number of products are now listed in Table 3-3 as having potential glass inclusion hazards;
- Dried fish is now listed as having a potential *C. botulinum* hazard;
- Fully cooked prepared foods are now listed as having potential pathogen survival through pasteurization and pathogen contamination after pasteurization hazards.

The recommendations in Chapter 4 for the control of pathogens from the harvest area are changed as follows for consistency with 1998 and 1999 Interstate Shellfish Sanitation Conference actions:

- Raw consumption warnings on tags of molluscan shellfish shellstock containers are now recommended only if the shellstock is intended for raw consumption and the recommended language has been modified;
- Additional information is included about the control of *Vibrio parahaemolyticus* in shellstock intended for raw consumption, including information about water sampling for *Vibrio parahaemolyticus* performed by Shellfish Control Authorities under certain conditions;
- Specific controls are now recommended for the control of *Vibrio parahaemolyticus* in oyster shellstock intended for raw consumption if the oysters are harvested in an area which has been confirmed as the original source of oysters associated with two or more *V. parahaemolyticus* illnesses in the past three years. The new control strategy example relies on the following critical limits for the time from harvest to refrigeration, and is based on the Average Monthly Maximum Air Temperature (AMMAT):
  - For AMMAT of less than 66˚F (less than 19˚C): 36 hours
  - For AMMAT of 66˚F to 80˚F (19˚C to 27˚C): 12 hours
  - For AMMAT greater than 80˚F (greater than 27˚C): 10 hours;
- For the control of *Vibrio vulnificus*, the critical limits recommended for the time from harvest to refrigeration for shellstock intended for raw consumption, based on Average Monthly Maximum Water Temperature (AMMWT), are now:
  - For AMMWT of less than 65˚F (less than18˚C): 36 hours
  - For AMMWT of 65 to 74°F (18 to 23°C): 14 hours;
  - For AMMWT of greater than 74 to 84°F (greater than 23 to 28°C): 12 hours;
  - For AMMWT of greater than 84°F (greater than 28°C): 10 hours;
- For the control of pathogens other than *Vibrio parahaemolyticus* and *Vibrio vulnificus*, the critical limits recommended for the time from harvest to refrigeration for shellstock intended for raw consumption are now:
  - For AMMAT of less than 66°F (less than 19°C): 36 hours;
  - For AMMAT of 66 to 80°F (19 to 27°C): 24 hours;
  - For AMMAT of greater than 80°F (greater than 27°C): 20 hours.

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The recommendations in Chapter 4 for the control of pathogens from the harvest area are additionally changed as follows:

- The information on pathogens in molluscan shellfish is now more clearly divided into two categories:
  - The control of pathogens of human or animal origin;
  - The control of naturally occurring pathogens;
- The recommended goal of pasteurization for the control of *Vibrio vulnificus* is now more clearly defined as the reduction of the pathogen to nondetectable levels [i.e., less than 3 MPN/gram, as defined by the National Shellfish Sanitation Program (NSSP)].

The recommendations in Chapter 5 for the control of parasites are changed as follows:

- The results of a survey of U.S. gastroenterologists on U.S. seafood-borne parasitic infections are now cited;
- The recommended freezing times/temperatures are now:
  - Freezing and storing at -4˚F (-20˚C) or below for 7 days (total time); or
  - Freezing at -31˚F (-35˚C) or below until solid and storing at -31˚F (-35˚C) or below for 15 hours; or
  - Freezing at -31˚F (-35˚C) or below until solid and storing at -4˚F (-20˚C) or below for 24 hours;
- Because of the changes in the recommended critical limits, the recommended control strategies now refer only to external temperatures during freezing and to the length of time that the fish is held at the appropriate freezer temperature or the length of time that the fish is held after it is solid frozen, whichever is appropriate;
- The parasite hazard is no longer considered reasonably likely to occur if the finished product is fish eggs that have been removed from the skein and rinsed.

The recommendations in Chapter 6 for the control of natural toxins are changed as follows:

- PSP in lobster is no longer considered a significant hazard because the levels found in lobster tomale are not likely to pose a health hazard unless large quantities are eaten from a heavily contaminated area.

