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21 CFR Parts 123 and 1240
Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 123 and 1240

[Docket No. 93N–0195]

RIN 0910–AA10

Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting final regulations to ensure the safe and sanitary processing of fish and fishery products (hereinafter referred to as seafood), including imported seafood. The regulations mandate the application of Hazard Analysis Critical Control Point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control that can be used by processors to ensure the safety of their products to consumers. FDA is issuing these regulations because a system of preventive controls is the most effective and efficient way to ensure that these products are safe.

DATES: Effective December 18, 1997. Submit written comments on the information collection requirements by February 16, 1996.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip C. Spiller, Center for Food Safety and Applied Nutrition (HFS–401), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3133.

For further information concerning the guidance entitled "Fish and Fishery Products Hazards and Controls Guide," contact: Donald W. Kraemer (address above).

SUPPLEMENTARY INFORMATION: The contents of this preamble are listed in the following outline:

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I. Background

A. The Proposal

In the **Federal Register** of January 28, 1994 (59 FR 4142), FDA published a proposed rule to establish requirements relating to the processing and importing of seafood for commercial distribution in the United States. The requirements involved the application of HACCP principles by processors and importers to ensure food safety to the maximum extent practicable. HACCP is a system by which food processors evaluate the kinds of hazards that could affect their products, institute controls to keep these hazards from occurring or to significantly minimize their occurrence, monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

In addition to publishing the proposed rule, FDA published in the **Federal Register** of April 7, 1994 (59 FR 16655), a notice of availability of draft guidelines, primarily directed toward processors, on how to develop HACCP controls for specific types of processing operations. The notice of availability requested comments on the draft. Among other things, these draft guidelines, which were titled the "Fish and Fishery Products Hazards and Controls Guide" (the Guide), inventoried known likely food safety hazards associated with many species of seafood and many processing methods and made recommendations on ways to control those hazards. Comments received by FDA on the draft Guide are under review. The agency intends to publish the first edition of the Guide before the effective date of these regulations.

FDA established on the proposed rule a comment period of 90 days, to end on April 28, 1994. The agency also asked for comment on the draft guidelines by the same date. During that comment period, FDA held public meetings in nine cities to help ensure that the public was aware of the proposal, to answer questions about its contents, and to encourage participation in the rulemaking process through the submission of comments. In addition, at these meetings, FDA staff explained to the public how to use the draft guidelines to develop HACCP controls in specific processing operations.

The agency received several written requests for an extension of the comment period. After considering these requests, FDA published a notice in the **Federal Register** on April 7, 1994 (59 FR 16578), announcing a 30-day extension of the comment period to May 31, 1994, for both the proposed rule and the draft guidelines.

B. Factual Basis for the Proposal—Summary

In the preamble to the proposed rule, FDA stated five principal reasons for this initiative: (1) To create a more effective and efficient system for ensuring the safety of seafood than currently exists; (2) to enhance consumer confidence; (3) to take advantage of the developmental work on the application of HACCP-type preventive controls for seafood that had already been undertaken by industry, academia, some States, and the Federal government; (4) to respond to requests by seafood industry representatives that the Federal government institute a mandatory, HACCP-type inspection system for their products; and (5) to provide U.S. seafood with continued access to world markets, where HACCP-type controls are increasingly becoming the norm.

The preamble to the proposal cited the conclusion of a 1991 study on seafood safety by the National Academy of Sciences' (NAS) Institute of Medicine that, while most seafoods on the market are unlikely to cause illness to the consumer, there are significant areas of risk and illnesses that do occur. The study concluded that improvements in the current system of regulatory control are needed and repeatedly recommended the application of HACCP controls where warranted.

Ensuring the safety of seafood presents special challenges to both the industry and the regulator. Seafood consists of hundreds of edible species from around the world. Depending upon species and habitat, seafood can be subject to a wide range of hazards before harvest, including bacteria and viruses, toxic chemicals, natural toxins, and parasites. The harvesting of previously underutilized species—a practice that is increasing because of the depletion of traditionally harvested species—can be expected to create new source and process hazards that must be identified and controlled.

Unlike beef and poultry, seafood is still predominately a wild-caught flesh food that frequently must be harvested under difficult conditions and at varying distances from processing, transport, and retail facilities. It is also subject to significant recreational harvest, some of which finds its way into commercial channels. As fish farming (aquaculture) increases, new problems emerge as a result of habitat, husbandry, and drug use.

An additional complicating factor in ensuring the safety of seafood is the fact that no other flesh food is imported in the quantity, or from as many countries, as seafood. Over 55 percent of seafood consumed in this country is imported from approximately 135 countries. Several of these countries have advanced regulatory structures for seafood safety, but many others are developing nations that lack infrastructures capable of supporting national programs for seafood regulations comparable to those in more developed nations.

To ensure safety, it is of utmost importance that those who handle and process seafood commercially understand the hazards associated with this type of food, know which hazards are associated with the types of products with which they are involved, and keep these hazards from occurring through a routine system of preventive controls. For the most part, however, seafood processors and importers are not required, through licensure or examination, to demonstrate an understanding of seafood hazards as a prerequisite to being able to do business. In fact, there is evidence that such an understanding does not exist in a significant portion of the industry. A survey conducted by FDA from 1992 to 1993 of manufacturers of ready-to-eat seafood products revealed that, in significant measure, firms have not been employing the types of preventive processing controls necessary to ensure a safe product by design. FDA and State surveys have also revealed that many

processors of smoked and smoke-flavored fish are operating outside of the parameters that have been demonstrated through scientific research to be necessary to ensure that the hazard from botulism is adequately controlled.

Because of seafood's unique characteristics (e.g., the fact that it is predominantly wild caught and presents a wide range of possible hazards), FDA began to question whether the current Federal regulatory system, which was developed for the general food supply, is best suited for the seafood industry. Seafood processors are subject to periodic, unannounced, mandatory inspection by FDA. These inspections provide the agency with a "snapshot" of conditions at a facility at the moment of inspection, but assumptions must be made about conditions before and after that inspection. Concern about the reliability of these assumptions over the intervals between inspections creates questions about the adequacy of the system.

Inspections today verify the industry's knowledge of hazards and controls largely by inference. Whether a company produces products that are adulterated, or whether conditions in its plant are consistent with current good manufacturing practice (CGMP), are measures of how well the company understands what is necessary to produce a safe and wholesome product. This system places a burden on the Government to find a problem and to prove that it exists, rather than on the firm to establish for itself, for the regulator, and for consumers, that it has adequate controls in place to ensure safety.

Given the nature and frequency of the current inspection system for seafood, it has failed to produce a situation in which the public has full confidence in the safety and wholesomeness of these products. There has been a similar failure with respect to imports.

Media and other public attention on seafood safety, and on the adequacy of the current regulatory program for seafood, has been substantial in recent years. Many hearings on the sufficiency and direction of the Federal seafood safety program have been held in both Houses of Congress since the late 1980's, and numerous bills have been considered for the stated purpose of improving seafood safety. This public concern has motivated representatives of the U.S. seafood industry to request that FDA develop a HACCP-based program for these products.

Although not a public health issue, international trade is also a major consideration in determining the advisability and benefits of a new system of seafood regulation. Participation in the international trade in seafood is critical to U.S. consumers and to the U.S. seafood industry. The United States is the world's second largest seafood importing nation and the second largest exporter of fishery products.

The international movement toward harmonization, coupled with the Codex Alimentarious Commission's adoption of HACCP for international use, clearly argue for the adoption of this approach in the United States for seafood. Failure by the United States to adopt a mandatory, HACCP-based system could ultimately undermine its export success, with considerable economic consequences. Such failure also would undermine the United States ability to meet growing international expectations that it enter into mutual recognition-type agreements with trading partners based on HACCP.

II. The Comments

FDA received over 250 submissions from over 200 commentors on both the proposed regulations and the draft Guide. Individual companies, the majority of which are in the seafood business, submitted slightly over half of the comments. Nearly 40 trade associations submitted comments. As with the companies, the majority of these associations represent seafood interests, but a significant minority have memberships reflecting a range of food products.

Comments were also received from consumer advocacy and similar groups, and coalitions of such groups. All totaled, the views of over 50 organizations were represented in these comments.

Other commenters included State agencies, the Association of Food and Drug Officials (AFDO), the Interstate Shellfish Sanitation Conference (ISSC), several scientific associations and bodies, departments of three universities, foreign governments, and about 25 individuals.

Overall, the comments covered virtually every aspect of the proposal and guidelines. FDA appreciates the effort, interest, and thoughtfulness reflected by these comments.

The following materials address the significant comments that were received on the proposed regulations, both on the specific provisions of the proposal and on related matters. The materials on the provisions of the proposed regulations explain, among other things, why the agency did or did not modify the provisions based on the comments. Any provisions not addressed below were not changed substantively or were not the subject of significant comment.

FDA will respond to those comments that relate solely to the draft Guide when the first edition of that document is completed and made available to the public. The agency intends to address those comments in a notice of availability to be published in the **Federal Register**.

A. Legal Basis

1. Introduction

About 25 comments addressed the legal basis for these regulations. Nearly half of these comments were either companies that process foods other than seafood or trade associations that represent such companies, some of who indicated that they were motivated to comment, at least in part, by the possible precedent that these regulations could set for HACCP programs beyond seafood. Some of these comments deferred comment on the legal basis for the HACCP regulations for seafood but commented on whether the legal basis that FDA was proposing for seafood would be appropriate for mandatory HACCP programs for other kinds of foods.

FDA is issuing these HACCP regulations for seafood under various sections of the Federal Food, Drug, and Cosmetic Act (the act), including, most significantly, sections 402 (a)(1) and (a)(4) and 701(a) (21 U.S.C. 342 (a)(1) and (a)(4) and 371(a)). Section 402(a)(1) of the act states that a food is adulterated if it bears or contains any poisonous or deleterious substance that may render the food injurious to health. Section 402(a)(4) of the act states that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. It is important to recognize that section 402(a)(4) of the act addresses conditions that may render a food injurious to health, rather than conditions that have actually caused the food to be injurious. See *United States* v. *1,200 Cans, Pasteurized Whole Eggs, Etc.*, 339 F. Supp. 131, 141 (N.D. Ga. 1972). The question is thus whether the conditions in a plant are such that it is reasonably possible that the food may be rendered injurious to health. The agency believes that, if a seafood processor does not incorporate certain basic controls into its procedures for preparing, packing, and holding food, it is reasonably possible that the food may be rendered injurious to health and, therefore, adulterated under the act. Section 701(a) of the act

authorizes the agency to adopt regulations for the efficient enforcement of the act.

2. General Authority

1. One comment stated that FDA had not met its responsibility to present the shortcomings in the existing law when demonstrating the need for these regulations.

FDA believes that this comment is misguided. The agency's statutory authority is not deficient in this area. FDA does have a responsibility, however, to demonstrate that there is a need for the regulations, and that the regulations are reasonably related to the purposes of the act that they are designed to advance. FDA has fulfilled this responsibility.

As outlined above, the act provides a broad statutory framework for Federal regulation to ensure human food will not be injurious to health and to prevent commerce in adulterated foods. As the record in this proceeding amply demonstrates, there is a range of circumstances and conditions that have raised concerns about how the safety of seafood sold in this country is ensured. Given these concerns and its responsibility under the act, FDA has concluded that it is necessary to require that firms incorporate certain basic measures into how they process seafood. The agency also concludes that failure to incorporate these measures into a firm's processing procedures would mean that the firm would be producing the product under insanitary conditions whereby it may be rendered injurious to health. (See *United States* v. *Nova Scotia Food Products Corp.*, 568 F.2d 240, 247 (2d Cir. 1977).)

2. A few comments took the view that FDA lacked the authority to issue these regulations because Congress had considered legislation relating to seafood safety in recent years but had not enacted it. Much of this legislation contained provisions authorizing the establishment of a mandatory Federal inspection program based on HACCP-type principles. According to the comments, Congress' failure to authorize this program after considering doing so indicated that the contents of FDA's seafood HACCP regulations remain within the domain of Congress and have not been delegated to FDA to implement.

FDA does not agree with this contention. Unquestionably, seafood safety has received considerable attention from Congress in recent years, most notably in the late 1980's through the early 1990's. Many hearings were held on the subject in both the House of Representatives and the Senate during this period, and several bills were introduced in both chambers. The high water mark for this activity occurred at the end of the 101st Congress when differing seafood safety bills passed both chambers. These bills could not be reconciled before the end of the term, however, so nothing was enacted. Legislation introduced in the 102d Congress did not pass either chamber.

The fact that Congress has considered the issue of seafood safety, however, does not preclude FDA from implementing a mandatory seafood HACCP program. The effect of legislation that was never enacted on a Federal agency's initiatives was considered in *National Confectioners Association* v. *Califano*, 569 F.2d 690, 693 n.9 (D.C. Cir. 1978), a case involving a challenge to FDA's statutory authority to issue good manufacturing practice regulations for candy making. The court rejected an argument that the existence of legislation that was not enacted that would have given FDA express authority to require some of the things that the agency included in its regulations indicated that Congress intended to exclude such authority from the act as it was then written. Instead, as will be discussed below, in upholding the validity of the regulations, the court looked at whether the statutory scheme as a whole justified the promulgation of the regulations.

It is true that a deliberate refusal by Congress to authorize a specific program would at least be one factor to be weighed in determining the validity of a regulation. See *Toilet Goods Association* v. *Gardner*, 387 U.S. 158 (1967). The expiration of the 101st Congress before competing seafood bills could be reconciled did not, however, amount to a refusal on the part of Congress to authorize a mandatory HACCP program, including HACCP-based inspections for seafood. Thus, FDA concludes that there is no merit to the comments' assertion.

3. Insanitary Conditions

3. Several comments, most of whom were trade associations or companies involved in the processing of products other than seafood, questioned whether section 402(a)(4) of the act was an appropriate authority upon which to base a mandatory HACCP program. Most of the concern hinged on whether a failure to have a HACCP plan, or to keep HACCP records, could really be considered an "insanitary" condition under section 402(a)(4) of the act. Some questioned whether safety issues relating to chemical or physical hazards, or to pesticides, unapproved additives, and drug residues, as included in the proposed regulations, could be deemed to have been the result of insanitary conditions. Two comments expressed the view that section 402(a)(4) of the act does not concern food safety generally but only safety problems caused by insanitary conditions.

The relevant case law supports a broad reading of "insanitary." In *Nova Scotia, supra*, 568 F.2d at 247, the court read "insanitary" to cover a wide set of circumstances necessary to ensure that food was not produced under conditions that may render it injurious to health. Specifically, the court concluded that FDA's regulations mandating time-temperature-salinity requirements for smoked fish products were within the agency's statutory authority under section 402(a)(4) of the act. The court rejected the argument that "insanitary" limited coverage under section 402(a)(4) of the act only to bacterial hazards that could enter the raw fish from equipment in the processing environment and not to proper processing to kill bacteria that entered the processing facility in the raw fish itself.

Acceptance of a restrictive reading of section 402(a)(4) of the act, the court in *Nova Scotia* noted, would probably invalidate several existing FDA regulations, including those relating to the thermal processing of low-acid canned foods in part 113 (21 CFR part 113). When dealing with the public health, the court concluded, the statute should not be read too restrictively but consistent with the act's overall purpose to protect the public health. (See also *United States* v. *Bacto-Unidisk*, 394 U.S. 784, 798 (1969); *United States* v. *Dotterweich*, 320 U.S. 277, 280 (1943).)

4. Notwithstanding these cases, one comment cited the case of *United States* v. *General Foods Corp*, 446 F. Supp 740 (1978), *aff'd* 591 F.2d 1332 (2d Cir. 1978), for the proposition that a failure to have a HACCP plan could not alone be a violation of section 402(a)(4) of the act because it would not constitute insanitation.

FDA does not agree that the *General Foods* case stands for this proposition. Rather, the court in *General Foods* explicitly recognized that "[b]ecause the purpose of 402(a)(4) is to prevent contamination, or nip it in the bud, actual contamination of the finished product need not be shown." *Id.* at 752. Significantly, the court appeared to be impressed with the preventive controls that were in place in the defendant's plant and took these into consideration in deciding that the agency had failed to prove that section 402(a)(4) of the act had been violated. However, the court did not deal at all with the limits on

FDA's authority to do rulemaking under sections 402(a)(4) and 701(a) of the act to establish standards for such preventive controls.

Thus, it is not inconsistent with *General Foods* for FDA to adopt HACCP regulations that are designed to define the minimum steps that a seafood processor must take to ensure that the food that it produces is not prepared under conditions that may render it injurious to health. Clearly, given the risks inherent in many seafood operations, if a processor does not identify the critical control points in its process, and does not monitor what goes on at those points, there is a reasonable possibility that the food that it produces will be injurious to health.

A primary objective of the seafood HACCP regulations is to establish a system of preventive controls for human food safety. The HACCP plan is a fundamental step in the development of these controls. It is the step in which the manufacturer analyzes its process, identifies the points at which problems may occur, and establishes the parameters that must be met if those problems are to be avoided. Thus, failure to have a HACCP plan would, in fact, constitute an "insanitary condition" as this term must be understood in light of the relevant case law.

Section 402(a)(4) was added to the act to ensure "the observance of those precautions which consciousness of the obligation imposed upon producers of perishable food products should require in the preparation of food for consumption by human beings." Hearings before the Senate Committee on Commerce, S. 2800, 73d Cong., 2d Sess., Mar. 1934, as cited in *United States v. 1,200 Cans, Pasteurized Whole Eggs, Etc., supra*, 339 F. Supp. 140–141. Clearly, HACCP reflects the emerging, internationally recognized understanding of the precautions necessary to produce safe food. These regulations embrace HACCP and provide processors with directions for establishing HACCP systems and operating them as a matter of routine custom and habit that will ensure the safety of the food that they produce. Thus, FDA finds that operation under an effective HACCP system is necessary to meet a processor's obligation under section 402(a)(4) of the act.

4. Records

In *Confectioners,* the court upheld FDA's authority to issue regulations under section 402(a)(4) of the act that included recordkeeping requirements. The recordkeeping provisions of the regulations were challenged on the grounds that they would permit prosecution where processing conditions were completely sanitary, but the records were deficient. Such an outcome, it was argued, would be beyond the scope of section 402(a)(4) of the act.

Citing *Toilet Goods,* the court rejected this argument and held that the primary consideration was whether the statutory scheme as a whole, not just section 402(a)(4) of the act, justified the agency's regulations. The court pointed out that this consideration involved an inquiry into practicalities as well as statutory purpose, i.e., enforcement problems encountered by FDA and the need for various forms of supervision in order to accomplish the goals of the act.

5. Two comments expressed the view that the holding in *Confectioners* should be limited to the specific facts in that case. One comment stated that the case only upheld FDA's authority to impose recordkeeping requirements on firms to facilitate recalls of potentially dangerous products. The other comment noted that the case only granted FDA access to shipping records. The comment pointed out that FDA already has access to such records from carriers under section 703 of the act.

While it is true that the records that FDA was requiring, and to which the agency claimed access under the regulations involved in *Confectioners,* were source coding and distribution records in order to facilitate recalls, the court's ruling involved broad principles relating to the validity of the regulations generally and was not limited to recalls or shipping records. The court stated that in light of the statutory scheme as a whole, "we find no basis for the Association's distinction between the FDA's role in preventing and remedying commerce in adulterated foods. The agency believes that the Act imposes on the FDA an equal duty to perform each role." *Id.* at 694. This statement simply is not consistent with the narrow reading suggested by the comment. Rather, it fully supports FDA's authority to adopt regulations to prevent the introduction of adulterated foods into interstate commerce. Clearly, compliance with FDA's seafood HACCP regulations will help to achieve that end.

It is also true, as one comment pointed out, that section 703 of the act expressly grants FDA access to shipping records and not to the kinds of processing records required in these regulations. FDA cannot agree, however, that *Confectioners* stands for the proposition that FDA should have access only to food manufacturers' shipping records because those are the only kinds of records to which FDA has access under section 703 of the act. The court concluded that the narrow scope of section 703 of the act is not a limitation on the right of the agency to require recordkeeping and have access to records that are outside the scope of section 703 of the act, so long as the recordkeeping requirement is limited, clearly assists the efficient enforcement of the act, and the burden of recordkeeping is not unreasonably onerous (569 F.2d at 693 n.9).

The recordkeeping required under these regulations passes the *Confectioners* test. First, the recordkeeping requirements are limited. The HACCP recordkeeping and record access requirements in the final rule are tied specifically to the critical control points (CCP's) in the manufacturing process. In other words, the recordkeeping requirements are limited to those points in the process at which control is essential if assurance that the resultant product will not be injurious to health is to be achieved.

Second, the recordkeeping assists in the efficient enforcement of the act. The recordkeeping requirements, by focusing on the CCP's, ensure that the processor and the agency focus on those aspects of processing that most jeopardize food safety. Unlike the current inspection system, recordkeeping in a HACCP-type system documents that preventive controls are being followed and enables the regulator to verify this fact. Such a system, therefore, assists in effective and efficient enforcement of the act.

Finally, the HACCP-recordkeeping burden is not unduly onerous. It is limited to those aspects of processing that are critical to food safety. Documentation that control is being maintained over these aspects of processing need only be a minor additional step in most instances. The documentation required in the final rule is narrowly tailored to ensure that only essential information needs to be recorded.

6. Several comments questioned whether FDA may have access to HACCP records and plans on the grounds that the act does not explicitly authorize such access. Some of these comments pointed to the lack of authorization in section 704 of the act (21 U.S.C. 74), the provision that authorizes the inspection of food processors and other types of establishments. The comments pointed out that section 704 of the act authorizes agency access to certain records relating to prescription drugs and medical devices during the course of those inspections but not to records relating to

foods. One comment felt that the specific grant of records access for drugs and devices in section 704 of the act precluded expansion of access to records not specifically mentioned in the act. Other comments felt that FDA was barred from access simply because the act does not expressly grant it.

FDA does not agree, as the agency's authority under sections 402 and 701(a) of the act to issue these regulations provides ample authority for records access. The line of cases cited above stands for the proposition that a lack of explicit delegated authority does not invalidate agency regulations so long as the regulations are consistent with the act's overriding purpose. In *Confectioners*, the court upheld FDA's authority to adopt recordkeeping requirements in the absence of an explicit delegation of authority. In that case, moreover, the court found no evidence that Congress intended to immunize food processors from limited recordkeeping (569 F.2d at 695). Similarly, the court in *Nova Scotia* concluded, in the absence of such evidence, that there was no impediment to a broad reading of the statute based on the general purpose of the Congress in protecting public health (568 F.2d at 248).

FDA has concluded, therefore, that these regulations are consistent with section 704 of the act and with the act as a whole. Because the preventive controls required by HACCP are essential to the production of safe food as a matter of design, the statutory scheme is benefited by agency access to records that demonstrate that these controls are being systematically applied. The case law supports FDA's authority to require such recordkeeping and to have access to such records.

Other countries, including Canada, the European Union (EU) Norway, Australia, and New Zealand, which have already implemented HACCP-type systems, have deemed it necessary to the success of their systems to provide for recordkeeping and record access along the lines of this regulation (for either their entire seafood industries or seafood export industries). Thus, it is widely accepted that recordkeeping and inspectional access are essential components of a HACCP-type seafood system. In addition, in order to maintain other countries' faith in the safety standards of U.S. seafood exports, FDA needs similar access to records showing HACCP implementation.

7. One comment expressed the view that the copying of records by FDA, as authorized by these regulations, is beyond the scope of section 704 of the act.

FDA points out that it is not acting under section 704 of the act. To effectuate the broad purposes of the act, there may be some circumstances in which access to the records would be meaningless without the opportunity to copy them. While the agency does not anticipate that copying will be necessary in most instances, perhaps the most readily predictable circumstance in which copying would be necessary is when an investigator needs assistance from relevant experts in headquarters to evaluate the record. Without copying, it would be necessary for the agency to rely solely on the notations and report of the investigator.

This reliance may not be adequate in many circumstances. For example, there may be a deviation from a critical limit (CL) that poses no health risks. Without the ability to show a copy of the records to someone within the agency with the necessary expertise in the area, an investigator would have to cite the company for a violation. If, however, an agency expert determined that the deviation posed no safety risks, the agency could use its enforcement discretion not to pursue a violation.

8. One comment expressed the view that the act does not support a mandatory HACCP program that includes access to records for the entire seafood industry. According to the comment, the act permits FDA access to records only under extreme conditions where there is a potential for injury, but, the comment noted, hazards are only associated with a small percentage of fish.

FDA cannot agree. While it is true that those seafood-related illnesses that are reported to public health authorities tend to be associated with a limited number of species, potential hazards are much broader. As indicated above, the 1991 NAS report on seafood safety provides an extensive inventory of hazards.

For the benefit of the commentor it is worth noting that if a processor is involved with species and processes for which there are no food safety hazards that are reasonably likely to occur, a HACCP plan will not be necessary under these regulations. As will be discussed later in this preamble, the agency anticipates a post-implementation dialog with firms on whether they have hazards that must be controlled in accordance with these regulations and, if so, how many.

9. One comment expressed the view that the authority to inspect ordinary food records has not been asserted before. This statement was made in support of the contention that there is no statutory basis for FDA access to ordinary food records.

The legal basis for FDA's access to records has already been fully addressed in this preamble. It is important to note that the agency is not claiming a right of access to food records coextensive with that for drugs and devices under section 704 of the act. Rather, FDA is asserting a right to access to records that is narrowly tailored to advance the purposes of the sections of the act that it is implementing here, i.e., records relating to the CCP's in a firm's process.

While the agency is not sure what the comment meant by "ordinary" food records, it is worth pointing out that the position in this regulation on agency access to records is a longstanding interpretation for regulations of this type. Agency access to processing and production records has been required since the early 1970's in FDA's regulations for thermally processed low-acid foods packaged in hermetically sealed containers (part 113) and for acidified foods part 114 (21 CFR 114). As discussed in the new section, these regulations were issued primarily under the authority of both sections 402(a)(4) and 404 of the act (21 U.S.C. 344), neither of which specifically mention access to records.

5. Relevance of Section 404 of the Act

10. Several comments expressed the view that FDA should base HACCP regulations on section 404 of the act rather than on section 402(a)(4) of the act. Some of these comments were referring to these seafood HACCP regulations, while others were primarily concerned with any HACCP regulations that FDA might issue for other foods. Other comments expressed the view that FDA's existing low-acid canned food regulations should serve as a model for new HACCP programs. Because some of the low-acid canned food regulations have been issued under section 404 of the act, all of these comments may have been making the same general point.

Most of those that advocated use of section 404 of the act as the legal basis expressed concerns about the appropriateness of relying on section 402(a)(4) of the act and the narrow grants of access to records in the act, especially in section 704 of the act, and concluded that the act only grants the agency access to records under extreme situations. One comment urged that FDA issue the seafood HACCP regulations under the authority of section 404 of the act in order to enhance the agency's ability to achieve compliance through the permit system.

Section 404 of the act is entitled "Emergency Permit Control." It authorizes FDA to establish a permit system for processors of food that may be injurious to health when two conditions are met: (1) Contamination is with microorganisms, and (2) the injurious nature of the product cannot be adequately determined after the product enters interstate commerce. Section 404 of the act authorizes FDA to inspect firms that operate under this permit system but does not mention records or FDA access to records.

As indicated previously, FDA has issued regulations under this authority. Regulations at part 108 (21 CFR part 108) subpart A establish the permit system generally. Regulations at part 108 subpart B establish that acidified foods and thermally processed low-acid foods in hermetically sealed containers (i.e., low-acid canned foods, or "LACF") meet the criteria in section 404 of the act and are therefore subject to the permit system. Subpart B requires processors of these foods to register with FDA and to submit detailed information to FDA on their manufacturing processes.

As an adjunct to these regulations, FDA has also issued the regulations, referred to previously, at part 113 and part 114 for these products. These latter regulations require the maintenance of day-to-day processing records that are retained by the processor and are in addition to the processing information that must be sent to FDA. FDA investigators have access to, and may copy, these records (§§ 108.25(g) and 108.35(h)).

While the permit system may have some compliance advantages, as pointed out by one comment, there are other considerations in this case that are more important. The permit system is, as the title of section 404 of the act declares, an "emergency" system. Because it is an extreme remedy for extreme situations, FDA has used section 404 of the act relatively sparingly.

In the case of seafood, although FDA strongly believes that a HACCP system will correct deficiencies in the current system and provide significant further assurance of safety, the agency cannot conclude that seafood is in an overall state of emergency from a public health standpoint. This conclusion is consistent with the position taken by the NAS. The NAS' Institute of Medicine, in its 1991 report entitled "Seafood Safety," devoted hundreds of pages to areas of risk and made numerous recommendations about control measures, including the application of HACCP where appropriate. However, the NAS also concluded that most seafood in the U.S. marketplace is unlikely to cause illness.

FDA believes that, for seafood at least, HACCP should be the norm rather than an exceptional remedy for an extreme situation. A functioning HACCP system reflects an understanding of the wide range of hazards to which seafood may always be subject and provides for a systematic application of the preventive controls necessary to minimize the occurrence of those hazards. It is the most effective and efficient way known of ensuring food safety as a matter of design. In this regard, FDA has concluded that, for seafood, the efficient enforcement of the act should not have to depend on a finding of an emergency under section 404 of the act.

It is also worth noting that section 404 of the act would limit the application of HACCP to hazards by reason of contamination from microorganisms. FDA is not aware of any HACCP expert or authoritative body, including the National Advisory Committee for Microbiological Criteria for Foods (NACMCF), which advocates limiting HACCP to these hazards only. A full discussion of hazards to which seafood HACCP should apply appears later in this preamble.

FDA does not agree that section 404 of the act is the only basis for these seafood HACCP regulations, or that it would be a more appropriate basis. It is not clear, moreover, how section 404 of the act can be cited as supporting the proposition that the agency only has access to records in extreme situations. As indicated earlier, section 404 of the act contains no express grant of access to records. Again, FDA has concluded from the case law that, under appropriate circumstances, the agency has access to specific types of records on foods and food processing for specific purposes, where such access is not expressly provided for in the act, but the agency cannot conclude that this right is limited to extreme situations. Some of the comments provided examples of extreme situations to which HACCP regulations should be limited from their standpoint. These examples raise important issues that will be addressed elsewhere in this preamble.

11. Two comments expressed the view that the LACF regulations should serve as a model for the types of records that would be accessible under HACCP regulations.

FDA did in fact use the LACF regulations as a model in that regard. The HACCP plan required here is similar to the scheduled processes that processors must submit in the LACF regulations. Likewise, there is little difference between the HACCP-monitoring records required here and the day-to-day processing records that are required in LACF regulations.

B. HACCP Pro and Con

1. Overview

Nearly half of the comments included specific statements of support or opposition for the concept of a mandatory HACCP program to ensure the safety of seafood. The supporters outnumbered the opponents by over 10 to 1.

Nearly all of those who supported the approach also had technical comments on various provisions in the proposal. Some conditioned their support on the availability of additional enforcement authorities or resources for FDA. These aspects of their comments will be responded to elsewhere in this preamble. A small number of these comments supported the concept of a mandatory HACCP program for seafood but opposed the proposal as drafted.

The supporters of the concept included most of the seafood trade associations that commented, businesses, consumer advocacy organizations, Federal and State agencies, professional societies, academics, and a member of Congress. The reasons for this support included: Enhancement of consumer confidence, the superiority of HACCP-type preventive controls over traditional CGMP-type controls and end-product sampling, the view that HACCP is the most efficient and effective way to ensure safety, and the view that a mandatory HACCP system reflects an appropriate assigning of primary responsibility to industry for producing safe food. Other reasons included a leveling of the competitive playing field, both domestically and internationally; the need for prompt adoption of a mandatory HACCP program by FDA to enable the seafood industry to maintain its market position in Europe and elsewhere throughout the world; greater productivity; and increased industry control over processing.

One large seafood trade association stated:

> [The association] strongly supports the adoption of a comprehensive regulatory program by the FDA which is designed for fish and seafood using HACCP principles. HACCP systems have been applied successfully by individual firms in our industry, and they have been shown to be a very cost-effective way of controlling safety hazards. Of equal importance, the adoption of a HACCP-based regulatory program should lead to more effective and efficient use of FDA resources, and less disruption of the processing and importing of seafood for consumers.

A small number of comments expressed opposition to the mandatory HACCP approach for seafood, however. One State comment expressed the view that HACCP would not have any significant effect on reducing illnesses from molluscan shellfish. Another comment stated that, overall, seafood-related illness data do not justify mandatory HACCP for seafood. (Several other comments questioned the need for these regulations in light of the NAS' conclusion that commercial seafood is generally safe. These comments either generally opposed the proposed regulations as drafted, or opposed its application to the comments' segments of the seafood industry, but did not express opposition to mandatory HACCP as a concept.) None of these comments supplied any new seafood-related illness data.

2. The Significance of the Illness Data

The preamble to the proposed regulations described broadly what is known and not known about the extent of seafood-related illness in the United States. Foodborne illnesses tend to be significantly underreported to public health authorities. Consequently, precise data on the numbers and causes of foodborne illness in this country do not exist. FDA does know, however, that illness from seafood does occur, and that a wide variety of hazards have been identified that could cause illness from seafood (see Ref. 7, pp. 1–13). The overwhelming majority of these hazards are amenable to preventive controls. FDA's draft Guide addresses controls for over 20 specific types of safety hazards.

The primary purpose of these regulations is to ensure that preventive controls are systematically applied in seafood processing as a matter of routine custom and usage, and in a way that can be verified by company management as well as by regulatory authorities. Thus, while the reported illness data are highly relevant to whether these regulations should be issued, they are not the sole basis for the regulations.

For molluscan shellfish in particular, FDA agrees with the commenters who believe that the principles of the National Shellfish Sanitation Program (NSSP) should continue to form the basis for the molluscan shellfish safety program in this country. There is no clear alternative to proper water classification and patrol by State authorities as the basis for molluscan shellfish safety. HACCP provides processors with an excellent system for ensuring that these preventive-type controls are adhered to in a systematic way.

It may be argued—and some comments made the point—that the best way to reduce the overall number of illnesses from raw molluscan shellfish is to provide additional resources to the States to enhance their water classification and monitoring abilities. Classifying and patrolling shellfish harvesting waters are important means of preventing molluscan shellfish that have been contaminated from sewage from entering the marketplace. However, additional Federal resources will probably not be available for this purpose in the foreseeable future. It is imperative, therefore, that the system that is in place be made as efficient as possible.

It would be incongruous to exempt from a national system of preventive controls the processors of products identified by the NAS as the source of the greatest numbers of seafood-associated illnesses. FDA strongly believes that HACCP controls will help shellfish processors and regulators alike to better focus on potential safety problems and less on tangential matters than historically has been the case. A full discussion of the application of HACCP to raw molluscan shellfish appears later in this preamble.

3. Exempt Specific Industry Segments?

12. Comments stating that HACCP systems should not be mandated for specific industry segments usually referred to either the crab processing or the catfish industries. These comments generally expressed the view that HACCP requirements for these industries were not necessary.

FDA advises that these regulations are flexible enough so that HACCP-type controls are not required where they are not necessary, i.e., where it is reasonably likely that hazards do not exist. It is the agency's experience, however, that there are reasonably likely hazards associated with crabmeat as a cooked, ready-to-eat product, including the growth of pathogens as a result of time-temperature abuse of the product and the potential for pathogen survival from inadequate pasteurization. There are reasonably likely hazards associated with the processing of catfish (e.g., contamination from agricultural chemicals, improperly used aquaculture drugs, and a variety of hazards resulting from the in-plant processing operations). It is incumbent on processors of these products to know and control such hazards.

The agency recognizes that whether reasonably likely hazards exist involves case-by-case determinations. As will be discussed in the "HACCP plan" section of this preamble, processors will be given every opportunity to demonstrate why no hazards exist in their operations.

4. Would Voluntary HACCP Be Superior?

13. Some comments believed that a voluntary approach to HACCP for seafood would be preferable to a mandatory approach. One reason given for this view was that, under a mandatory system, the risk of regulatory action by FDA would compel processors to design HACCP controls that were the minimum necessary to comply with the rule. There would be a significant disincentive for processors to design HACCP plans that have the greatest practical impact on food safety out of fear that occasional failure to meet those higher standards would trigger a regulatory response.

If voluntary HACCP systems were already universal, or nearly so in the seafood industry, and they generally applied safety controls that were beyond the minimum needed for safety, FDA would see little reason to establish a mandatory system. However, HACCP is not the norm, and given the current situation in the seafood industry, FDA finds that making HACCP mandatory is necessary to ensure that safe, wholesome, and unadulterated product is produced. Thus, FDA is adopting part 123 (21 CFR part 123).

The agency acknowledges the possibility that, under a mandatory system, firms will perceive that they are on safer ground with FDA if they establish minimum acceptable controls that are more easily met, rather than more stringent controls that are beyond the minimum necessary to ensure safety and, therefore, are harder to meet. For example, in deciding what CCP's to identify in a HACCP plan, a processor might err on the side of inclusion under a voluntary plan but keep the number of CCP's down to the minimum acceptable to FDA if having a plan is mandatory.

It remains to be seen whether processors will really choose to behave this way under a mandatory system. The choices that processors will make may depend, in part, on FDA policy toward HACCP plans that are beyond the minimum. The logic in favor of the agency initiating regulatory action when a processor fails to meet its own CL but succeeds in meeting a minimum level that would have been an acceptable CL to FDA, would be that the firm is out of control vis a vis its own preventive process. The logic against initiating regulatory action would be that the processor is still in control in terms of meeting minimum necessary safety parameters, and that the product is, in

FDA's opinion, safe to eat. As an additional factor, FDA does not want to discourage firms from establishing preventive controls for themselves that are beyond the minimum necessary to ensure safety.

In evaluating monitoring records, FDA will first determine whether the recorded values are within the processor's critical limits as set out in its HACCP plan. Where values are found that are outside the CL's, the agency will determine the cause and extent of such occurrences, and what corrective action, if any, the processor has taken. Where product that was involved in a CL deviation was distributed without first being subjected to appropriate corrective action, FDA will determine the cause and extent of the control failure.

In determining the appropriate agency regulatory response to CL deviations, FDA will assess the public health risk that the product poses. This assessment will, in part, involve a determination of whether the minimum limit necessary to ensure safety was breached. FDA acknowledges that this level and the processor's CL may not always be the same. The agency is not likely to take action against a product that it finds poses no significant public health risk, regardless of whether it has or has not met the processor's CL.

Nonetheless, processors must establish controls to ensure that appropriate corrective actions are taken when their CL's are breached. Where such controls fail, FDA expects processors to redesign their control mechanisms as necessary. Chronic failure to appropriately respond to CL deviations demonstrates that a processor's HACCP system is inadequate, and that fact could cause FDA to have some regulatory concern.