The recommendations in Chapter 7 for the control of scombrotoxin formation are changed as follows:

- Information is now provided about the salt-tolerant and facultative anaerobic nature of some of the histamine-forming bacteria, raising concern for scombrotoxin formation in some salted and smoked fishery products and in fishery products packed in reduced oxygen environments (e.g. vacuum packaging);
- The on-board chilling recommendations are significantly modified as follows:
  - Generally, fish should be placed in ice or in refrigerated seawater or brine at 40˚F (4.4˚C) or less within 12 hours of death, or placed in refrigerated seawater or brine at 50˚F (10˚C) or less within 9 hours of death;
  - Fish exposed to air or water temperatures above 83˚F (28.3˚C), or large tuna (i.e., above 20 lbs.) that are eviscerated before on-board chilling, should be placed in ice (including packing the belly cavity of large tuna with ice) or in refrigerated seawater or brine at 40˚F (4.4˚C) or less within 6 hours of death;
  - Large tuna (i.e., above 20 lbs.) that are not eviscerated before on-board chilling should be chilled to an internal temperature of 50˚F (10˚C) or less within 6 hours of death;
- It is now recommended that, when refrigerated brine or seawater is used for chilling fish on the harvest vessel, the temperature of the cooling media be monitored and recorded (harvest vessel control strategy only);
- It is now recommended that the critical limits at receiving from the harvest vessel include a requirement that the chilling of fish on the harvest vessel be continued to bring the internal temperature of the fish to 40˚F (4.4˚C) or less (harvest vessel control strategy only);
- It is now recognized that certain data previously expected to be recorded by the harvester on harvest vessel records may, under certain circumstances, be more efficiently recorded by the primary (first) processor on receiving records (harvest vessel control strategy only), such as:
  - Method of capture;
  - Air and water temperature;
  - Method of onboard cooling;
  - Estimated date and time of death;

• It is now recognized that, as an alternative to the primary processor receiving harvest vessel records that are maintained by the vessel operator, certain harvest operations may lend themselves to monitoring and record keeping entirely by the primary processor. This arrangement is suitable only if the primary processor has direct knowledge about those aspects of the harvesting practices that must be controlled to ensure that the appropriate critical limits are met. For example, if the harvest vessel leaves from the processor's facility and returns with the iced or refrigerated catch to the processor's facility within the appropriate time limits for on board icing or refrigeration of the catch, under certain circumstances it may be possible for the processor to perform all of the monitoring and record keeping functions ordinarily performed by the harvester;

• It is now recommended that the critical limits at receiving from the harvest vessel include a requirement that fish delivered in less than 12 hours after death should exhibit evidence that chilling began on the harvest vessel (e.g. at receipt the internal temperature of the fish is below ambient air and water temperature);

• It is now recommended that the date and time of off-loading be recorded on receiving records maintained by the primary processor;

• It is no longer recommended that primary (first) processors check for the adequacy of ice, refrigerated seawater, refrigerated brine, or other cooling media at receipt from the harvest vessel;

• It is no longer recommended that secondary processors check the internal temperature of fish received from other processors. However, it is now recommended that the checks for the adequacy of ice or other cooling media at receiving be verified periodically by measuring the internal temperature of the fish to ensure that it is at or below 40˚F (4.4˚C);

• It is now recommended that the accuracy of time/temperature data loggers or recorder thermometers on vehicles delivering fish to secondary processors be checked on all new suppliers' vehicles and at least quarterly thereafter;

• The table of approximate safe shelf-life for scombrotoxin-forming species which was previously present is replaced with more generalized guidance because the values contained in the table were apparently being misused as binding limits;

• The recommended critical limits for storage and processing are significantly modified as follows:

- For fish that have not been previously frozen: the fish are not exposed to ambient temperatures above 40˚F (4.4˚C) for more than 4 hours, cumulatively, if any portion of that time is at temperatures above 70˚F (21˚C); or the fish are not exposed to ambient temperatures above 40˚F (4.4˚C) for more than 8 hours, cumulatively, as long as no portion of that time is at temperatures above 70˚F (21˚C);
- For fish that have been previously frozen: the fish are not exposed to ambient temperatures above 40˚F (4.4˚C) for more than 12 hours, cumulatively, if any portion of that time is at temperatures above 70˚F (21˚C); or the fish are not exposed to ambient temperatures above 40˚F (4.4˚C) for more than 24 hours, cumulatively, as long as no portion of that time is at temperatures above 70˚F (21˚C);

• There is no longer a minimum length of frozen storage in the definition of "previously frozen product;"

• It is now recommended that ambient air temperature be monitored at the processing and packaging critical control points;

• A new concept is introduced to assist in the assessment of whether the hazard is significant at receiving by the primary (first) processor: the hazard may not be significant if the worst case environmental conditions (i.e. air and water temperatures) during the harvest season in a particular region would not permit the formation of histamine during the time necessary to harvest and transport the fish to the primary processor;

• The recommendations previously provided for refrigerated storage are now also recommended for refrigerated processing;

• For purposes of selecting fish for histamine analysis and sensory examination it is now recommended that lots be identified that contain only one species;

• It is now recommended that the number of fish tested for internal temperature at receipt by the primary (first) processor be one per ton for lots of 10 tons or more, and one per 1000 lbs. for lots of under 10 tons, as long as at least 12 fish per lot are examined;

• It is now recommended that no less than 18 fish per lot be analyzed for histamine at receipt by the primary (first) processor except where the lot is smaller than 18 fish (histamine testing control strategy only). The fish

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collected for analysis may be composited for analysis if the critical limit is reduced accordingly;
• A sample size of 60 fish and a reject level of any fish at or above 50 ppm histamine is now recommended as one option for corrective action when the processing critical limits have been violated;
• Another option is now provided for corrective action when the sensory critical limit has been violated (primary processor):
  - Perform histamine analysis on the lot (i.e. fish of common origin) by analyzing 60 fish (or the entire lot for lots smaller than 60 fish) and rejecting the lot if any are found with histamine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the same rate, rejecting those portions where a unit greater than or equal to 50 ppm is found. The fish collected for analysis may be composited for analysis if the critical limit is reduced accordingly;

AND

  - Perform a sensory examination of all fish in the lot;

• It is now recognized that when refrigerated fish are transported only short distances (4 hours or less) from processor to processor, a suitable alternative to requiring continuous monitoring during transit may be for the secondary processor to check the internal temperature of the fish upon receipt;
• It is no longer recommended that maximum indicating thermometers be used to monitor ambient air temperature in storage coolers;
• It is now recommended that high temperature alarms used to monitor ambient air temperature in storage coolers be connected to a 24-hour monitoring service.

The recommendations in Chapter 11 for the control of aquaculture drugs are changed as follows:

• Additional information is now provided about the labeling of approved conditions of use on aquaculture drugs;
• Information is now included about the newly approved drug, chorionic gonadotropin;
• Information is now included about additional approved uses for formalin solution;
• An additional approved manufacturer of tricaine methansolfonate is now listed;
• Thiamine hydrochloride is now listed as a low regulatory priority drug for treatment of thiamine deficiency in salmonids;
• Discontinued use of the supplier until corrections are made is now recommended as a corrective action for all control strategy examples in which aquacultured fish are received from the producer.

The recommendations in Chapter 12 for the control of pathogen growth and toxin formation (other than *Clostridium botulinum*) as a result of time/temperature abuse are changed as follows:

• A third set of recommended critical limits is now provided for control during processing steps: If the product is held at internal temperatures both above and below 70˚F (21.1˚C), exposure times above 50˚F (10˚C) should ordinarily be limited to 4 hours, as long as no more than 2 of those hours are above 70˚F (21.1˚C);
• Additional information and guidance is now provided to assist in the development of critical limits during processing and storage, including:
  - Examples of product time/temperature profiles;
  - A recommendation that most microbiologically sensitive products be stored at or below 40˚F (4.4˚C), except where control of nonproteolytic *C. botulinum* by refrigeration is necessary, in which case storage at 38˚F (3.3˚C) is usually appropriate;
• Additional verification is now recommended, as follows:
  - The accuracy of recorder thermometers and other instruments used to monitor temperature in transportation cargo areas should be checked on new suppliers' vehicles and at least quarterly for each supplier thereafter;
  - When visual checks of ice or cooling media are used to monitor the adequacy of coolant, the internal temperatures of the fish should be periodically checked to ensure that the ice or cooling media is sufficient to maintain product temperatures at 40˚F (4.4˚C) or less;
• There is now a specific acknowledgement that frozen product storage and receipt of frozen raw materials are not likely CCPs;
• Background information on the pathogens of concern now indicates that the infective doses of *Listeria monocytogenes* and *Vibrio parahaemolyticus* are unknown;