14. Another comment urged that HACCP for seafood should be voluntary on the grounds that FDA lacks the resources and statutory enforcement authorities to operate a mandatory system. Other comments expressed the same types of concerns about FDA resources and enforcement authorities without concluding that a voluntary system would be preferable. One comment, from a consumer advocacy organization representing several other organizations, supported the concept of a mandatory HACCP system but expressed reservations about FDA's ability to adequately perform HACCP-based inspections of processors without additional resources. Other commenters expressed the same kinds of concerns. The comment pointed out that because HACCP inspections will take longer than current inspections, the intervals between inspections will increase significantly, creating "an unenforced industry honor system." The commenter, and some others, also advocated additional enforcement authorities.

The success of this program will depend on a number of factors. One of these factors, unquestionably, will be the ability of a regulatory authority, or authorities, to adequately monitor processors' HACCP systems through inspections. If the frequency of inspections is too low, safety may not be ensured, consumer confidence may be eroded, and the accusation that the program is self-regulatory may have merit, even though a HACCP-based inspection allows the investigator to view a firm's critical operations over time, not just at the moment of the inspection.

The use of a HACCP-based system bears on the adequacy of FDA's inspection resources in two important respects. The first is the effect of the use of HACCP-based inspections on inspection frequencies. The time needed to conduct a HACCP-based inspection will undoubtedly vary depending on the number of hazards, complexity of the operation, and other factors. The first round of HACCP inspections will likely take longer—possibly as much as twice as long in high-risk and complex operations—as the CGMP-based inspections FDA presently conducts, but the time-per-inspection is likely to drop significantly thereafter. It remains to be seen whether inspection times will eventually shorten to current times, or whether HACCP-based inspections will always take longer on average. In any event, FDA finds some merit in the comments' basic concerns about inspection frequencies.

Second, as a countervailing matter, a HACCP-based inspection can be a more efficient and effective inspection than a CGMP-based inspection, largely because it can be highly focused on matters that are critical to safety, and because access to key safety monitoring records allows the investigator to evaluate the process over time. Thus, some compensation for increased intervals between inspections will be provided by the fact that the investigator gets not merely a snapshot of the operation of the plant in time but a broad view of how the plant has been operated over the preceding months or even years, as reflected in the plant's records. Thus, FDA concludes that, on balance, the somewhat longer inspection intervals that might occur under a HACCP-based system would be fully compensated for by the broader view provided by a HACCP-based inspection.

In addition, FDA intends to increase the frequency and improve the consistency of processor inspections through HACCP-based work sharing partnerships with the States. One of the agency's goals is for these regulations to serve as a basis for partnerships that involves a pooling of resources.

While FDA acknowledges the comments' concerns about resources, the agency would not agree that the HACCP program should be abandoned because of resource constraints. Quite the contrary, resource constraints make it imperative that FDA seafood inspections be based on the most effective and efficient system devised to date. HACCP is that system. Moreover, the agency believes that there is enough flexibility in a HACCP-based inspection system to permit gradations in implementation (e.g., focusing on the most extreme hazards; selectively reviewing records) to accommodate whatever resource situation exists at any given moment.

With regard to enforcement authorities, as made clear above, the act provides ample authority for the establishment and implementation of a HACCP-based system by FDA. Regardless of whether additional authorities might be desirable, there simply is no reason for FDA not to proceed to establish and implement a HACCP-based system forthwith.

15. Another comment expressed opposition to mandatory HACCP for the seafood industry on the grounds that HACCP diverts the responsibility for ensuring a safe product from the government to the fish processors.

FDA's intent is not to transfer its legitimate responsibilities with regard to food safety to the regulated industry. In point of fact, the industry already has responsibility under the law to produce a safe product. HACCP helps to clarify, however, how responsibility for human food safety is divided between industry and the regulator.

Industry, as stated above, must take primary responsibility for the production of safe food, while the regulator must be responsible for setting standards (including program regulations such as these), verifying that the industry is doing its job, and taking remedial action when it is not. HACCP requires that the industry be aware of the human food safety hazards that are reasonably likely to occur, and that industry operate under a system that is designed to ensure that those hazards are not realized. Thus, HACCP enables the industry to demonstrate that it is meeting its legitimate responsibilities.

5. Other Issues

16. One comment supported the concept of HACCP but expressed the view that the regulation drafting process should be started over by forming a committee consisting of representatives from various segments of the seafood industry, and appropriate government and university personnel. A few other comments expressed the view that FDA had acted too quickly in issuing the proposed regulations and also requested that FDA start over by engaging in discussions with industry, foreign regulatory agencies, academia, and consumers. These latter comments, which were mostly from companies not primarily involved in the processing of seafood, preferred a voluntary approach to HACCP, with mandatory applications only in exceptional situations. FDA did not act too quickly, or without appropriate consultation, in issuing the proposal in this proceeding. As the preamble to the proposed rule documented at some length, the proposal was the culmination of an extensive process by FDA and others, including the seafood industry itself, that led major representatives of that industry to request the issuance of the proposal. Before that, industry trade associations testified repeatedly before Congress in the late 1980's through the early 1990's in support of legislation that would have required a mandatory inspection system for seafood based on HACCP principles.

FDA participated in pilot programs in the past such as the seafood HACCP pilot conducted jointly by FDA and the National Marine Fisheries Service (NMFS) of the Department of Commerce (DOC) in 1990 to 1991. In addition, FDA ran programs with seven other countries. In developing these regulations, the agency also took advantage of information from the Model Seafood Surveillance Project (MSSP). The MSSP was conducted by the DOC at the request of Congress in 1986 to design an inspection system for seafood consistent with HACCP principles. As part of the MSSP project, 49 workshops were conducted involving 1,200 industry, State, and university participants. Canada currently has a HACCP system, and the EU has issued directives that move in that direction. The agency has concluded that sufficient field trials have already taken place to conclude that HACCP is a viable method of hazard control for the seafood industry.

Public input into the development of the HACCP approach contained in these regulations has been substantial. As described earlier in this preamble, FDA engaged in a series of "town meetings" in nine cities across the country shortly after the proposal was published in order to answer questions about the proposed regulations and encourage comments. The public response to FDA's proposal contributed substantially to the contents of the final regulations.

C. *Should Some Types of Processors Be Exempt?*

In the preamble to the proposed regulations FDA asked for comment on whether either processors of "low-risk" products or small processors, or both, should be exempted from the requirements of the final regulations. The agency asked for information on whether the regulatory burden could be reduced without compromising the public health protection goals of the regulations, and whether there exists a rational way to distinguish "high risk" from "low risk," and big processors from little processors, for purposes of HACCP.

1. Exempt Low Risk?

The most obvious way of distinguishing high-risk products from low-risk products would be on the basis of reported, confirmed, seafood-related illnesses. The preamble to the proposed regulations pointed out some problems with this approach. First, the agency pointed out that the underreporting and skewed reporting that occurs with respect to foodborne illness creates significant concern as to whether reported illnesses represent a reliable enough factor to serve as the basis for an exemption to these regulations. Second, FDA stated that it was concerned that there could be a significant potential for harm that could be controlled by HACCP but that would not have shown up in the data that is relied on to establish risk. For example, while there may be no reported cases of botulism associated with some products that have the potential for *Clostridium botulinum* toxin, the severity of the consequences of the hazard warrant preventive controls. Likewise, while there may be no reported cases of domoic acid intoxication associated with shellfish from a particular area, preventive controls are warranted as soon as a such a case is made public. Thus, the preamble asked whether potential for harm might be a reasonable way to distinguish high-risk from low-risk products for purposes of an exemption. FDA was interested in whether comments could provide usable criteria for such an exemption.

About 45 comments addressed the question of whether the regulations should apply to high-risk products only. Roughly two-thirds of these comments preferred a high-risk approach. For the most part, they either did not define "high risk," or defined it as including essentially the top three reported seafood- related illnesses (virus-related from raw molluscan shellfish, scombrotoxin, and ciguatoxin). For the most part, other hazards were assumed to represent a low risk.

17. One comment recommended that the regulations initially cover the hazards reported at the highest levels of to the Centers for Disease Control and Prevention (CDC) because these hazards are at least known to be causing illness, and that the agency should phase in other hazards as appropriate if the foodborne-illness reporting system were to reveal a need to do so.

Few comments were received on whether there could be a basis for distinguishing high risk from low risk other than reported illnesses. Some comments suggested that the agency should consider severity of illness as a criterion. Some of these comments specifically cited smoked and smoke-flavored fish as products that should be covered on this basis because of the devastating effects of botulism. A few comments expressed the view that mandatory HACCP should be limited to hazards that can cause loss of life or irreversible injury.

Several comments objected to a "low risk" exemption in any form. Some pointed out that, given the underreporting and skewed reporting that exists, the CDC foodborne-illness reporting system does not provide a suitable basis for making determinations of comparative risk (i.e., high risk versus low risk). These comments expressed concern that linking the requirements of these regulations to illness reporting that has already occurred would have the effect of exempting emerging hazards, at least until they caused reported illness.

Other comments stated that there is no significant advantage to exempting low-risk products because processors of these products will have simpler HACCP plans than those who process products with more potential safety hazards. One comment stated that a high risk-only approach made some sense but, as a practical matter, would negate the added assurance to consumers from HACCP that seafood is safe and processed under some form of regulation. According to this comment, from a large seafood trade association, it is more important that the entire food category be recognized as having been subjected to modern safety assurance

procedures than that the regulations exempt the low risk end of the industry.

FDA has considered these points of view and has concluded that, at least for now, there is no reasonable way to divide seafood products into high risk and low risk for purposes of these regulations. The comments that suggested defining "high risk" in terms of the most frequently reported illnesses are correct that the volume of reporting tends to concentrate substantially in the three hazard areas mentioned above. Because illnesses that are confirmed and reported tend to be those that are the most easily traced or diagnosed, however, the relative significance of the high level of reporting in these three areas—as well as the drop-off in reporting in other areas—is not fully known. Moreover, illnesses associated with chronic hazards are virtually unreported because of the difficulties in associating such illnesses to specific food sources.

The comments did not include any new data that would reveal whether the risks associated with the most reported illnesses are actually the highest risks or only the most apparent. No new information was provided to allow FDA to determine whether distinguishing high risk from low risk on the basis of reported illnesses would constitute a rational division for purposes of these regulations. Nor has FDA been supplied with information that would allow it to conclude whether other valid criteria exist.

FDA agrees with the comments that pointed out that the requirements of HACCP are less when risks are low. Moreover, as will be discussed later in this preamble, FDA has revised the final regulations to provide that HACCP plans are not required when there are no reasonably likely safety hazards to control. Thus, HACCP inherently tends to distinguish between high- and low-risk products without the need for explicit exemptions.

FDA also agrees that broad exemptions would put at risk some of the principal objectives of these regulations. Explicit exemptions make the system less flexible and might not cover emerging situations for which preventive controls are necessary to keep illnesses from occurring in the first place. A system that includes such exemptions would likely not provide as much consumer confidence as would a complete HACCP system. In addition, FDA notes that the benefits to the industry in international trade from adopting a HACCP system might be minimized if such exemptions were adopted because the United States' international trading partners are opting for complete systems.

2. Exempt Small Processors?

18. Over 60 comments addressed the question of whether the regulations should exempt small businesses. About five out of six of these comments opposed an exemption.

Those that supported an exemption for small businesses expressed concern about the effect of the general costs of implementation, particularly the costs of training and recordkeeping. One comment observed that many small businesses are economically-strapped, old, family enterprises that support an often fragile local economy. Another comment expressed the view that small businesses should be exempt because they are not involved in international trade. One comment noted that the highest volume producers (i.e., large businesses) are where a mistake affects the most consumers.

One comment recommended that FDA develop exemption procedures to relieve small companies of paperwork and training requirements, especially if they produce low-risk products. A few comments suggested that small businesses, or at least small businesses with good records, be exempt from "positive" recordkeeping, i.e., recording the results of each monitoring. Under this kind of exemption, small businesses would only record unusual occurrences and corrective actions.

The majority of comments that argued against exempting small businesses provided a number of reasons. One comment pointed out that as much as half of seafood consumed in the United States is from small firms. Several comments stated that size is not related to risk. Small firms are the major producers of many high-risk products (e.g. cooked, ready-to-eat and raw molluscan shellfish). Thus, according to the comment, the final regulations would represent a futile exercise if small firms were not included. One comment observed that small companies sometimes represent more of a risk potential than large companies due to lack of enough trained quality control personnel. Other comments pointed out that small businesses with simple operations would have simple plans and a minimum of recordkeeping.

One comment pointed to difficulties that FDA would have in administering exemptions to the regulations, particularly in distinguishing between firms that were and were not entitled to an exemption. Another concern expressed by comments was the potential unfairness of exempting some companies while requiring HACCP of others.

One State that has implemented mandatory HACCP for seafood processors observed that HACCP requirements had not proven to be an excessive burden to small businesses in that State.

Some comments that supported including small businesses in the coverage of the HACCP requirement recommended, nonetheless, that FDA should provide assistance to small businesses through guidelines, model plans, and technical and financial assistance. Some comments acknowledged that small firms can work through trade groups on common plans and training.

Other comments felt that dropping small firms from the final regulations would adversely affect consumer confidence. One comment expressed fear that the international standing of FDA's seafood safety program would be in jeopardy if the regulations were to exempt some firms.

FDA does not know how to exempt small business without jeopardizing the public health objectives of the regulations. An exemption for small processors of "low-risk" products would run into the difficulties explained above in the discussion of whether these regulations should only apply to "high-risk" products. FDA agrees with the comments that, in the seafood industry, the size of the operation often does not coincide with the number or type of hazards that must be controlled in order to ensure a safe product (i.e., small size does not automatically mean minimal hazards). For example, cooked, ready-to-eat seafood processing, a relatively complex manufacturing operation, typically requiring a larger than average number of CCP's, is concentrated in the small business portion of the seafood industry. Additionally, the processing of raw molluscan shellfish, a product identified by NAS as being associated with a disproportionately large percentage of the seafood-borne illnesses, is most commonly performed by small firms. FDA also agrees that, because seafood businesses tend to be small, an exemption for small businesses could make HACCP the exception, rather than the rule, in this industry.

The concerns expressed in the comments about the possible adverse consequences of these regulations on small business, however, should not be taken lightly, and the agency has not done so. FDA has no desire to establish a mandatory regime that cannot be met by otherwise responsible companies,

small or otherwise, that are producing safe food. Indeed, these regulations are based on the premises that: (1) Preventive controls for safety should be within the reach of anyone who is producing seafood for commerce (i.e., preventive controls should not be prohibitively burdensome, either financially or conceptually); and (2) it is in the public interest that everyone who is producing seafood for commerce should practice preventive control for human food safety. The fundamental question that the issue of whether to exempt small business raises is whether these premises are valid.

Having fully considered the comments on this issue, FDA is not persuaded that awareness of likely food safety hazards would cause financial hardship to small businesses, or that having reasonable, practical controls for those hazards will cause undue harm. As will be discussed in the "Records" section of this preamble, the costs associated with the recordkeeping requirements of HACCP are really incidental to the cost of monitoring and need not place a significant burden on small businesses. For example, after checking the temperature of a refrigerator, the observer need only take an additional moment to document the result of the observation. The agency cannot emphasize too strongly that, in most instances, only very simple recordkeeping is needed to adequately serve the purposes of the system. The question from the agency's standpoint, therefore, is whether the actual monitoring of critical operations, at reasonable frequencies, would be prohibitively expensive to the small operator. FDA has not been provided with a basis for such a conclusion.

This leaves plan development and training as costs. The guidelines that FDA is making available on plan development should help substantially to keep development costs down. FDA is also aware that trade associations and others are interested in developing model plans that, when used in concert with the guidelines, should further reduce the resources that a firm will need for plan development. The creation of a HACCP plan does require some thought and effort by the processor to ensure that hazards and controls are understood and identified. Nonetheless, the guidelines and model plans will enable small processors to be able to apply the thought and effort necessary to create a HACCP plan with maximum efficiency and minimum cost.

FDA is requiring that all processors either employ at least one trained individual or contract for services from at least one trained individual, as needed. There are unavoidable costs associated with this requirement. It is imperative that these costs be affordable to small business and be no greater than necessary. As discussed at length in the "Training" section of this preamble, FDA has been extensively involved with a consortium called the "Seafood HACCP Alliance" (the Alliance) consisting of representatives from Federal and State agencies, industry, and academia, to create a uniform, core training program that will meet the requirements of these regulations and will cost very little. The agency is also aware of HACCP training that has been provided for years for members of industry by NMFS and others. As an additional matter, FDA is allowing job experience to serve as a form of training in order to avoid the unnecessary expense to a processor of having to pay for a HACCP course when at least one employee already has knowledge that is equivalent to that provided by the course.

These efforts should alleviate the concerns of those who believe that the training requirement will be too burdensome on small business. The agency will monitor the situation closely once this training gets underway. If costs turn out to be significantly higher than FDA anticipates, the agency will consider some modification to the requirement.

While the agency regrets that grant monies are not available to small businesses from FDA, the effort that the agency is investing in guidelines and training development is a form of subsidy that should keep costs down generally.

D. Definitions

1. General

In addition to relying on the definitions contained in the act and those in the umbrella good manufacturing practice regulations at part 110 (21 CFR 110), FDA proposed at § 123.3 (a) through (t) to define 20 terms that are essential to the interpretation of part 123. Approximately 100 comments addressed various aspects of the proposed definitions at § 123.3.

The majority of the comments on definitions were concerned with the meanings that FDA proposed for "processor" (§ 123.3(n)) and "processing" (§ 123.3(m)). These comments generally asked for clarification about the applicability of the definitions to a given commercial activity, or contended that the definitions should be amended to either include or exclude certain activities. Most of the other comments that addressed the definitions were primarily concerned with the meanings proposed for "fish," fishery product," "critical control point," "cooked ready-to-eat," and "importer." As a result of the comments as well as agency decisions to modify other provisions in part 123, FDA has deleted, revised, and added definitions to those proposed at § 123.3.

2. Cooked, Ready-To-Eat Fishery Product

19. The proposed regulations contained a definition for "cooked, ready-to-eat fishery product" at § 123.3(b). The term was used at proposed § 123.10(a) and in the appendices to the proposed regulations. The final regulations no longer contain this term, and the appendices are not being codified. For these reasons, FDA has eliminated the definition of "cooked, ready-to-eat fishery product" from the final regulations.

Nonetheless, a large number of comments expressed concerns about the definition as it was proposed. In general, the comments urged that certain products be excluded from the definition of "cooked, ready-to-eat fishery products;" those that are not fully cooked by the processor or that will be recooked by the consumer, and low-acid canned foods subject to the provisions of part 113.

FDA recognizes the significance of the use of the term. Because the agency has excluded use of the term in these final regulations, it will defer consideration of the comments until drafting of the Guide.

3. Critical Control Point (CCP)

FDA proposed at § 123.3(c) to define a critical control point as "a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard in the final food." The word "hazard" in this definition was intended to refer primarily to food safety hazards. It could also have applied to quality and economic hazards, however, because the agency was proposing at § 123.6(c) to encourage processors to apply HACCP to these hazards as well.

20. A significant number of comments urged the agency to modify the definition so that it clearly addresses only food safety. These comments recommended that the word "hazard" should be prefaced with either "food safety" or "health," or that FDA should codify the definition for "hazard" that has been recommended by the NACMCF.