• The example HACCP plans in Tables 12-1 and 12-2 are modified to correct an error in the Second Edition, in which the cooked crab cooler step was inadvertently included as a CCP in the Gulf Coast blue crab processing method (Table 12-1), rather than the East Coast blue crab processing method (Table 12-2).
• It is now recognized that when refrigerated fishery products are transported only short distances (4 hours or less) from processor to processor, a suitable alternative to requiring continuous monitoring during transit may be for the secondary processor to check the internal temperature of the fish upon receipt;
• It is no longer recommended that maximum indicating thermometers be used to monitor ambient air temperature in storage coolers;
• It is now recommended that high temperature alarms used to monitor ambient air temperature in storage coolers be connected to a 24-hour monitoring service.

The recommendations in Chapter 13 for the control of *C. botulinum* toxin formation are changed as follows:

• The introductory material is extensively reorganized and revised to provide greater clarity;
• Information is now provided on a recommended minimum oxygen transmission rate for oxygen-permeable packages (10,000 cc/m^2/24 hrs);
• Fishery products packaged in deep containers from which the air is expressed are now identified as presenting a *C. botulinum* toxin formation hazard;
• Hot smoked product in aerobic packaging is no longer identified as presenting a *C. botulinum* toxin formation hazard sufficient to require preventive controls in a HACCP plan. However, note that the Association of Food and Drug Officials recommends a minimum water phase salt content of 2.5% in aerobically-packaged smoked fish;
• Controls are no longer recommended specifically for the control of *C. botulinum* toxin formation as a result of time/temperature abuse during the processing of unpackaged product. Instead it is now recommended that the controls recommended for pathogens other than C. *botulinum* be applied as appropriate. The chapter also acknowledges that *C. botulinum* toxin formation is possible in unpackaged or aerobically packaged product, but that, under those conditions, it requires the type of severe temperature abuse that is not reasonably likely to occur in most food processing environments;
• It is now recognized that when refrigerated fishery products are transported only short distances (4 hours or less) from processor to processor, a suitable alternative to requiring continuous monitoring during transit may be for the secondary processor to check the internal temperature of the fish upon receipt;
• It now states that 20% salt is the level needed to ensure the safety of a shelf stable product relative to all pathogens (based on the maximum salt level for growth of *S. aureus*), rather than providing the apparently misleading statement that 10% salt is the level needed in a shelf stable product for the control of *C. botulinum* type A and proteolytic types B and F;
• It now provides instruction to consult Chapter 12 for information on refrigerated storage temperature critical limits suitable for the control of pathogens other than *C. botulinum*, rather than providing the apparently misleading statement that 50˚F (10˚C) is an appropriate critical limit for the control of *C. botulinum* type A and proteolytic types B and F. Refrigeration at or below 40˚F (4.4˚C) is recommended for the control of all pathogens;
• Specific guidance is now provided for control of *C. botulinum* toxin formation in refrigerated, reduced oxygen packaged, pasteurized fishery products, including: 1) those that receive a nonproteolytic *C. botulinum* pasteurization process in the final container; and 2) those that receive a nonproteolytic *C. botulinum* cook and are then hot filled into the final container;
• Specific guidance is now provided for control of *C. botulinum* toxin formation in refrigerated, reduced oxygen packaged pasteurized surimi-based products, including a recommended control of 2.5% salt in combination with a pasteurization process in the finished product container of 185˚F (85˚C) (internal temperature) for at least 15 minutes;
• The use of recorder thermometers or digital time/temperature data loggers throughout distribution and retail storage and sales is no longer recommended as an alternative to a second barrier to toxin formation by *C. botulinum* type E and nonproteolytic types B and F;
• It is now acknowledged that, for refrigerated products that are packaged in oxygen-permeable packaging, an oxygen-impermeable overwrap may be used to extend shelf life while the product is under the control of the processor, as long as the overwrap is removed before the product leaves the processor's control;

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• It is now recommended that nitrite analysis accompany water phase salt analysis, as appropriate, when such analysis is used as the means of monitoring the brining, dry salting and/or drying steps;
• It is now recommended that the accuracy of time/temperature data loggers or recorder thermometers on vehicles delivering fish to secondary processors be checked on all new suppliers' vehicles and at least quarterly thereafter;
• It is no longer recommended that maximum indicating thermometers be used to monitor ambient air temperature in storage coolers;
• It is now recommended that high temperature alarms used to monitor ambient air temperature in storage coolers be connected to a 24-hour monitoring service.

The recommendations in Chapter 14 for the control of pathogen growth and toxin formation as a result of inadequate drying are changed as follows:

• Controls are now provided for partial drying of refrigerated, reduced oxygen packaged foods, where drying is targeted for the control of *C. botulinum* type E and nonproteolytic types B and F. The controls are designed to ensure that the water activity of the finished product is below 0.97;
• The importance of packaging in preventing rehydration of dried products is now noted.

The recommendations in Chapter 16 for the control of pathogen survival through cooking are changed as follows:

• The concept of exceptionally lethal cooking processes is eliminated;
• Information is now provided about the target organism and degree of destruction for cooking processes, including recommendations that:
  - The target organism should ordinarily be *L. monocytogenes;*
  - The cook should ordinarily provide a 6D process;
• Information is now provided about cooking processes that are designed to eliminate the spores of *Clostridium botulinum* type E and nonproteolytic types B and F, such as cooking of soups and sauces that will be reduced oxygen packaged (e.g. vacuum packaged) and distributed refrigerated. The information includes the recommendation that such products be hot filled in a continuous filling system to minimize the risk of recontamination between cooking and finished product packaging.

The recommendations in Chapter 17 for the control of pathogen survival through pasteurization are changed as follows:

• Information is now provided about the target organism and degree of destruction for pasteurization processes, including recommendations that:
  - The target organism should ordinarily be *Clostridium botulinum* type E and nonproteolytic types B and F if the product is reduced oxygen packaged (e.g. vacuum packaged), does not contain other barriers that are sufficient to prevent growth and toxin formation by this pathogen, and is stored or distributed refrigerated (not frozen);
  - The target organism should ordinarily be *L. monocytogenes* for other products (e.g. frozen products)*;*
  - The pasteurization process should ordinarily provide a 6D reduction in the numbers of the target pathogen.

The recommendations in Chapter 18 for the control of pathogen introduction after pasteurization are changed as follows:

• Information is now provided on hot filling products such as soups and sauces that are cooked to eliminate the spores of *Clostridium botulinum* type E and nonproteolytic types B and F, and then reduced oxygen packaged (e.g. vacuum packaged) and then distributed refrigerated (not frozen). The minimum recommended hot fill temperature, 185˚F (85˚C), is designed to minimize the risk of recontamination between cooking and finished product packaging;
• It is now recommended that cooling water flow rate be controlled when UV treatment is used to treat container cooling water.

The recommendations in Chapter 19 for the control of allergens, food intolerance substances and prohibited food and color additives are changed as follows:

• Controls similar to those previously recommended for use by primary processors are now recommended for use by secondary processors, except that reliance on raw material labeling or documents accompanying the raw material shipment (in the case of unlabeled product) are included as recommended control strategies when the raw material is received from another processor;

• Undeclared sulfiting agents are now identified as a potential hazard in cooked octopus;
• General information is now provided on the control of allergenic proteins in foods. Controls similar to those previously recommended to ensure proper labeling for certain food and color additives are now recommended if foods that contain allergenic proteins are part of or are directly added to a fishery product. Additionally, reference is made to controlling inadvertent introduction of allergenic proteins, because of cross-contact, through a rigorous sanitation regime, either as part of a prerequisite program or as part of HACCP itself.