Several of the comments urged FDA to adopt the NACMCF definition for

"critical control point" so that the agency's regulations would be consistent with nationally and internationally agreed upon HACCP definitions. One objected to the phrases: "high probability," because of its connotation in statistical applications; "improper control," because of a lack of a standard for proper control; and "cause, allow, or contribute," because it could allow the elevation of trivial concerns to critical control point status.

FDA is persuaded by those comments that urged consistency with the NACMCF definition for "critical control point." The agency has, therefore, modified proposed § 123.3(c) (redesignated as § 123.3(b)) to read, "*Critical control point* means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." The modified language is consistent with the agency's decision to limit the HACCP provisions of part 123 to the avoidance of food safety hazards (see the "HACCP Plan" section of this preamble for discussion). It is also compatible with modifications described elsewhere in this preamble aimed at greater consistency with the NACMCF recommendations. The wording change will not have any practical impact on the requirements of the regulations because the definition still reflects the agency's intent to require that seafood be processed in a way that eliminates, to the extent possible, the chance that it will be rendered injurious to health by procedures that are under the control of the processor.

The NACMCF definition does not contain the phrases that were objected to by one of the comments as described above. Thus, the concerns raised by this comment have been resolved.

21. A few comments, however, stated that the definition should also apply to the control of all decomposition because it is a major problem associated with seafood.

FDA acknowledges that, because of the highly perishable nature of fish, decomposition is probably the most common problem associated with seafood. The agency further acknowledges the comments that expressed concern that failure to control this problem will continue to adversely affect consumer confidence. The industry especially should heed this concern and consider the application of HACCP principles to decomposition, if necessary, to help maintain the quality of its products.

Nonetheless, decomposition that is not associated with safety is not appropriately a part of these mandatory HACCP regulations but should remain subject to traditional good manufacturing practices controls (see, e.g., § 110.80(b) (21 CFR 110.80(b))). As discussed earlier, these regulations are being issued, in part, under section 402(a)(4) of the act. That section provides that a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. While decomposition in some species can be injurious to health and is therefore within the scope of section 402(a)(4) of the act, most decomposition affects the quality of seafood but not its safety. Decomposition that affects quality but not safety is subject to section 402(a)(3) of the act. Therefore, FDA is not subjecting decomposition that is not safety related to the requirements of these final regulations but will continue to regulate decomposition under traditional CGMP control.

FDA points out that it has defined "food safety hazard," a term that the agency uses in the definition of "critical control point," in § 123.3(f). The agency discusses this definition, which is consistent with the NACMCF recommended definition, later in this section.

4. Critical Limit (CL)

FDA proposed in § 123.3(d) to define a "critical limit" as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk of occurrence of the identified hazard." In the preamble to the proposed regulations, the agency explained that the proposed definition was intended to be consistent with the concept of the NACMCF recommended definition, which reads, "a criterion that must be met for each preventive measure associated with a critical control point." However, the proposed definition was also intended to be more explanatory than is the NACMCF definition, especially as it relates to the assignment of a minimum or maximum value and in the relationship of these values to a minimization of the risk, rather than to an absolute elimination of risk.

22. Several comments stated that the proposed definition of a "critical limit" should be modified to be the definition recommended by the NACMCF. The comments asserted that the NACMCF definition is the internationally accepted standard, and that its use in the regulations would avoid confusion. A few comments argued that FDA's use of the phrase "minimize the risk" implies that the CL must be set to attain the lowest possible risk, unlike the "reduce to an acceptable level" standard in the NACMCF definition for CCP.

Although FDA agrees that the definitions in these regulations should closely adhere to the NACMCF's recommended definitions, the agency concludes that, in this instance, FDA's wording is more descriptive for regulatory purposes and more useful to processors. However, FDA has been persuaded that the phrase "minimize the risk" may be misinterpreted as requiring outcomes that are not realistically achievable by a processor. To provide clarification and consistency with the revised definition of "critical control point," FDA has replaced the phrase "minimize the risk" with the phrase "prevent, eliminate, or reduce to an acceptable level" in the final regulation (now codified as § 123.3(c)). As noted previously, this language also appears in the NACMCF definition of "critical control point." The new language correctly provides for the making of scientific judgments about appropriate degrees of hazard reduction, based on the nature of the hazard and the availability of controls, and is more consistent than the proposed language with accepted HACCP convention.

23. One comment stated that the word "identified" should be deleted from the proposed definition.

FDA is not persuaded to make any modification to the definition in response to this comment. The "identified hazard" refers to the hazard identified in the HACCP plan.

24. One comment stated that the phrase "in the end product" should be added following the word "hazard" in the proposed definition.

FDA is not persuaded to make any modification to the definition in response to this comment. Food safety hazards are, by definition, those that cause "a food to be unsafe for human consumption." This definition implies a consideration of the end product that will be offered for human consumption.

25. One comment objected to the phrase "the maximum or minimum value" in the definition, stating that, as in the case of certain food additives, there are situations where both a maximum and a minimum value exist, and a processor is required to maintain the process between these values.

FDA is not persuaded to make any changes to the proposed language in response to this comment. The word "or," which the agency uses in the definition, is inclusive. Thus, properly read, § 123.3(c) states that a CL is the maximum value, the minimum value, or both the maximum and minimum

values within which the parameter must be controlled to protect against the occurrence of a food safety hazard.

For consistency with the definition of "critical control point," FDA has added the phrase "food safety" before the word "hazard" in the text of § 123.3(c). The language in the final regulation now reads, "*Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard."

5. Fish

26. FDA proposed to define "fish" as "fresh or saltwater finfish, molluscan shellfish, crustaceans, and other forms of aquatic animal life other than birds or mammals." A significant number of comments suggested that FDA should modify this definition to clarify whether it includes species such as sea snails, abalone, frogs, alligators, turtles, other reptiles, amphibians, sea cucumbers, plants, or algae.

FDA agrees that this type of clarification would be helpful and has modified the definition at § 123.3(d) to read:

Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

The term "mollusks" includes abalone, sea snails, and land snails (e.g., escargot and any other terrestrial gastropods, such as the giant African land snail (*Achatina fulica*)). The addition of examples of aquatic animal life and the mention of mollusks are intended to make clear which species are covered by the term "fish." Water-dwelling reptiles and amphibians other than alligators, turtles, and frogs have not been specifically listed because they are not significant commercial food sources in the United States. Finally, FDA notes that, consistent with the proposed definition, aquatic plants (including algae) are excluded. This definition is consistent with the traditional treatment of these products by FDA.

The new language also serves to emphasize that these regulations apply only to those products that are intended for human consumption. This point was explicit in the proposed definition for "fishery product" but was inadvertently not mentioned in the proposed definition of "fish."

27. Two comments contended that there should be separate definitions for finfish and shellfish, to differentiate between relative levels of safety concerns (e.g., high and low risk).

FDA disagrees with this comment. Such a differentiation would serve no purpose in these regulations. The purpose of these regulations is to set up a unitary system that responds to a particular product based on the risks it presents, not to establish a system that is divided up based on risk presented. The merits of differentiating between products on the basis of risk is addressed in the section of the preamble entitled "Should Some Types of Processors be Exempt?"

6. Fishery Product

FDA proposed to define "fishery product" as "any edible human food derived in whole or in part from fish, including fish that has been processed in any manner." The preamble to the proposed regulations stated that the intent of the definition was to include products that contain seafood as an ingredient as well as those products that are comprised of seafood alone, because hazards derived from seafood are reasonably likely to occur in both types of products.

28. A few comments urged that FDA exclude from the meaning of "fishery product" any product that is made in whole or in part from commercially sterilized fishery products subject to the requirements of parts 113 and 114, (i.e., thermally processed low-acid canned foods and acidified foods).

FDA disagrees with this comment. Although such foods are required to be produced in accordance with certain HACCP-type control procedures to reduce the risk of the hazard of *C. botulinum* toxin production, these control measures do not address other potential hazards. For example, part 113 provides no assurance that the raw material used in the canning of tuna will be free from contamination with dangerous levels of histamine. Likewise, products made in part from low-acid canned foods and acidified foods can also present hazards that must be addressed. For example, a salad made in part from canned tuna can be subjected to recontamination with pathogenic microorganisms and time-temperature abuse during preparation.

Although FDA cannot exclude those products made in whole or in part from low acid canned foods or from acidified foods from the definition of a "fishery product," it is worth noting that the agency has exempted processors who are following the requirements of part 113 or part 114 from having to include controls for *C. botulinum* in their HACCP plans. This hazard is already addressed by the requirements in those parts (see § 123.6(e) of these regulations and the "HACCP Plan" section of this preamble).

29. One comment suggested that the language of the proposed definition inappropriately excludes fish roe.

FDA points out that the phrase "any edible human food product derived in whole or in part from fish," in the proposal was intended to cover these products. FDA, however, has modified the definition of "fishery product," and it no longer includes this language. Therefore, to make clear that roe are covered, FDA has made explicit in the definition of "fish" that the roe of the covered animals are included.

30. A significant number of comments urged that the definition exclude products that contain only a minimal amount of fish. These comments suggested various standards that FDA should apply to exclude such foods from the definition. These included: Products that contain less than 50 percent fish; products that contain less than 10 percent fish; products that contain 2 percent or less of cooked, or 3 percent or less of raw, fish; products in which fish is not a characterizing ingredient; and products that contain any nonfish ingredient unless a hazard analysis identifies a significant hazard associated with the fish ingredient. The comments provided no justification for the percentages suggested.

FDA agrees that foods that contain inconsequential amounts of fish, such as Worcestershire sauce, are not the types of foods that should come under the purview of these regulations. It is doubtful that they pose reasonably likely hazards associated with their fish components. Moreover, these products are neither represented nor perceived as being fish-based foods.

The comments provided FDA with no basis, however, upon which to select a specific minimum content of fish ingredient for the definition of "fishery product." There is no obvious minimum percentage of fish on which to exempt a food that contains only a small amount of fish from the provisions of these regulations.

Instead, the agency accepts the comment that, to meet the definition of a "fishery product," a food should be characterized by the qualities of the fish that it contains. Thus, these regulations will apply to those foods whose basic nature is defined by the fish that they contain. Accordingly FDA has modified the proposed definition (§ 123.3(e)) to read in part, "*Fishery product* means any edible human food product in

which fish is a characterizing ingredient." This revision will serve to ensure that mandatory HACCP requirements do not apply to products that contain inconsequential amounts of fish from a public health standpoint.

31. One comment stated that fish oil that is intended for use in human food should not be subject to the requirements of these regulations until it has been separated, through initial processing, from the oil that will be used for animal feeds and other industrial purposes. FDA does not find that the comment provided sufficient justification to treat this product differently from other human food products processed from fish. The agency acknowledges that the hazards associated with these products may be minimal. If that is the case, the fish oil processor's burden will also be minimal, perhaps limited to training expenses and the performance of a hazard analysis. Moreover, these regulations do not apply to products that are not for human consumption and fish oil processors that are confident that their production will not be used for human consumption need not apply the requirements of these regulations.

7. Food Safety Hazard

32. A number of the comments recommended that FDA define "safety hazard" or "food safety hazard." Several of these comments recommended that FDA adopt a definition that is consistent with the NACMCF recommended definition for "hazard." The comments were primarily concerned with the coverage of these regulations. They urged that the regulations be clear that only food safety hazards need be addressed by the HACCP plan and argued that a definition would help to accomplish that.

The NACMCF definition of "food safety hazard" reads, "A biological, chemical, or physical property that may cause a food to be unsafe for consumption." While FDA provided no definition of "food safety hazard" in the proposed regulations, it did raise the issue of the coverage of the regulations in proposed § 123.6(b) (redesignated as § 123.6(c)), which mandated coverage of food safety hazards only and listed nine types of food safety hazards posed by the various types of fish and fishery products. This list included examples of biological, chemical, and physical hazards. Additionally, the preamble to the proposed regulations discussed at length the significance of a number of these types of hazards.

FDA agrees that the meaning ascribed by the agency to a food safety hazard should be as clear as possible in these regulations. The examples of hazards in the proposed regulations—and codified in these final regulations—are consistent with the NACMCF definition for a food safety hazard. Therefore, for the sake of clarity, FDA has decided to characterize these examples in a definition § 123.3(f), which reads, "*Food safety hazard* means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." The only difference between this definition and the NACMCF recommendation is the addition of the word "human." FDA has included this word to prevent confusion about the application of these regulations to pet or animal feed.

In keeping with the new definition, and to provide further clarification about the nature of the hazards that are required to be addressed by these regulations, the term "hazard" has been changed to "food safety hazard" where it appears throughout the codified portion of this document.

8. Harvester

FDA proposed to define "harvester" as "a person who has an identification number issued by a shellfish control authority for commercially taking molluscan shellfish by any means from a growing area." After review, the agency has concluded that it was not necessary to limit "harvesters" to those persons who have an identification number, primarily because in some jurisdictions, identification numbers may not be issued by a shellfish control authority. Without this limitation, FDA has concluded that there is no need to establish a particular meaning for this term for the purposes of these regulations. Therefore, the agency has removed this definition from the final regulations.

9. Importer

FDA proposed to define "importer" as "a person, or his representative in the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation." The preamble to the proposed regulations explained that the importer is the owner of the imported goods or the owner's representative in the United States. The preamble further noted that freight forwarders, food brokers, food jobbers, carriers, and steamship representatives would not usually be considered to be the importer of the product for the purposes of these regulations because they are not usually in a position to make decisions that can ensure the safety of the product. However, the preamble did not categorically rule out that these individuals could be the importer because sometimes they may be in a position to make decisions relevant to safety.

33. Several comments stated that FDA should modify the definition of "importer" to specifically exclude intermediary agents involved in the importing process, such as freight forwarders, licensed U.S. customs brokers, food brokers, food jobbers, carriers, and steamship representatives. These comments noted that, although imported products may enter the United States under the name of an intermediary, this practice is done for convenience in handling the paperwork at the port of entry. The comments stated that the intermediary has little responsibility for conducting the negotiations with an overseas producer and rarely takes possession of the products. Therefore, the comments stated, the intermediary has limited influence on the safety of the imported goods. Two comments pointed out, for example, that customs brokers that provide their clients with the service of using the broker's customs bond are listed as the "importer of record" and may thereby, unintentionally, be regarded as importers under the proposed definition, even though they do not own or control the product being imported.

Conversely, two comments argued that agents, such as food brokers, should be included in the definition of an "importer" because they bring product into the United States and sell it. The comments argued that the brokers should, therefore, be held responsible for ensuring that the foreign processor complies with the provisions of these regulations, to avoid an unfair advantage over domestic processors.

FDA concludes, based on the information provided in the comments, that these intermediaries can neither be categorically included or excluded. However, the agency recognizes that the number and type of comments on this issue demonstrate that the language of proposed § 123.3(h) was inadequate to convey the agency's intent, as articulated in the preamble. For this reason, FDA has clarified the definition of "importer" in § 123.3(g) to read, in part:

Importer means either the U.S. owner or consignee at the time of entry into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation.

Reference to the owner or consignee of the imported goods parallels the language in section 801 of the act (21 U.S.C. 381).

Because the ownership of imported products can change many times in a relatively short period of time after entry, the party who is the owner or consignee at the time that these products are offered for entry must be identified as the importer. As the person that has the ability to decide whether to offer the product for entry, this person is in a position to ensure that the product is processed under appropriate controls and to demonstrate this fact to FDA.

FDA must be able to verify the existence of the evidence of compliance by the foreign processor. This evidence, according to the provisions of § 123.12, is to be in the possession of the "importer." It must be available in the United States, however, if FDA is to consider the information in deciding whether to admit the products. Thus, where products are offered for entry by a U.S. owner or consignee, that owner or consignee will, for purposes of these regulations, be considered the importer because it will have control of this evidence. Where products are often offered for entry without a U.S. owner or consignee, the U.S. agent of the foreign owner or consignee will be considered the "importer" for purposes of these regulations to make clear who will be expected to have this evidence for such products.

FDA recognizes that the U.S. owner or consignee of the product, or the U.S. representative of the foreign owner or consignee, at the time of entry into the United States may also serve other functions. For example, it may also be a food broker for, or warehouser or processor of, the product. It may, in some instances, also be the freight forwarder, customhouse broker, or carrier for the product. These other functions will not matter, however, if the person is the U.S. owner or consignee of the product, or the U.S. representative of the foreign owner or consignee, at the time of entry into the United States. From FDA's experience, while certainly not impossible, it is at least unlikely that this qualification will be met by the customhouse broker, the freight forwarder, the carrier, or the steamship representative.

The agency has attempted to clarify this definition by including a sentence that reads, "For the purposes of this definition, ordinarily the importer is not the custom house broker, the freight forwarder, the carrier, or the steamship representative." Further, FDA does not intend to rely exclusively upon the assignment of the "Importer of Record" or the holder of the U.S. Customs Surety Bond in determining the "importer" for the purposes of these regulations, as was suggested in the preamble to the proposed regulations. In some instances the "Importer of Record" or the holder of the U.S. Customs Surety Bond will not meet the qualifications of an importer that are set out in § 123.3(g).

10. Lot of Molluscan Shellfish

FDA proposed to define a "lot of molluscan shellfish" as "a collection of shellstock or containers of shellstock of no more than 1 day's harvest from a single, defined growing area harvested by one or more harvesters." Because of language changes that FDA has made in subpart C of part 123, this term isno longer used in the regulations. Consequently, FDA has decided that there is no need to define this term and has eliminated the definition.

11. Molluscan Shellfish

34. Comments from a number of State agencies, trade associations, seafood processors, and the ISSC objected to the use of the term "fresh or frozen" in the proposed definition of "Molluscan shellfish." The comments were concerned because this definition would have the effect of exempting canned and any other heat-processed molluscan shellfish from the source control, recordkeeping, and tagging provisions of proposed subpart C of part 123 and proposed § 1240.60(b).

The comments stated that limiting these provisions to raw products would allow foreign firms to continue to heat-treat or can molluscan shellfish that are harvested from foreign waters that do not meet National Shellfish Sanitation Program (NSSP) standards and to export them to the United States. The comments stated that this situation was not in the best interest of the public health because of the potential for the presence of heat-stable natural toxins, such as paralytic shellfish poison or amnesiac shellfish poison, as well as chemical contaminants. The comments also complained that, because State laws and regulations require that all molluscan shellfish harvested in the United States come from waters approved by a shellfish control authority regardless of whether they are to be consumed raw or cooked,continuing to allow foreign processors who export cooked shellfish to the United States to use molluscan shellfish from unapproved growing waters places the domestic shellfish industry at a competitive disadvantage.

FDA believes that these comments are generally valid but are beyond the scope of this rulemaking. The point of this rulemaking it to determine whether FDA should require that HACCP be followed in the processing of seafood. The question of whether cooked molluscan shellfish that is being offered for import into this country is being harvested in a manner that creates public health concerns and unfair competitive advantages is a separate matter that the agency will address, if necessary, in the future.

Similar issues with respect to the use of the term "fresh or frozen" and the term "raw" in proposed subpart C of part 123 of these regulations and in proposed part 1240 are discussed in the "Molluscan Shellfish" section of this preamble (see comment 144).

12. Potable Water

FDA proposed to define "potable water" as "water which meets the U.S. Environmental Protection Agency's Primary Drinking Water Regulations as set forth in 40 CFR part 141." Because of changes that the agency has made in proposed § 123.10 (redesignated as § 123.11), the term is no longer used in these regulations. Consequently, FDA has eliminated the definition.