The recommendations in Chapter 20 for the control of metal inclusion are changed as follows:

• The reference to the point at which FDA's Health Hazard Evaluation Board has supported regulatory action is corrected to indicate a metal fragment of between 0.3" [7 mm] and 1.0" [25 mm];
• The recommended corrective actions to regain control over the operation after metal is detected in the product now include:
  - Locating and correcting the source of the metal fragments; and
  - Making adjustments to the materials, equipment, and/or process, as needed, to prevent future introduction of metal fragments;
• Injection needles and metal ties are now identified as additional sources of metal fragments in the processing environment;
• It is now recognized that visually inspecting equipment for damage or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders, and wire-mesh belts.

Chapter 21 has been added to provide guidance on the control of glass inclusion as a result of the use of glass containers.

The recommendations in the Appendices are changed as follows:

• The maximum water phase salt level for growth of *Bacillus cereus* is now given as 10 percent;
• The maximum water phase salt level for growth of *Staphylococcus aureus* is now given as 20 percent;
• The minimum temperature for growth of pathogenic strains of *Escherichia coli* is now given as 43.7˚F (6.5˚C);
• The maximum temperature for growth of *Vibrio parahaemolyticus* is now given as 113.5˚F (45.3˚C);
• Maximum cumulative exposure times are now provided for *Bacillus cereus,* as follows: 5 days at temperatures between 39.2 and 43˚F (4-6˚C); 17 hours at temperatures between 44 and 50˚F (7-10˚C); 6 hours at temperatures between 51 and 70˚F (11-21˚C); and 3 hours at temperatures above 70˚F (above 21˚C);
• Maximum cumulative exposure times are now provided for *Clostridium perfringens*, as follows: 21 days at temperatures between 50 and 54˚F (10-12˚C); 1 day at temperatures between 55 and 57˚F (13-14˚C); 6 hours at temperatures between 58 and 70˚F (15-21˚C); and 2 hours at temperatures above 70˚F (above 21˚C);
• The maximum cumulative exposure times for proteolytic *Clostridium botulinum* are now given as: 11 hours for temperatures between 50 and 70˚F (10-21˚C); and 2 hours for temperatures above 70˚F (above 21˚C);
• The maximum cumulative exposure times for nonproteolytic *Clostridium botulinum* are now given as: 7 days for temperatures between 37.9 and 41˚F (3.3 - 5˚C); 2 days for temperatures between 42 and 50˚F (6-10˚C); 11 hours for temperatures between 51 and 70˚F (11-21˚C); and 6 hours for temperatures above 70˚F (above 21˚C);
• The maximum cumulative exposure times for *Listeria monocytogenes* are now given as: 7 days for temperatures between 31.3 and 41˚F (-0.4 - 5˚C); and 2 days for temperatures between 42 and 50˚F (6-10˚C);
• The maximum cumulative exposure time for *Shigella* spp. is now given as 12 hours for temperatures between 51 and 70˚F (11-21˚C);

• Tables of lethal rates and process times for 6D cooks for a range of internal product temperatures are now provided for *Listeria monocytogenes* and nonproteolytic *Clostridium botulinum* type B (Tables A-3 and A-4, respectively).
• The FDA guideline for hard or sharp objects, found in Compliance Policy Guide #555.425, is included in the listing of FDA and EPA guidance levels – generally 0.3" [7 mm] to 1.0" [25 mm] in length;
• A listing of the most common food allergens is included (Appendix 6).

Numerous additional references are now included in the Bibliography, and a number of the original references are corrected.

In addition to using the above listing to direct you to relevant changes in this guidance, you should carefully review the chapters that are applicable to your product and process.

Additional Copies

Single copies of this guidance may be obtained as long as supplies last from FDA district offices and from:

U.S. Food and Drug Administration
Office of Seafood
200 C St., S.W.
Washington, D.C. 20204
202-418-3133 (phone)
202-418-3196 (fax)

Multiple copies of this guidance may be obtained from:

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