Nonetheless, a significant number of comments questioned when it would be necessary for processing water to meet the definition of "potable water." Because it is likely that both terms (i.e., processing water and potable water) will be used in the first edition of the Guide, FDA will consider these comments during the redrafting of the Guide.

13. Preventive Measure

FDA has added a definition for the term "preventive measure" at § 123.3(i). Although the term was not used in the proposal, the concept of preventive measures was a fundamental part of the hazard analysis that was implicit in proposed § 123.6(b). "Preventive measure" is used in the final regulations in § 123.6(a) in the description of a hazard analysis.

FDA proposed to require that all processors create a HAACP plan. Based on comments received, however, as explained below, FDA has decided to require that processors conduct hazard analyses to determine whether they need to develop a HACCP plan. This decision necessitates that FDA define "preventive measure." In accordance with the recommendations of the NACMCF (see Ref. 34, p. 189), a hazard analysis must identify both the food safety hazards that are reasonably likely to occur and the preventive measures that are available to the processor to control such hazards.

Identifying the preventive measures is necessary in order to determine whether a processing step is a CCP for that hazard. A processing step cannot be a CCP for a hazard if no preventive measure is available at that step to control the hazard. The definition of "preventive measure" in these regulations is essentially the same as that recommended by the NACMCF.

14. Process Monitoring Instrument

The term "process control instrument" was used in the proposal for consistency with the phrase "the procedures * * * that will be used to control and monitor each of the critical control points." For consistency with the NACMCF principles of HACCP, FDA has modified the language of § 123.6(c)(4) to eliminate the word "control." In order to achieve consistency within these regulations, the agency has concluded that the appropriate term for such instruments is, therefore, a "process monitoring instrument."

15. Processing and Processor

Along with the term "importers," the terms "processor" and "processing" collectively define who is subject to these regulations.

FDA proposed to define "processing" as:

[W]ith respect to fish or fishery products, handling, storing, preparing, heading, gutting, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, or holding. Practices such as heading or gutting intended solely to prepare a fish for holding on board a harvest vessel are excluded. This regulation does not cover the operation of a retail establishment.

FDA proposed to define "processor" as:

[A]ny person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. Persons engaged in the production of foods that are to be used in market or consumer tests are also included. Persons who only harvest or transport seafood, without otherwise engaging in processing, are not covered by these regulations.

a. *Vessels, carriers, and retail.* As explained in the preamble to the proposed regulations, the definitions of "processor" and "processing" excluded fishing vessels that essentially only harvest, transportation companies that carry but do not otherwise process fish and fishery products, and retail establishments. FDA invited comment on these exclusions.

In the preamble, FDA acknowledged that food safety hazards can be introduced at these three points in the commercial distribution chain. However, FDA tentatively decided to exclude fishing vessels, carriers, and retailers from the definition of "processor"—and thus from direct coverage under these regulations—because of practical considerations, such as the fact that the large size of the U.S. fishing fleet and the large numbers of carriers and retailers would overwhelm any rational Federal inspection system, and because the agency believed that the public health goals of the regulations could still be met.

FDA expressed its tentative view that the HACCP regulations would affect fishing vessels and carriers indirectly though the controls that processors impose to meet their obligations under HACCP. As for retail establishments, the preamble explained that, historically, they have been the regulatory responsibility of State and local governments. FDA traditionally has provided support through training, technical assistance, and the development of model codes. Since the issuance of the proposal, FDA has published its retail and institutional "Food Code," with the recommendation that it be adopted by State and local jurisdictions. The Food Code covers handling and receiving practices at retail, and its most recent version includes HACCP elements.

FDA's approach to these issues is based on agency discretion and does not derive from a lack of statutory authority. FDA has broad authority to regulate Food that is shipped in interstate commerce. While carriers are exempt from most direct FDA regulation in accordance with section 703 of the act (21 U.S.C. 373), the food being transported is not exempt. Moreover, FDA has authority under the Public Health Service Act (the PHS Act) (42 U.S.C. 264) to take such measures as it deems necessary to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the States or from one State or possession into any other State or possession.

FDA received a significant volume of comment on the question of coverage by these regulations of fishing vessels, carriers, and retail establishments. The majority of comments strongly favored inclusion of these entities within the scope of the these regulations.

35. The arguments relating to vessels and carriers tended to overlap. Those who favored inclusion noted that hazards—particularly those associated with time-temperature abuse and insanitation—can originate with fishing vessels and carriers. The comments argued that not controlling the conditions under which seafood is harvested and transported would amount to leaving CCP's unregulated. One comment observed that carriers have an incentive to turn off refrigeration units to save gas.

Several comments expressed the view that exclusion of vessels and carriers from the coverage of these regulations unfairly makes processors responsible for these aspects of seafood production. One comment pointed out that vessels, especially those that harvest scombroid toxin-forming species, should be legally responsible for any safety hazards that they cause through improper handling. Some comments asserted that HACCP can be practiced on fishing vessels and by carriers, at least with regard to temperature controls.

One State agency expressed the view that holding processors responsible for the behavior of fishing vessels has, in its experience, not worked, nor has education of fishing vessel owners or voluntary compliance by owners. The comment did not document the basis for these conclusions, however. Some comments argued that, while it would be difficult to include all vessels and carriers, those involved with high-risk products should be included.

Comments in favor of excluding vessels and carriers from these HACCP regulations noted that FDA's rationale for exclusion was prudent given the number, location, and diversity of the U.S. fishing fleet and the complexity of transport arrangements. For carriers, one comment noted that partial loads that are dropped off in different locations would be especially difficult to control. Some comments asserted that direct regulation of these entities was not necessary because processors could establish minimum requirements as a condition of purchase, as part of their HACCP systems. Some comments urged, however, that fishing vessels be subject to HACCP requirements when they deliver directly to an entity that is not subject to these regulations (e.g., a restaurant). One comment argued that receiving firms should require that product be in the same condition that it was in when it left the previous processor.

Some comments questioned the ability of fishing vessels and carriers to comply with HACCP requirements. A number of comments favored alternatives to HACCP, such as guidelines and standard operating procedures (SOP's).

FDA is impressed by the strong support for inclusion, of fishing vessels and carriers in the coverage of these regulations. Some of this support was based on concern over the loss of quality because of poor handling

practices (e.g., the effect of time-temperature abuse on shelf life and spoilage unrelated to safety) rather than on food safety considerations. Nonetheless, members of these two industries should be aware that significant concerns have been expressed with regard to their practices.

For some species and products, the practices of fishing vessels and transporters can have significant public health consequences. These practices can put pressure on a processor who is receiving these products to carefully scrutinize the condition of incoming materials. The practices can also put pressure on a processor to determine whether carriers are suitable to transport their finished products (e.g., that carriers have proper refrigeration).

The agency appreciates the argument that all entities that can affect safety in the distribution chain should accept and share this responsibility. These points notwithstanding, FDA received no comment that provided information about how the agency could operate an inspection program for carriers and harvest vessels with its current resources. For this reason, the agency concludes that such a program is impractical at this time.

When processors accept raw materials for processing, especially from vessels, they assume some responsibility for the condition of the incoming materials, regardless of how others are regulated. This is true under both general commercial law and the laws administered by FDA. Carriers likewise have responsibilities. If a carrier fails to exercise such controls as are necessary, food that it carries may be rendered adulterated and the owner of the product, i.e., the processor, could suffer product loss. Food handlers generally should exercise sufficient control over the products in their custody to ensure that any food safety hazards that are reasonably likely to occur during that period are being addressed.

As an additional matter, FDA agrees with those comments that advocated a step-wise regulatory approach to these entities.

Mandatory HACCP for seafood is a pioneering venture. While the groundwork has been prepared for it through pilot projects and other efforts over the years, there is no substitute for actual experience once it is operating. The agency would prefer, therefore, to construct the system through a series of manageable steps if it needs to do so, rather than to risk overextending itself and the system initially. While these regulations exempt carriers and harvest vessels from direct coverage, experience with the application of a mandatory HACCP program may, at some later date, cause the agency to reconsider its approach.

For fishing vessels, FDA intends, for the time being, to issue good handling practice guidelines. To that end, the agency is studying those issued by the State of Alaska and by the Codex Alimentarius Commission of the Food and Agriculture Organization/World Health Organization, among other such available guidance. FDA will evaluate the effect of these guidelines, in addition to any requirements that States have or may adopt regarding fishing vessel practices, and reassess at a later date whether there is a need for mandatory Federal controls. The agency invites continued correspondence and the sharing of views on this matter.

The comments that recommended that vessels that sell directly to "non-HACCP" establishments (e.g., restaurants) should be required to have HACCP plans are advised that the Food Code addresses the subject of source control for retail establishments and recommends the requirement of HACCP plans for retail establishments in some circumstances. This matter relates principally to State and local laws and is addressed below in the discussion of retail establishments.

For carriers, the situation is complicated by the restriction in section 703 of the act that was described previously. As one comment recommended, FDA has had conversations with other Federal agencies on the subject of transportation of food and will continue to do so. In the meantime, FDA strongly recommends that processors review the material in the Guide on how they can exercise control over incoming raw materials as well as over shipments of their own products. One emerging area that the agency is monitoring—and processors should consider also—is the development of inexpensive time-temperature sensors that indicate whether proper temperatures have been maintained over a period of time.

36. The question of the inclusion of retail establishments within the mandatory seafood HACCP system involves some different considerations. Processors have less influence, if any, over how their products are handled at retail than they do over how their products are handled by vessel operators or carriers. Some comments pointed out, for example, that a processor's best efforts could be for naught if the product is subsequently mishandled at retail.

Several comments pointed out that many retail establishments carry out activities that meet the definition of "processing." According to these comments, such establishments should not be exempt from HACCP requirements.

Other comments took the view that these regulations should not apply to retail establishments, primarily for the reasons provided in the preamble to the proposal. Some recommended that retail establishments should not be subject to the regulations so long as the Food Code applies to them. Others suggested that HACCP should apply if the retail establishment buys directly from a fishing vessel or from sport fishermen. Some suggested better consumer education and voluntary HACCP-type programs.

FDA agrees that there are hazards that occur at the retail level that can render meaningless the controls that may have been in place elsewhere in the chain of production and distribution. The NAS has cited retail and food service establishments as sources of seafood-related illnesses (see Ref. 7, p. 27). FDA is convinced—and the comments support—that proper controls at the retail level are imperative to ensuring a safe product.

Nonetheless, FDA's observation in the preamble to the proposed regulations remains valid that retail establishments pose an inspection burden well beyond the capacity of FDA. No comments have provided any basis for the agency to conclude otherwise or would justify the significant shift of resources that would be necessary for FDA to even begin to address the retail sector in a meaningful way. FDA notes that State and local governments provide significant regulation of the retail food sector. FDA has committed the resources that it has available for addressing retail problems, by providing training and technical assistance to State and local governments. Most significantly, FDA has provided guidance in the form of the Food Code, which provides the latest and best scientifically based advice about preventing foodborne illness for adoption by those jurisdictions that have regulatory responsibility for food service, retail, and vending operations.

It is worth noting that the Food Code suggests the use of HACCP controls at retail in some circumstances where comments argued for such controls as part of these regulations. Under the regulatory controls suggested in the Food Code, a retail establishment that purchases a scombroid toxin forming species of fish from a recreational harvester, for example, would need a HACCP plan relating to how it will ensure that fish had been handled so as to avoid time-temperature abuse. Under

the Food Code, fish caught recreationally generally require the approval of a regulatory authority in order to be sold to a retail establishment. The States should be aware that the Food Code is responsive to concerns raised by comments in these respects. FDA urges the States to consider adopting the Food Code for retail and institutional operations.

It is worth noting that the Food Code applies HACCP requirements to retail establishments as an exception for extreme situations, rather than as the rule. There is still much to be learned about the application of HACCP to retail establishments. Also, it may not be wise to single out seafood for the application of HACCP at retail. Retail operations can be complex and involve the handling of many types of foods. Trying to operate a HACCP system solely for seafood could divert attention away from important safety practices for high-risk products other than seafood.

For all these reasons, therefore, the agency concludes that FDA should not mandate HACCP systems for the seafood component of retail establishments at this time. Also, the agency has not been provided with any information on how an FDA inspection program for such establishments would be feasible. Nonetheless, the agency will take all comments on retail establishments under advisement for future consideration as the system evolves.

It is important to note, however, that where a processor engages in mixed operations (i.e., some retail and some wholesale), as in the case of cash-and-carry warehouses noted by one of the comments, the wholesale portion of the operations will be subject to the provisions of these regulations. As a further point of clarification in response to one comment, FDA has traditionally, and will continue to, classify central kitchens that distribute product to retail outlets that are owned by the same firm as a retail operation.

b. *Warehouses.* In the preamble to the proposed regulations FDA stated that the definition of "processor" included warehouses. Warehouses store fish and fishery products, one of the operations included in the proposed definition of "processing." A "processor" is simply an entity that engages in processing.

There are food safety hazards that can be introduced while storing a product (e.g., in a warehouse). These hazards include, among other things, pathogen growth in cooked, ready-to-eat products and histamine development in scombroid toxin-forming species, as a result of improper storage temperatures. Nonetheless, the warehouse environment usually has few hazards compared to complex processing operations. Consequently, the preamble to the proposed regulations invited comment on whether warehouses should be exempted from the definition of "processor" and, by implication, whether "storing" should not be included in the definition of "processing," as one way of scaling the regulations back in terms of cost and burden.

37. The comments split about evenly on this subject. Those that gave a reason for including warehouses cited the need to monitor storage temperatures for species that are prone to safety hazards if they are temperature abused. Those that opposed and provided a reason tended to argue that storage alone should not subject an establishment to the requirements of the regulations. A related concern was the view that warehouse operators do not have a thorough knowledge of the products that they handle and only store products that are provided to them by others. This concern was expressed both by those who objected to the inclusion of warehouses and those who simply asked for clarification about the role of warehouses. Others who asked for clarification expressed the view that warehouses could be responsible for conditions during storage.

After consideration of these comments, FDA has decided to retain warehouses (e.g., public storage warehouses, foodservice distribution warehouses, and wholesale grocers) within the definition of "processor" and to retain "storing" within the definition of "processing." It is important to recognize that section 402(a)(4) of the act covers storage along with other forms of processing. It states that a product is adulterated if it is "prepared, packed, or held under unsanitary conditions * * * whereby it may have been rendered injurious to health." These regulations are being issued for the efficient enforcement of section 402(a)(4) of the act. Moreover, as described above, hazards can be introduced as well as controlled during storage. HACCP is an appropriate system for the control of these hazards.

FDA believes that the burden on warehouses will be minimal given the simplicity of the operation and the fact that, in most cases, a warehouseman's responsibility under HACCP will only extend to conditions within the warehouse that could cause a safety hazard to occur.

For the most part, hazards deriving from the environment (pesticides, etc.) will be controlled during the initial processing of the product (i.e., by the first processor to take possession). As a result, subsequent processors will receive products that are generally free of environmental hazards and thus will not need to establish HACCP controls for them. More often than not, storing will not be the first processing operation. Thus, a warehouse will not usually be responsible for environmental hazards. The same principle holds true for hazards arising during processing operations that occur before storage in a warehouse. Those hazards must be controlled during the prior processing and generally not during storage.

There may be occasions, however, when storage is the first processing operation (e.g., when a warehouse will be the first processor to receive raw material fish from a fisherman or aquacultural producer). Under these circumstances, the warehouse, rather than a distant owner of the product, may be in the best position to obtain information that may be needed about harvest site, fishing practices, and transportation to the dock that would be germane to safety. There should be some arrangement between the warehouse and the owner on this matter to ensure that environmental hazards are properly addressed.

38. One comment objected to the inclusion of storage within the definition of processing on the grounds that FDA should not dictate where CCP's should be.

The agency is not attempting to do so. FDA acknowledges that whether storage is a CCP will depend on the circumstances. For example, refrigerated storage of a scombroid species will likely be designated as a CCP, whereas dry storage of canned fish will not likely be considered as such.

39. Another comment objected to including "airline warehousing" within these regulations.

If airlines hold product as part of their usual course of business as carriers, they are exempt from having HACCP plans in accordance with section 703 of the act.

c. *Other processing operations.* 40. A few comments requested clarification on whether waterfront facilities that unload vessels and pack the catch for shipment to buyers are engaging in processing and thus meet the definition of "processor."

These firms perform activities such as handling and storing that are included in the definition of processing and fall within the purview of the "prepared, packed, or held" clause of section 402(a)(4) of the act. Additionally, these activities warrant coverage under these regulations because of their relationship to reasonably likely hazards. For example, these firms are, by design, usually the first processors to receive

the product from the fisherman or aquacultural producer. As such, they are often in the best position to control environmental hazards, as was previously discussed. They also often store the product, at least for short periods of time. In this capacity, they may be responsible for ensuring that the product is not exposed to time-temperature abuse, a phenomenon that critically affects the safety of some products.

For these reasons, FDA has clarified the definition of "processing" at proposed § 123.3(m) (redesignated as § 123.3(k)) to specifically include dockside unloading.

41. One comment took the view that only processors who own the products that they are processing should be subject to these regulations and suggested that the term "processor-owner" be substituted for "processor." Several other comments questioned whether custom processors that do not own the product, should be subject to the provisions of these regulations.

The definition of "processor" does not hinge on ownership. As indicated earlier, whether a product is adulterated under section 402(a)(4) of the act depends on the condition under which it was "prepared, packed, or held." Ownership is not a relevant factor. Consistent with this principle, these regulations define a processor as simply an entity that engages in processing. "Processing" is defined as including a number of activities, such as manufacturing and packing, that are normally performed by a custom packer.

Like warehouses that store products for distant owners, custom packers are often in the best position to exercise HACCP controls for the products that they process. Because of the real-time nature of HACCP (i.e., because monitoring provides immediate feedback as to whether a hazard is being controlled), the processor can most effectively apply HACCP monitoring controls to a food being processed, regardless of whether the processor is the actual owner of the food. FDA recognizes that it will often be beneficial for the custom processor and the owner of the product to fully discuss and agree upon the HACCP controls that will be effected by the custom processor while the product is in its possession.

42. One comment argued that custom packers should be included within the scope of these regulations because these processors often can or smoke recreationally caught products and are often the only commercial entity that can assure the safety of such products. While the definition of "processing" clearly covers the kinds of activities performed by custom packers, it is not the intent of these regulations to address arrangements between a recreational fisherman and a custom packer for the processing of fish for the personal use of the fisherman. The regulations only cover custom packing that is performed on behalf of an owner who intends to introduce the fish into interstate commerce. Nonetheless, the agency does not believe that clarification to the regulations is needed on this point.

43. One comment urged that aquacultural producers that also eviscerate the fish before delivery to a processing plant be required to comply with the requirements of these regulations.

FDA agrees with the comment and further states that the process of eviscerating is specifically included in the definition of "processing." Eviscerating is excluded from the definition only when it occurs on a harvest vessel for the purpose of preparing the fish for holding en route to the processor.

44. A few comments objected to FDA including labeling in the definition of "processing." The comments argued that labeling operations are unlikely to introduce hazards to the product. FDA has considered these comments but finds that there is potential during some labeling operations for the development of hazards. For example, improperly controlled labeling operations for scombroid species could result in time-temperature abuse of the product, increasing the risk of histamine contamination. Cooked, ready-to-eat products could similarly be subjected to time-temperature abuse, resulting in the potential for pathogen growth. The inclusion of labeling in the list of processing operations is not intended to imply that this step should always, or even frequently, be considered a CCP. That can only be determined through the conduct of a hazard analysis.

FDA proposed to exempt "heading or gutting intended solely to prepare a fish for holding on board a harvest vessel" from the definition of "processing." In drafting the proposed regulations, FDA was concerned that, in the absence of such an exemption, harvest vessels that are presently heading or gutting fish would stop the practice to avoid being subject to the requirements of these regulations. FDA did not want an inadvertent consequence of these regulations to be a reduction in product quality. In addition, FDA tentatively concluded that safety hazards introduced by these operations are generally minimal.

45. One comment noted that FDA should include the practice of freezing fish on harvest vessels in the list of exempted operations.

FDA agrees that freezing is an operation that is routinely used onboard a harvest vessel in order to preserve the quality of the fish until it is landed for further processing (e.g., freezing performed onboard tuna harvesting vessels). For this reason, the agency has revised the definition of "processing" to include an exemption for onboard freezing.

46. One comment suggested that FDA also exempt onboard scallop shucking operations.

Unlike shucking other molluscan shellfish, shucking scallops involves eviscerating, a procedure that falls within the exemption in § 123.3(k). Consequently, onboard shucking of scallops does not constitute processing for purposes of these regulations. The agency does not believe that a change in the definition is necessary in this regard.

47. One comment suggested that, with respect to molluscan shellfish, "processors" should include shellfish shippers, reshippers, shucker-packers, repackers, and depurators.

The persons that perform all of these types of operations are "processors" under § 123.3(k)(1) and subject to the provisions of these regulations. Thus, the agency has concluded that no change in the definition is necessary.

16. Scombroid Toxin-Forming Species

The term "scombroid toxin-forming species" appears in § 123.6(c)(1)(vi) of this final rule. While FDA did not propose to define this term in the codified portion of the proposed regulations, it did propose to define it in part 123 appendix B as:

> [T]una, bluefish, mahi mahi, mackerel, sardines, herring, kahawai, anchovies, marlin, and other species, whether or not of the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

Appendix B of part 123 is no longer included in these regulations, as is discussed elsewhere in this preamble. Consequently, FDA is transferring the definition from part 123 appendix B to § 123.3(m) to clarify the meaning of § 123.6(c)(1)(vi).

48. A number of comments objected to the inclusion of herring in the list of scombroid toxin-forming species, arguing that there has been no association between herring and cases of histamine poisoning.

In response to the comments, FDA has modified the definition of scombroid

toxin forming species to make specific reference to only tuna, bluefish, and mahi mahi, since the overwhelming majority of scombroid poisonings are associated with these types of fish. Processors should assess the potential of other species to product histamine. The key to the definition is whether significant levels of histamine may be produced in the flesh of the fish.

17. Shellfish Control Authority

FDA proposed to define "shellfish control authority" as "a Federal or State health authority, or foreign government health authority, legally responsible for the administration of a program that includes classification of molluscan shellfish growing areas, enforcement of harvesting controls, and certification of molluscan shellfish processors."

49. A few comments pointed out that the definition should not require that a shellfish control authority be a State "health" authority because in some States the responsibility is vested in other than a health agency, such as a resource management agency.

FDA recognizes that these comments are correct. For this reason, the agency has modified the language in § 123.3(o) to read, in part, "State agency." FDA believes that this term is sufficiently broad to encompass any of the present State arrangements. FDA has made a parallel change with respect to foreign government authorities, in order to accommodate the same kind of variations in regulatory arrangements. These final regulations similarly refer to a "foreign agency."

50. One comment, from a State regulatory agency, stated that within the United States, FDA should be the responsible shellfish control authority and should mandate that processors register with FDA, much as it has done with low-acid canned foods and medical devices. The comment further stated that a requirement in Federal regulations that State agencies perform this function may be unconstitutional.

The comment misconstrued the provision. The provision is intended to define the term "shellfish control authority" rather than to provide substantive requirements. Furthermore, these regulations at no point mandate that States perform certain functions.

51. Some comments expressed concern that the proposed definition of "shellfish control authority" was too narrow in that it did not include any entities that could serve the function of a shellfish control authority for Federal waters. The effect of the proposal, the comments pointed out, would be to close unnecessarily all molluscan shellfish harvesting in Federal waters.

It was never FDA's intent to close Federal waters to molluscan shellfish harvesting. These waters are beyond the jurisdiction of State shellfish control authorities, and no Federal agency classifies them in the same way that States classify their own waters. FDA is seeking a means to classify Federal waters. An agreement with NMFS relating to the classification of Federal waters is one possible solution. For this reason, FDA has modified proposed § 123.3(o) to state that a shellfish control authority may be "a Federal agency." This subject is also discussed in the "Molluscan Shellfish" section of this preamble.

52. One comment urged that FDA provide for the possibility of sovereign tribal governments serving as shellfish control authorities.

FDA recognizes that the proposed definition was deficient because it failed to include tribal governments in the list of possible shellfish control authorities. The agency, the State of Washington, and 19 Indian tribes have recently entered into a settlement that will likely result in such an arrangement in the State of Washington (Ref. 202). When such governments meet the necessary criteria, it is the intent of the agency to formally recognize them for purposes of classifying shellfish growing waters and certifying shellfish processing plants for inclusion on the Interstate Certified Shellfish Shippers List. To provide for this situation, FDA has modified the definition of "shellfish control authority" to include "sovereign tribal governments."

FDA has also recognized that in many cases the functions of "classification of molluscan shellfish growing areas, enforcement of harvesting controls, and certification of molluscan shellfish," as listed in the proposed regulations, are not carried out by a single agency. To provide for such a situation, FDA has modified the proposed language at § 123.3(o) to read, "program that includes activities such as," rather than simply "program that includes."

18. Smoked and Smoke-Flavored Fishery Products

The terms such as "smoked fishery products," "smoked fish," "smoked and smoke-flavored fishery products" were used in the proposed regulations and throughout appendix 1 to the proposal. As a result of decisions discussed elsewhere in this preamble, reference to "smoked and smoke-flavored fishery products" has been eliminated in these regulations except in part 123, subpart B.

While no definition of "smoked and smoke-flavored fishery products" was included in the definitions section of the proposed regulations, the terms "smoke-flavored fish" and "smoked fish" were separately defined in appendix 1 to the proposal as: "*Smoked-flavored fish* means fish that is prepared by treating it with salt (sodium chloride) and then imparting to it the flavor of smoke by other than the direct action of smoke, such as immersing it in a solution of liquid smoke," and "*Smoked fish* means fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the direct action of smoke from burning wood, sawdust, or similar material." FDA solicited comment on the materials in appendix 1. Because the term is used in these final regulations and FDA is concerned that there may be confusion about its application, the agency has determined that a definition of "smoked and smoke-flavored fishery products" is needed in the codified portion of these regulations. FDA has included one at § 123.3(s) that is consistent with those proposed in the appendix 1 to the proposal. Section § 123.3(s) reads:

Smoked or smoke-flavored fishery products means the finished food prepared by: (1) Treating fish with salt (sodium chloride), and (2) subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

FDA received numerous comments on the regulatory treatment of smoked and smoke-flavored fishery products, but none that would affect this definition.

E. The HACCP Plan

Approximately 100 comments addressed one or more of the provisions of proposed § 123.6. This section of the proposed regulations set out who must write and implement a HACCP plan, and what the HACCP plan must include.

1. Preliminary Steps

FDA proposed in § 123.6 to require that all processors of fish and fishery products prepare and implement a HACCP plan that identifies the hazards that are reasonably likely to occur and thus that must be controlled for that product. In the proposal, FDA acknowledged the process recommended by the NACMCF for developing a HACCP plan but did not propose to require that processors follow it. The process recommended by the NACMCF includes: Assembling a HACCP team, describing the food and its distribution, identifying the intended use and consumers of the food, developing a flow diagram, verifying the

flow diagram, and performing a hazard analysis (Ref. 34, pp. 187–188). All but the last of these have been identified by NACMCF as the "five preliminary steps" of HACCP.

It was, and still is, the agency's belief that processors would benefit from a process that included these five steps as well as a hazard analysis in order to successfully arrive at an appropriate HACCP plan. Nonetheless, the agency did not propose to require adherence to the "five preliminary steps," or explicitly propose to require that a hazard analysis be performed. So long as the processor had, in the end, a HACCP system that was appropriate for species and process, and was being implemented effectively, the agency tentatively concluded that these regulations did not need to manage the process any further.

53. A number of the comments contended that FDA should require that firms adhere to these procedures in preparing a HACCP plan. Specifically, a few comments argued that the proposed rule significantly diminished the potential effectiveness of HACCP by not requiring that processors engage in the "five preliminary steps." The comments argued that inclusion of the preliminary steps would facilitate international trade and reduce confusion on the part of seafood importers and exporters through consistency with an internationally recognized standard for HACCP.

Several other comments urged that the NACMCF recommendation for the development of a process flow diagram, in particular, by a processor be made mandatory. These comments identified several benefits from such a requirement: To facilitate employee implementation of the plan, to facilitate processor verification activities, to reduce the time needed for regulators to review the manufacturing process, and to enable the regulator to determine whether the processor properly considered the entire manufacturing process. One comment stated that FDA's assumption that flow diagrams are burdensome or unnecessary is contrary to the 1992 NACMCF Report which notes that flow diagrams could be simple representations that accurately depict the steps in a process, rather than detailed, technical drawings.

FDA acknowledges that, for the reasons stated in the comments, many processors will find that the development of a flow diagram is a useful preliminary step to the preparation of a HACCP plan. Other processors may find, however, that, because of the simplicity of their operations, the preparation of a written flow diagram is an unnecessary step. In either case, FDA is convinced that a processor's decision to develop or not to develop a flow diagram will be, and should be, driven by its perception of the benefits of doing so. The comments received on this subject were not sufficiently persuasive for the agency to conclude that a flow diagram should be made mandatory. The comments provided no basis to find that in the absence of a flow diagram, a processor could not properly develop a HACCP plan, or that a plan, so developed, would likely cause the HACCP program to fail.

As some of the comments pointed out, there may be some benefit to the regulator to have access to a flow diagram during an inspection, but this convenience is not a sufficient reason to mandate it. FDA investigators will likely develop their own flow diagrams during their in-plant inspections and compare them with the decisions reached by the processor in the development of the HACCP plan (e.g., the identification of hazards and CCP's). While it may be beneficial for the investigator to be able to compare his or her flow diagram with that of the processor, it is not essential to the conduct of the inspection.

FDA agrees with the comments that stated that the other four elements of the "five preliminary steps" are desirable attributes of the HACCP development process. However, the agency has not been persuaded that, in the absence of a regulatory requirement that they be followed, the HACCP program is unlikely to succeed. In order to write an appropriate plan some or all of these steps will likely have to be performed, even without a regulatory requirement to do so. However, if a processor can write a plan without these steps, the goals of the regulations will still have been met. For FDA to require them to be performed and documented in every case would add burden and reduce flexibility unnecessarily. Moreover, FDA is unconvinced that any inhibition to foreign trade is likely to occur if adherence to these steps is not required. FDA believes that foreign trading partners will be satisfied by the presence of a successful HACCP system and will not reject U.S. exports because steps preliminary to HACCP were not documented.

Even without a requirement mandating specific preliminary steps, FDA believes that most processors will follow the spirit, if not the exact letter, of the recommended procedures. These procedures provide the processor with a recognized method of plan development that will help lead to a successful outcome. FDA is primarily interested in that outcome. The NACMCF recommendation for the assembly of a HACCP team, in particular, could be a significant burden for the many small businesses operating in the seafood industry. For these reasons, the final regulations do not mandate any preliminary steps that processors must perform as a prerequisite to conducting a hazard analysis or drafting a HACCP plan.

2. Conducting a Hazard Analysis

54. A number of comments from trade associations and processors objected to the requirement in the proposal that every processor have and implement a written HACCP plan. These comments contended that FDA should revise this provision to require that a processor first conduct a hazard analysis to determine whether any food safety hazards exist that can be controlled through HACCP and then prepare and implement a HACCP plan only when the hazard analysis identifies at least one such food safety hazard. One comment stated that conducting a hazard analysis is the first step in a two-step process, with developing a HACCP plan being the second step. The comments urged consistency with the NACMCF recommendations in this regard.

FDA agrees with the approach suggested by the comments and believes that it is essentially consistent with what the agency proposed. Although FDA did not explicitly propose to require that every processor conduct a hazard analysis, completion of such an analysis by every processor was implicit in the requirement in proposed § 123.6(b)(1) and (b)(2) that processors identify both the hazards that are reasonably likely to occur and the CCP's for each of these hazards.

In response to the comments, FDA has decided to clarify its regulations to make the requirement that a hazard analysis be conducted explicit rather than implicit in order to clarify the steps that are required as part of a HACCP system. Moreover, this change allows the agency to make clear that conducting the analysis may or may not lead to the preparation of a HACCP plan.

Thus, FDA is providing in § 123.6(a) that processors shall conduct a hazard analysis or have one conducted on their behalf. It is the agency's expectation that most seafood processors will, after performing a hazard analysis, find it necessary to control for at least one hazard and, therefore, be obligated to prepare a HACCP plan. However, when no hazard is reasonably likely to occur, there is no reason to prepare a HACCP plan. Therefore, § 123.6(b) states, in

part, "(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."

The agency does not believe that the methodology of conducting hazard analyses is sufficiently standardized at this time to justify mandating what the analysis must include. FDA encourages processors to utilize the NACMCF document as guidance in performing this activity. In addition, the agency recognizes that the best way for it to verify a processor's hazard analysis is indirectly, through its own evaluations of whether a processor ought to have a HACCP plan, and whether a HACCP plan appropriately identifies the food safety hazards and CCP's that are reasonably likely to occur. In other words, it is the end product of the hazard analysis, the HACCP plan and its implementation, that should be judged by the regulator. For this reason, the agency is not requiring that hazard analyses be performed according to a standardized regimen, or that they be documented in writing for FDA review.

Even though FDA is not requiring that the hazard analysis be available to the agency, there may be cases in which it would be to the processor's advantage to have a carefully documented written hazard analysis to show to FDA. Such documentation may prove useful in resolving differences between the processor and the agency about whether a HACCP plan is needed and about the selection of hazards, CCP's, and CL's. Written hazard analyses may also be useful to processors in that they may help provide the rationale for the establishment of critical limits and other plan components. Having the basis for these decisions available may be helpful when processors experience changes in personnel, especially those associated with the HACCP process, and in responding to unanticipated CL deviations.

3. Types of Hazards

FDA received a number of comments on the types of hazards that a mandatory HACCP system should control, and that the hazard analysis should examine. The proposed regulations did not distinguish among hazards but proposed to require that HACCP plans identify all food safety hazards that are reasonably likely to occur. The comments that addressed the question of what types of hazards mandatory HACCP should address generally preferred that its focus be on some subset of hazards, rather than on the entire spectrum that could cause seafood to be adulterated. The comments argued that the hazards that were not the focus of the HACCP regime established by the regulations could be covered by more traditional food safety mechanisms. A review of these comments follows.

55. Several comments, from processors and trade associations, stated that the hazard analysis should only be used to identify those food safety hazards that have the potential to cause "serious adverse health consequences." These comments stated that such consequences included those that would trigger a "Class I" recall as defined by FDA, particularly those that involve contamination of the food with pathogenic microorganisms. A Class I recall involves a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death and would not be used to respond to situations in which the health consequences are temporary, medically reversible, or remote (21 CFR 7.3(m)(1) and (m)(2)). Other processor comments suggested the use of the phrase "significant food safety hazard" to limit the scope of the HACCP regime without proposing a definition for the phrase.

One comment stated that focusing on truly serious hazards is the only way to keep the number of CCP's to a minimum, so that a HACCP plan can realistically be implemented. The comment also stated that having too many CCP's, or CCP's that are not related to serious health risks, would so burden food processing personnel that effective compliance with the HACCP plan would be undermined, and it would be significantly more difficult to control truly critical processes.

Several of these comments argued that hazards should have immediate, as well as serious, health consequences before being required to be identified in a HACCP plan. These and several other processor comments generally expressed the view that hazards that can cause a food to be adulterated under the act, but that do not have the potential to cause acute illness, should not be required to be included in a HACCP plan. For example, two of the comments stated that FDA should not use the HACCP regulations to ensure conformity with food additive regulations, pesticide residue tolerances, or action levels for environmental contaminants. One comment stated that although process controls that are similar to HACCP controls are often used by food manufacturers to monitor these kinds of contaminants, the controls should not be regarded as part of HACCP because they do not address acute health hazards. A few comments suggested that existing regulatory programs are adequate to address these types of hazards.

On the other hand, comments from one trade association and a number of individuals acknowledged that drug residues and pesticide residues should be addressed by HACCP plans; where they are likely to occur at levels over tolerance. Comments from a number of processors of aquaculture-raised finfish acknowledged that drug and pesticide residues are food safety hazards that affect their industry, but these comments questioned the appropriateness of the control mechanisms provided in FDA's draft Guide. Finally, comments from several consumer advocacy groups expressed continued concern for the hazards posed by environmental contaminants.

Having considered these comments, FDA confirms its tentative view, reflected in the proposal, that HACCP should be the norm, rather than the exception, for controlling safety related hazards in the seafood industry. Existing standards for such contaminants as drug residues, pesticides, and industrial contaminants, are established to ensure that their presence in foods does not render the food unsafe. Processors of fish and fishery products are obliged to produce foods that meet these standards.

Processors are obliged to exercise control over all food safety hazards that are reasonably likely to occur. A failure to do so would mean that the food was prepared under insanitary conditions whereby it may have been rendered injurious to health or is otherwise adulterated. The criteria for including a food safety hazard in a processor's HACCP plan should be the degree to which the hazard is likely to develop in that product (e.g., based on the processing technique, the harvest location, the species) and not the nature or immediacy of the illness or injury that it is likely to cause.

FDA views as highly speculative the concerns, expressed by a few comments from the food industry, that inclusion in HACCP of those hazards that generally require chronic exposure to produce disease will dilute HACCP systems to the point of shifting industry resources away from acute toxicity hazards. No evidence was submitted to support such claims. The pilot HACCP program conducted jointly by FDA and NMFS, the current NMFS voluntary HACCP program, and the NMFS Model Seafood Safety Program all included controls for food additives, primarily a nonacute

food safety hazard, and there has been no diminution of control of acute hazards as a result. Moreover, the agency is convinced that when determining, in accordance with § 123.6(a), what contaminant hazards are "reasonably likely" to occur in a particular type of product, most processors will have very few, if any, of these chronic exposure-type hazards to manage through HACCP as opposed to through some other method of control.

FDA intends to monitor the progress of the seafood HACCP program to judge, among other things, whether the application of HACCP to food safety hazards generally, rather than to the most extreme acute hazards, overloads the HACCP system and dilutes its effectiveness for all hazards. Until such an effect is actually found to occur, FDA is persuaded that the systematic application of preventive controls to food safety hazards generally will provide the American consumers with the most effective and efficient food safety system that has been devised to date. If FDA were to determine that HACCP needs to be scaled back in order to make it work, the agency will take appropriate steps to make such a change.

One other factor bears mention in this regard. FDA has long been aware of consumer concern about environmental contaminants in fish and fishery products. As previously mentioned, this concern was expressed in the comments to the proposed regulations. The chance that these regulations will increase consumer confidence in the safety of seafood products would be greatly diminished if these regulations did not require processors to consider the risks from these contaminants as part of their hazard analysis.

56. A comment from a trade association stated that, while there is potential for an unapproved direct or indirect food or color additive to be a health hazard, the use of an additive that has not been listed for use in fish but is routinely used throughout the food industry would not necessarily be likely to cause harm to human health. The comment said that a control for use of the additive should not be required to be included in a HACCP plan.

Under the act, certain products, such as food additives, new animal drugs, including new animal drugs intended for use in aquaculture, and pesticides, require premarket approval before they may be legally used. Moreover, this approval can be limited so that the product may only be used legally on or with specific foods, or for specific purposes, for which approval has been obtained. This limitation reflects a longstanding realization that the safety of these types of products is variable and must be established on a use-by-use basis. Whether an additive, drug, or pesticide is safe for a particular use, in a particular food, at a particular level, depends on factors such as the amount of the food that is consumed and, if the additive, drug, or pesticide is ingested in a living animal before capture, how the product is metabolized in that animal.

Therefore, a food additive that has been approved for use in some foods, but not fish and fishery products, is deemed by the act to be unsafe for use with fish and fishery products. FDA is not in a position to change this aspect of the law through regulations. Consequently, the agency has not created an exemption from the requirement for HACCP controls for safety hazards caused by the presence of unapproved additives or other products that lack premarket approval for fish or fishery products.

The agency is aware that it is possible that some of these products may pose no meaningful risk in fish and fishery products at levels approved or allowed in other foods. It is the obligation of the proponent of the use of the substance to follow applicable statutory procedure to establish this fact to FDA's satisfaction.

57. In the preamble to the proposed regulation, FDA specifically invited comment on whether, in order to reduce the burden of HACCP on the industry, as in the Canadian fishery products HACCP regulation, the agency should limit its HACCP approach to cover only those hazards that are introduced within the confines of the processing plant. This type of limitation would eliminate mandatory control of environmental hazards such as pesticides, natural toxins, industrial contaminants, and aquaculture drugs through the HACCP system.

One comment contended that a processor of fishery products would be in a difficult position attempting to exercise control over problems that occur during harvesting. The comment stated that the purpose of HACCP is to require that each processor be responsible for minimizing those serious hazards that it is in the best position to control, but that the proposed regulations would force the processor to take responsibility for hazards that it may be poorly suited to control. The comment argued that FDA's intent was to deploy HACCP solely as a way of reducing the agency's inspectional burden. The comment further stated that the focus should be on finding those few CCP's within a specific process where a serious hazard can best be controlled. Several other comments expressed confusion about the application of HACCP to environmental hazards.

The preamble to the proposed regulations described the link between environmental hazards, such as natural toxins (e.g., ciguatera toxin, domoic acid, and saxitoxin), histamine, and various viral and bacterial pathogens, and human disease. The NAS' "Seafood Safety" report (Ref. 7, p. 1) suggested that the most significant reduction in illness from seafood would come from the control of environmental hazards. To eliminate coverage of such hazards from these regulations would be to eliminate the greatest share of anticipated benefits.

The preamble to the proposed regulations provided a number of ways in which the processor can exercise control over environmental hazards. This control derives from the fact that responsible processors already exercise discretion in obtaining their raw materials. Control is achieved by checking tags on containers of molluscan shellfish to ensure that they are harvested only from approved waters, checking with fishermen to ensure that finfish do not originate from harvest areas that are closed due to the presence of excessive agricultural or industrial contaminants, and physically examining incoming histamine-forming species for evidence of decomposition and insisting that harvest vessels exercise control over the time and temperature of storage for these species. Similarly, processors of aquaculture-raised species can audit or otherwise insist on a producer controls over the use of animal drugs or other hazards resulting from inappropriate husbandry practices. In a HACCP system, these are examples of controls that can be applied at the first CCP, i.e., at the receipt of raw materials.

FDA concludes that the measures that a processor takes to ensure that its raw materials are free of environmental hazards are a critical part of a seafood HACCP program. Responsible processors already exercise the kind of control necessary to ensure that their raw materials do not present such a hazard. If a likely hazard exists, it would not be sufficient to use the price offered for raw materials to be the only measure to protect against the hazard.

For these reasons, FDA has retained environmental hazards in the list of food safety hazards that processors should consider in § 123.6(c)(1). To clarify that there are hazards that occur before receipt of raw materials that can be controlled nonetheless by examination or discretion at the

receiving CCP, FDA has modified § 123.6 by including the following sentence in § 123.6(a), "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."

For consistency, § 123.6(c)(2) needs a space here provides for both types of CCP's, and now reads:

(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.

Because most of the environmental hazards to which fish are exposed will be controlled by the first processor to take possession of the fish from the fisherman or aquacultural producer, whether that processor is located in the United States or in another country. subsequent processors need not focus on these hazards in their HACCP plans. For example, pesticide contamination of inland and near shore finfish can be effectively controlled by the first processor by purchasing from fishermen who do not harvest in areas that have been closed by regulatory authorities, and drug residue contamination can be effectively controlled by the first processor by purchasing from aquaculture producers who use animal drugs properly.

4. When Is a Hazard Reasonably Likely To Occur?

In the proposal, FDA identified nine categories of safety hazards that might occur in fishery products. The agency tentatively concluded that a processor must establish HACCP controls when one or more of the listed hazards is reasonably likely to occur.

58. A number of comments, from processors and a trade association, questioned whether certain of these nine hazard categories by themselves justify a HACCP plan. The comments challenged the likelihood that some of these hazards would cause harm and asked for clarification on how a processor is to determine whether a hazard is "reasonably likely to occur." One comment held that, if the term "reasonably likely to occur" is linked to actual incidents of illness caused by a given hazard, it would be inappropriate to define some of the listed hazard categories as reasonably likely to occur. This comment also requested that FDA clarify whether the hazards identified in its draft Guide are those that the agency believes are reasonably likely to occur under all conditions for the listed species and processing methods. The comment further noted that residues of industrial or agricultural chemicals present in seafood are usually not present at levels that are reasonably likely to be a safety hazard, even in many of those species that are listed in the Guide as presenting that hazard.

As discussed in the preamble to the proposed regulations, FDA recognizes that HACCP need not be used to control every theoretical hazard, no matter how remote the likelihood of its occurrence. Moreover, as discussed earlier in this preamble, case law interpreting section 402(a)(4) of the act has held that conditions must be such as to create a reasonable possibility that a hazard will occur in order for product to be adulterated under that section of the law. (See *United States* v. *1,200 Cans, Pasteurized Whole Eggs, Etc.*, 339 F. Supp. 140–141.)

Unquestionably, historical occurrence of reported illness is an appropriate starting place for the identification of food safety hazards that are reasonably likely to occur in the absence of controls. For example, illness from scombrotoxin in those species that form the toxin if subjected to time and temperature abuse after harvest is one of the most frequently reported illnesses from seafood. Moreover, the relationship between abuse after harvest and the formation of the toxin is well established. FDA can say with comfort, therefore, that scombrotoxin poisoning is a hazard that is reasonably likely to occur in the absence of appropriate controls for scombrotoxin-forming species of fish.

For some hazards, however, the incidence of reported illness is very low. A good example is illness from the consumption of raw fish species that are prone to parasites. The low number of reported illnesses is probably attributable to underreporting and to the fact that controls for this hazard (e.g., commercial blast freezing that kills parasites) generally exist. However, it is well established that in the absence of controls, infection from parasites is a hazard that is reasonably likely to occur when a species that is prone to parasites is consumed raw.

The incidence of reported illness that is linked to a specific food is virtually nonexistent when the illness is the result of chronic exposure to a chemical contaminant. It is extremely difficult, for example, to link a specific case of cancer to a specific contaminant in food. However, where public health officials have determined that a contaminant represents a chronic health hazard, the standard control strategy to be employed by processors for such contaminants is to ensure that their presence in food remains below specific levels.

Processors are advised of such chronic health hazard determinations through FDA action levels, publications (e.g., **Federal Registers** at 55 FR 14359, April 17, 1990; 58 FR 11609, February 26, 1993; and 58 FR 48368, September 15, 1993), or other similar guidance documents. If the contaminant is present in food in an amount that is above that level, the food represents a hazard to health that the evidence from the chronic studies shows is reasonably likely to occur. The question, then, is whether the likelihood of finding a fish in which the contaminant is at a higher than acceptable level is an event that is reasonably likely to occur. For open ocean species of fish, for example, a finding of pesticide residues above nationally established tolerances can be a very rare event. For near shore species in certain locations, however, a finding above tolerance can occur often enough so as to warrant controlling for it as a matter of reasonable prudence.

The incidence of reported illness for a particular hazard may also be nonexistent or very low because the hazard may be too new to have generated reported illnesses. The emergence of natural toxins harmful to humans in species or in locales where the toxin has not been found before is a well known phenomenon in seafood. While FDA does not expect that HACCP controls should be in place to control for the possibility of such hazards—the hazard may or may not ever occur—the agency strongly believes that once a hazard does emerge and is identified, HACCP controls are highly appropriate to keep illnesses from occurring. For the duration of the a hazard, it must be treated as one that is reasonably likely to occur.

To provide clarification on the above points, FDA has modified § 123.6 by including the following sentence in new § 123.6(a):

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.

To reinforce that it was not FDA's intent to suggest that all of the nine hazard categories that it listed in § 123.6(c)(1) are reasonably likely to

occur in all circumstances, the agency has modified the language in this provision to read in part, "Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:" (the list of nine categories follows in the text).

The Guide is not intended as a definitive list of the hazards that are reasonably likely to occur, under all conditions, for those species and processing methods listed.

HACCP is a operation-specific process. For this reason, the processor must decide on a case-by-case basis what hazards it needs to address; that is, what hazards are reasonably likely to occur. The purpose of the hazards portion of the Guide is to provide a listing of hazards, by fish species and by finished product type, that FDA knows to have a reasonable potential for occurrence in the product.

FDA encourages processors to use the Guide, as well as any other available information, to decide what hazards need to be addressed in any particular plan. Processors need to recognize that they need to use judgment in applying the Guide to their own particular circumstances. For example, a processor of one species of fish may find that pesticide contamination is listed as a hazard for the species, but may be aware of credible data that demonstrate that the water from which it obtains its fish is free of such contamination. In that case, the processor is free to deviate from the guidance. FDA intends to clarify the Guide on this point by distinguishing between hazards that are reasonably likely to occur all of the time (e.g., histamine in species that are prone to it) and hazards that are reasonably likely to occur under certain circumstances (e.g., certain toxins when a "bloom" is occurring).

5. The Plan: Specific Considerations

59. FDA proposed that HACCP plans be specific to each processing location and to each kind of fish and fishery product processed by a processor, except that the plan may group kinds of fish and fishery products together if the hazards, CCP's, CL's, and procedures required to be included in the plan are identical. A few comments from processors and trade associations suggested that production methods should also be allowed to be grouped together so long as the hazards and the control procedures for the production methods are identical. The comments suggested that grouping would reduce the paperwork burden on some processors without altering the benefits attainable through HACCP.

FDA agrees with the suggestion for the reason presented by the comments and has modified § 123.6(b) accordingly, to read, in part:

> 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.

60. In the proposal, FDA specified that a HACCP plan must identify: The applicable food safety hazards; the CCP's; the CL's; the control and monitoring procedures; and the recordkeeping procedures. A few comments suggested that FDA use the word "list" or "include" rather than "identify" to describe a requirement for an item to appear in the HACCP plan. The comments suggested that it is not clear from the word "identify" whether the regulations are intended to require that the plan contain or include the actual values (e.g., the temperature of a refrigerator) or a description of the procedures, or whether it is permissible simply to make reference to their existence in a guideline or other source.

FDA's intent is that a HACCP plan explicitly include the value or a description of the procedures for each of the required HACCP elements. FDA agrees that a word such as "list" would be less ambiguous. Therefore, FDA has revised § 123.6 (c)(1), (c)(2), (c)(3), and (c)(4) by substituting the word "list" where the word "identify" appeared in the proposed regulations.

FDA has also revised § 123.6(c) by making another clarifying change. The agency has added the phrase "at a minimum" to the introductory statement to make clear that the required plan contents do not restrict a processor from including additional information in the plan, where it may be appropriate.

61. Two comments requested that FDA specify that decomposition, listed as one of the hazard categories in the proposal, is a hazard only in scombroid toxin-forming species.

These comments stated that decomposition in other species is not a safety hazard but is an economic and aesthetic problem.

FDA agrees with the comments in part. FDA's intent was to require control of decomposition in a HACCP plan only when it represents a food safety hazard. As described in the preamble to the proposed regulations, histamine (scombroid toxin) development as a result of microbiological decomposition in certain species of fish is a well recognized food safety hazard (Ref. 5, p. 24). There are some early indications, however, that the development of putrescine and cadaverine, also byproducts of decomposition of fish, under certain circumstances, may also represent food safety hazards (Ref. 203, p. 240). For this reason, FDA is hesitant to limit the safety concern associated with decomposition to the production of histamine. Accordingly, FDA has modified § 123.6(c)(1)(vi) to read, "Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition."

62. Comments from two State government agencies and a trade association stated that FDA should eliminate parasites as a safety hazard that must be considered for inclusion in a processor's HACCP plan. The comments noted that, with respect to pathogens, FDA makes the assumption that raw fish will be further processed by cooking, and that, therefore, that the pathogens will be destroyed and not pose a health hazard. The comments urged that the same rationale be applied to raw fish that may contain parasites. The comments further suggested that the retail level is appropriate point of control for parasites, and that the provisions of the Food Code are adequate to address this issue.

The comments further argued that parasites pose a hazard only in certain species that are consumed raw, and that mandatory control procedures for all fish that are consumed raw would create an enormous economic hardship for some segments of the industry. In particular, one of the comments contended that parasites have never been a problem in the large tunas that are eaten raw, and that it should not be necessary to freeze such fish before they are sold for raw consumption.

FDA's intent is to require control of parasites in a HACCP plan only in those instances when parasites are reasonably likely to occur in the portion of the flesh that is consumed, and the presence of the parasites will present a food safety hazard (e.g., where the fish is offered for raw consumption). To clarify this intent, FDA has modified § 123.6(c)(1)(vii) to read:

> 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 remove the hazard, or where the processor represents, labels, or intends for the product to be so consumed.

With regard to the comparison made by comments that FDA is requiring control of parasites in raw fish but not pathogens in raw fish, the characterization of FDA's policy towards pathogens is inaccurate. The sanitation provisions of these regulations are designed, in large part, to minimize the presence of pathogens in fish and fishery products, whether they are raw or further processed. The major opportunity for the introduction of enteric pathogens to processed fish and fishery products is from the processing environment as a result of insanitary practices rather than by the carcass of the animal (Refs. 3, p. 267; and 7, p. 33). For this reason, sanitation controls designed to prevent contamination of fish flesh are important to minimize the levels of enteric pathogens found on processed fish (Refs. 3, p. 10; 7, p. 27; 204; and 205). The agency is convinced that, if followed, these controls will be effective in minimizing the presence of such pathogens. Moreover, FDA has long enforced a zero tolerance for the presence of *Salmonella* on raw fish, based, in part, on the avoidability of such contamination through the application of CGMP's.

63. One comment stated that the term "physical hazards" in the proposal could be interpreted to include nonsafety related hazards.

In § 123.6(c), physical hazards are one of nine listed causes of "food safety hazards" that processors should consider for listing in their HACCP plans (§ 123.6(c)(1)(ix)). Thus, the agency believes that the language of this section clearly applies to food safety hazards only, and no modification of the provision is necessary in response to this comment.

FDA proposed that HACCP plans include the CL's that must be met at each CCP. FDA received no significant comment on this section (§ 123.6(c)(3)) and has made no substantive changes to it.

FDA proposed to require that HACCP plans include the procedures for both "monitoring" and "controlling" the CCP's. FDA recognizes that monitoring and controlling serve different purposes, and that the appropriate HACCP principle is the monitoring of CCP's to ensure conformance with the CL (Ref. 34, p. 197). How a processor exercises control is not critical to product safety so long as the CL is not exceeded. There are many ways to maintain control. No one way or list of ways needs to be stated in the plan so long as monitoring is taking place at an appropriate frequency to ensure that control is occurring and to detect CL deviations when they occur. For this reason, FDA has modified § 123.6(c)(4) to read, "(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."

FDA has also eliminated the reference in § 123.6(c)(4) to consumer complaints as a monitoring tool. As explained in more detail in the "Consumer Complaints" section of this preamble, FDA has concluded in response to comments that consumer complaints generally do not provide the processor with the kind of immediate feedback about whether the process is under control that monitoring should provide in a HACCP system. Consumer complaints may provide the processor with information that would be useful for verification purposes, however. These regulations therefore require processors to take consumer complaints into account as verification tools (§ 123.8(a)(2)(ii)).

Likewise, FDA has moved the reference in the proposed regulations to the calibration of process monitoring instruments to the new "Verification" section of these regulations (§ 123.8), and it has eliminated the specific reference to computer software validation. As explained in more detail in the "Verification" section of this preamble, FDA has concluded in response to comments that calibration is a verification function that provides the processor with information about whether its monitoring equipment is functioning properly. Computer software validation is a form of calibration and need not be addressed separately in these regulations.

64. In the preamble to the proposed regulations, FDA asked for comment on whether guarantees from suppliers should be considered as an acceptable way of meeting the proposed monitoring requirement. Comments from a number of processors responded that a certificate from a producer that a lot of raw material fish is free from unacceptable levels of pesticide and drug residues should be an acceptable means of monitoring the hazards of animal drug and pesticide residues in aquaculture-raised fish. The comment held that reliance on suppliers' certificates may be necessary because of the logistical problems that could be associated with analyzing raw materials for pesticides and drug residues. Of particular concern, the comments said, is the time necessary to analyze the samples. The comments further stated that the certificates should be based on participation in an industry wide quality assurance program designed to ensure that the raw materials are free from these hazards.

FDA believes that caution is warranted on the subject of supplier guarantees. Where more direct controls are available, they should be used. In the case of aquaculture-raised fish, more definitive controls than the acceptance of a certificate attesting to the absence of unapproved drug residues alone are available to a processor, and these controls are not unduly burdensome. They include the review of the supplier's animal drug control records when the lot is offered for sale and a system of onsite audits of the supplier, either by the processor or by a third party. Such alternatives are also available for most raw material hazards (e.g., checking container tags and harvester licenses as a means of controlling microbiological contamination in molluscan shellfish, and checking vessel storage records as a means of controlling histamine development in scombroid species). However, the agency recognizes that there may be some instances in which such controls are not possible, and suppliers' certificates or guarantees are the only available monitoring tool. In those cases, verification of the effectiveness of the certificates may be critical. Thus, the extent to which suppliers' guarantees can be relied upon will have to be considered on a case-by-case basis. However, FDA has made no change in § 123.6(c)(4) in response to the comments.

FDA has added § 123.6(c)(5) that describes requirements of the HACCP plan with regard to corrective actions. As explained in more detail in the "Corrective Actions" section of this preamble, FDA has concluded in response to comments that these regulations should provide the processor with the option of predetermining corrective actions. Predetermined corrective action procedures have the potential to enable a processor to take faster action when a deviation occurs than would be possible in the absence of such procedures, and to make a more timely response to the deviation when trained or otherwise qualified individuals are not readily available.

FDA has also added § 123.6(c)(6), which describes the requirements of the HACCP plan with regard to verification. As explained in more detail in the "Verification" section of this preamble, FDA has concluded in response to comments that a processor needs to specifically include in its HACCP plan the verification procedures that it will use and the frequency with which it will use those procedures. FDA finds

that inclusion of this information in the plan is necessary to underscore that a processor has an ongoing obligation to be sure that the verification steps that it has determined are necessary are readily ascertainable by the processor and its employees as well as by regulatory officials.

FDA proposed to require that HACCP plans provide for a recordkeeping system that documents the monitoring of CCP's. The proposed regulations also provided that the records must include the actual values obtained during monitoring and any consumer complaints that relate to the operation of CCP's or possible CL deviations. FDA has removed the latter provision, relating to consumer complaints, from § 123.6(c)(7). As explained above, these final regulations treat consumer complaints as verification tools rather than monitoring tools. Consequently, consumer complaints need not be included in a recordkeeping system that documents the monitoring of CCP's. A full discussion of issues relating to consumer complaints is presented in the "Consumer Complaint" section of this preamble.

6. Positive Versus Negative Recordkeeping

The preamble to the proposed regulations invited comment on whether it was necessary for the results of monitoring (i.e., the actual values) to be recorded regardless of whether a CL was met (positive recordkeeping), or whether it was only necessary to record information when a CL was not met (negative recordkeeping). The agency noted that negative recordkeeping is presumably less expensive than positive recordkeeping.

65. A substantial number of comments addressed this issue. Approximately two-thirds of these comments, including those from trade associations, processors, Federal, State, and foreign government agencies, consumer advocacy groups, and a professional society, supported requiring positive records. The remaining one-third of the comments that addressed this issue, from trade associations, processors, and Federal and State government agencies, argued that records should only be required when a CL deviation occurs, or that positive records should be required or encouraged, but that FDA should be granted access to only the negative records.

In general, the comments supporting the need for positive records recognized that monitoring records serve two major purposes: To facilitate the identification of trends that would lead to a loss of control if not caught in time and to document compliance with, or deviations from, CL's. Comments from a large processor and a trade association stated that, based on their extensive experience with HACCP, positive monitoring records provide a pattern of results and values that is much more meaningful than sporadic negative records alone. Several comments stated that positive recordkeeping facilitates the taking of corrective action before the CL's are exceeded.

Several comments stated that a provision that required only negative records would penalize the firms that already maintain records of all CCP observations. A few comments suggested that neither firm management nor FDA could verify that the monitoring procedures specified in a processor's HACCP plan are being carried out if only records of deviations from CL's are kept, because there would be no records to indicate that the other checks were actually being made. A comment from a consumer group further argued that allowing the use of negative records alone could create the opportunity for processors to limit their monitoring, because no records would be needed to demonstrate that such monitoring was performed.

Most comments that supported the use of negative records alone stated that positive recordkeeping and the review of positive records was overly burdensome for both the industry and the regulator. A few comments stated that positive records generate massive databases that disguise CL deviations, rather than illuminate them. No examples of this phenomenon were provided, however. One comment suggested that since FDA inspects most processors once a year or less, it is questionable whether the agency would be in a position to pick up trends in the data from a review of all the positive records that would be retained. Another comment stated that it is just as unrealistic to expect FDA investigators to review all positive records as it is for FDA to inspect all fish. A few comments argued that the sheer volume of the paperwork produced with positive recordkeeping would result in technical or clerical errors by processors that could result in products being deemed by FDA to be adulterated.

Several comments suggested that a system where CL deviations trigger remedial actions, which are properly documented, should be sufficient for FDA's verification purposes. One comment suggested that because processors can falsify positive records as well as negative records, FDA was mistaken if its motive for proposing to require positive records over negative records was to help prevent unscrupulous processors from circumventing the system. An additional comment supported limiting mandatory HACCP recordkeeping to negative records because FDA could not rule out the possibility that future court decisions or changes in FDA policy might permit the disclosure of HACCP records in FDA's possession, and negative recordkeeping would reduce a company's potential exposure.

FDA's reasons for proposing positive records match those in the comments that support these kinds of records. As the preamble to the proposed regulations noted, recordkeeping is the key to HACCP, enabling the processor and the regulator to see the operation through time. Negative records alone do not allow this assessment over time and do not provide assurance that the appropriate monitoring was even performed.

FDA cannot conclude from the comments that supported negative records that the burden of positive recordkeeping is excessive or otherwise outweighs the benefits. The agency acknowledges that a requirement for positive records may be more burdensome than one that only requires negative records. However, FDA received no new data on this issue. Positive recordkeeping can be extremely simple and need not take much longer to perform than the monitoring necessary to determine whether the process is in control (e.g., noting the temperature of a refrigerator in a logbook located next to the refrigerator) The agency is convinced that this minimal additional effort greatly increases the chances that a processor's HACCP program will be successful.

Based largely on FDA's experience with the positive recordkeeping requirements in the low-acid canned food and the acidified food industries, FDA does not agree that the volume of positive records that a system will generate will defeat the system by hiding CL deviations or trends toward such deviations. FDA's regulations at parts 113 and 114 require that these industries perform positive recordkeeping at identified CCP's. The industry itself requested this requirement.

FDA has found that these processors have no trouble making positive records, and that both the processors themselves and the regulators become adept at reviewing them and deriving benefits from them that would not have been available from negative records. These benefits have included being able to pinpoint with confidence when a

deviation began and ended, being able to react to trends toward a loss of control, and being able to prove that CCP's were actually being monitored as often as necessary to ensure control. The relative volume of records has not served as a roadblock in this regard.

It is unlikely that FDA investigators will review all monitoring records during routine inspections, except in highly unusual circumstances. As has been the case with FDA inspections of low-acid canned foods and acidified foods, the agency will, in most cases, select records to represent the production since the last inspection. This technique has proven to be both effective and efficient.

As for the concern that the agency will declare product adulterated on the basis of technical or clerical errors in positive-type records, the agency advises that it is not its intent to pursue regulatory action against product solely because of clerical or related errors in mandatory records. FDA does not take such actions against processors of low-acid canned foods or acidified foods, and it will not do so against seafood processors. FDA will consider the entire situation, and its potential for impact on human health, in formulating a response to deviations from these regulations.

As for the comment that FDA might as well mandate negative records because positive records can be successfully falsified, FDA advises that the possibility that records will be falsified—and that falsifiers will get away with it—is an issue that involves the fundamental credibility of the system. From FDA's standpoint, the agency's decades-long experience reviewing positive records on low-acid canned foods and acidified foods gives it confidence that its investigators can detect falsifications. However, FDA did not propose positive records for the purpose of catching falsifiers. FDA proposed positive records because this approach confers benefits on both the industry and the regulator that outweigh the additional work of maintaining them. Aside from the view, to which FDA strongly adheres, that most processors are honest and will not falsify records, the agency strongly believes that most processors will quickly see the benefits to themselves of a properly operating HACCP system based on positive records and will insist that their records be accurately completed.

One such benefit should be a more motivated workforce. HACCP monitoring and recordkeeping can and should be done by the workers who operate the system at the CCP's, not by quality control personnel. To the extent that these workers experience a sense of responsibility and pride associated with making accurate daily notations, the processor can expect to benefit.

Regarding public disclosure of records as mentioned by one of the comments, FDA continues to believe that possession of monitoring records by the agency will be more the exception than the rule, and that these kinds of records are protected from public disclosure in any event. The protection of records is addressed in detail in the "Records" section of this preamble.

FDA has therefore not modified the requirement that processors' monitoring records include the actual values obtained during the monitoring.

7. Signing the Plan

66. In the preamble to the proposed regulations, FDA specifically invited comment on whether HACCP plans should be required to be signed by a representative of the firm and, if so, by whom. Approximately 30 comments responded to the inquiry. About two-thirds of these comments, from processors, trade associations, professional associations, and Federal, State, and foreign national governmental agencies, supported the need for a signature. The remaining comments, mostly from processors and trade associations, argued that a signature was unnecessary.

Those that favored a requirement for a signature on HACCP plans stated that the signature does the following: Demonstrates formal adoption of the HACCP plan, solidifies responsibility for adherence to the plan, and fosters a sense of management ownership. The comments made the following suggestions with regard to who should be the signatory (in order of preference): Onsite manager, most responsible individual of the firm, any senior manager, HACCP coordinator, and all HACCP team members. Those comments that argued against a mandatory signature on the plan stated that the existence of a HACCP plan itself constitutes management support for the plan.

FDA agrees with the comments that recommended a requirement for HACCP plans to be signed by a representative of the firm. As suggested by the comments, such a signature will provide direct evidence of management's acceptance of the plan for implementation. FDA cannot stress enough that for HACCP to succeed, there must be a clear commitment to it from the top of the firm on down. Management must set a strong example in this regard. A signature requirement will remind management of this important responsibility and will signal to all employees that the firm regards the HACCP plan as a document to be taken seriously. Additionally, the representative's signature, along with the date of signing, would serve to minimize potential confusion over the authenticity of any differing versions or editions of the document that might exist. FDA has concluded that the burden of such a requirement would be minimal, and has added a new paragraph at § 123.6(d), that reads:

(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 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 * * *."

As will be discussed fully in the "Verification" section of this preamble, the adequacy of the HACCP plan must be reassessed, and modified as needed, whenever significant changes in the firm's operations occur, but no less than once per year. These reassessments and modifications are necessary to ensure that the plan remains current and is responsive to emerging problems. The signature of the firm representative will be valuable in documenting that these reassessments and modifications are performed as required. Particularly if no modification of the plan is needed, reassessment can be verified by FDA only if documentation, such as a signature, is maintained by the firm.

8. Relationship to Parts 113 and 114

67. A few comments urged that the final regulations provide that if a processor of low-acid canned fishery products is in compliance with FDA's regulations for these products under part 113, it would also be in compliance with these HACCP regulations with respect to the control of the hazard of *C. botulinum* toxin production. The regulations at part 113 establish HACCP-type controls for this hazard.

FDA agrees that there is no need for a processor to restate in its HACCP plan the requirements of part 113 or 114. It is also not necessary for such a processor to institute controls in addition to those specified in parts 113 and 114 in order to control the hazard of *C. botulinum* toxin production. Consequently, processors who must comply with the requirements of part 113 or 114 need not address this hazard at all in their HACCP plans. However, it is important to note that other hazards may be reasonably likely to occur in an

acidified or low-acid canned fishery product. These hazards must be addressed in the HACCP plan, as appropriate. For example, processors of canned tuna will likely need to identify in their HACCP plans how they will control the development of histamine before the canning process. Accordingly, to clarify what is required of processors of acidified and low-acid canned fishery products, FDA has added § 123.6(e), which reads:

> For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, 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.

9. Sanitation in the Plan

The question of the role of processing plant hygiene (i.e., traditional sanitation controls) in HACCP is addressed at length in the "Sanitation" section of this preamble. As explained in that section, FDA is requiring that processors address plant sanitation by monitoring for certain key sanitation conditions and practices apart from critical control point monitoring activities, or by including sanitation controls as part of the HACCP plan, or by adopting some combination of these two approaches, at the option of the processor. To reflect this approach, in paragraph (f) in § 123.6 on the inclusion of sanitation controls in the HACCP plan FDA has stated: "(f) Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitoring in accordance with § 123.11(b), they need not be included in the HACCP plan and vice versa."

FDA recognizes that, in many processing operations (e.g., cooked, ready-to-eat fishery products, smoked fishery products, and molluscan shellfish) sanitation controls, such as hand and equipment washing and sanitizing, are critical to the safety of the food because they serve to minimize the risk of pathogen introduction into finished products that may not be further cooked before consumption (Ref. 3, p. 267). For this reason, some processors may elect to include the control of sanitation conditions and practices in their HACCP plan in addition to, or in place of, monitoring for such conditions and practices apart from the HACCP plan. Based in part on experience gained from the seafood HACCP pilot project operated jointly by FDA and DOC, however, FDA also recognizes that sanitation controls may be difficult to fit in HACCP plans, with appropriate CL's and corrective actions sometimes being elusive. For this reason, some processors may elect to rely exclusively on sanitation controls that are not part of the HACCP plan. FDA considers either approach to be acceptable, so long as whatever approach is chosen is fully implemented and followed.

10. Nonsafety Issues

68. FDA proposed in § 123.6(c) to recommend, but not to require, that HACCP plans include controls for such nonsafety hazards as economic adulteration and decomposition that are not related to safety. Additionally, FDA proposed to append to the regulations at Appendix D guidance on how a processor can use a HACCP-based approach to ensure that fish and fishery products are in compliance with the economic adulteration and misbranding provisions of the act. Approximately 75 comments addressed these proposed provisions. The vast majority of these comments urged that proposed § 123.6(c) and proposed Appendix D of part 123 be eliminated from the regulations. Some of these comments suggested that it might be appropriate for the contents of proposed Appendix D to be included in the Guide.

Those that argued for removal of the recommendation that HACCP be used to control nonsafety hazards from the regulations stated that: (1) HACCP for safety purposes will be a big enough challenge for both the industry and regulators, and that inclusion of nonsafety hazards might be overwhelming; (2) nonsafety hazards, such as economic fraud and decomposition, are covered adequately by existing FDA regulations and standards and by industry quality control programs; (3) inclusion of nonsafety hazards deviates from the internationally recognized NACMCF recommendations; and (4) inclusion of nonsafety hazards, even as a recommendation, would dilute and jeopardize a desirable industry focus on safety. One comment stated that processing plant personnel and supervisors should be trained to expect serious consequences when CL deviations occur because this heightens their attention to monitoring and control. However, the comment further argued, the consequence of violating a nonsafety CL is likely to be relatively minor. The comment argued that, as a result, plant personnel and supervisors will become confused about the significance of CL deviations.

A significant minority of the comments favored the treatment of nonsafety hazards such as economic fraud and decomposition in the same manner in which safety hazards are treated in these regulations, with mandatory HACCP controls. These comments argued that: the same conditions of processing that affect the occurrence of safety hazards affect the occurrence of such nonsafety hazards a decomposition and economic fraud, making the two control systems compatible; an improvement in consumer confidence in seafood canno be achieved without improvements relative to economic deception and decomposition; decomposition is the number one cause of FDA legal action with respect to seafood; decomposition is a good indication of time and temperature abuse, which has a significant impact on the growth of pathogens; the seafood industry considers economic fraud to be the mo significant hazard affecting the marketing of its products; species substitution can be safety related, as in the case of the substitution of a scombroid species for a nonscombroid species; HACCP controls would likely enhance compliance with existing nonsafety standards; and inclusion of controls for economic fraud and decomposition would not significantly increase the costs to industry.

FDA concludes that the HACCP system will have to mature, and much will have to be learned, before it can b determined whether a mandatory HACCP program should include nonsafety matters. Because these regulations reflect a first step in terms of mandating HACCP, the agency is comfortable as a matter of policy that they should initiate a system that focuses on food safety. Additionally, tl statutory provisions that form the basi for these regulations are safety provisions. FDA's application of HAC is intended for the effective enforceme of sections 402(a) (1) and (a)(4) of the act, which apply to products that contain substances that may render th product injurious to health and to processing conditions that are insanita and that could render a product injurious to health. Thus, the only rea issue is whether the final regulations should retain the recommendations with regard to the application of HAC to nonsafety matters.

FDA is persuaded by the comments that the proposed recommendations fc HACCP controls of nonsafety matters, coupled with the presence of propose Appendix D of part 123, have the potential for causing confusion about the agency's expectations and

enforcement policies. FDA recognizes the point raised by a number of comments that advisory provisions are often confused with or misapplied as requirements. Given this fact and the emerging nature of HACCP, FDA has decided to eliminate proposed § 123.6(c) and Appendix D of part 123. FDA will consider including the concepts that underlay these provisions in the first edition of the Guide, however, because the Guide is understood as being the repository for recommendations relating to seafood HACCP.

The agency's decision to eliminate reference to nonsafety hazards from these regulations notwithstanding, such hazards as economic adulteration, decomposition not normally associated with human illness, general unfitness for food, and misbranding constitute violations of the act and are subject to regulatory action by FDA (see sections 402(a)(3) and 403 of the act (21 U.S.C. 343)). When inspections by FDA investigators reveal violations of these provisions of the act, FDA will take enforcement action as it deems appropriate. Processors who are able to accommodate a HACCP system that covers both safety and nonsafety hazards may find advantage in doing so, in order to better ensure compliance with existing nonsafety regulations and standards.

11. "Shall Render Adulterated"

FDA proposed to provide that: Failure of a processor or importer to have and implement an HACCP plan that complies with this section or to operate in accordance with the requirements of this part, shall render the products of that processor or importer adulterated under section 402(a)(4) of the act.

The preamble to the proposed regulations explained that the proposed regulations set out those requirements that the agency had tentatively concluded are the minimum necessary to ensure that the processing of fish and fishery products will not result in product that is injurious to health. FDA tentatively determined that such minimum requirements include the establishment of HACCP preventive controls. The preamble further explained that section 402(a)(4) of the act, among other things, deems a food to be adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

69. A significant number of comments, primarily from processors and trade associations, opposed the proposed language of this provision. The comments urged that the word "may" replace the word "shall" in order to establish that instances of noncompliance with the regulations do not automatically constitute adulteration. They contended that, because FDA will not be preapproving HACCP plans, a negative finding on the first FDA inspection could, under the language that was proposed, cause the agency to consider all product produced to that point to be adulterated. The comments stated that each case of noncompliance should be evaluated on its own merits.

FDA fully agrees that each case should be judged on its merits but does not agree that it is necessary to change the regulations in order to establish this principle. The purpose of § 123.6(g), which sets out this language, is not to create a legal presumption that food is adulterated if there is not perfect adherence to these regulations but to make clear that certain types of preventive controls are so fundamental to ensuring the safety of seafood that if there is not adherence to them, the food cannot be considered to have been produced in accordance with section 402(a)(4) of the act.

As a practical matter, FDA expects to exercise broad regulatory discretion in deciding when violations of these regulations warrant regulatory action, just as it does now for other situations. The agency will analyze each case on its merits, based at least in part on the potential for harm that exists.

The agency's primary concern is that processors develop HACCP plans that address the hazards that are reasonably likely to occur. When deficiencies in HACCP plans are detected during FDA inspections, the agency usually will first attempt to seek voluntary correction of the situation. Only when such voluntary correction is not forthcoming is it likely that FDA will elect to pursue regulatory action. It must be noted, however, that, where HACCP plan deficiencies result in significant potential for consumer harm, the agency will evaluate the need for corrective action with respect to the product that has been produced as well as to the HACCP plan itself.

In this regard, FDA notes that a change from "shall" to "may" in the provision would be more compatible with guidelines than with regulations. Consequently, the agency has retained the term "shall" in § 123.6(g). However, to clarify that a decision on whether to take regulatory action will involve discretion based on the public health significance of the violation, a sentence has been added to indicate that when a violation occurs, FDA will evaluate the processors overall implementation of its HACCP plan in deciding how best to remedy the violation.

Consistent with the revisions to the requirements for imported products contained in § 123.12, the word "importers" has been eliminated from § 123.6. As described in the "Imported Products" section of this preamble, the proposed requirement that an importer develop a HACCP plan (§ 123.11) has been eliminated in favor of a requirement for importer verification procedures. This change eliminated the relevance of § 123.6 to importers.

Consistent with the revision to § 123.6(a) and (b) that processors have HACCP plans only when a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, § 123.6(g) has been amended to state that a processor's failure to have a HACCP plan shall render the fish or fishery products adulterated only when a HACCP plan is necessary.

F. Corrective Actions

The fifth HACCP principle, as articulated by the NACMCF, is that processors establish the corrective actions that they will take should monitoring show that a CL has been exceeded. The NACMCF's expectation is that these corrective actions should b predetermined and written into the processor's HACCP plan.

In the proposed regulations, FDA tentatively chose to incorporate the principle of corrective action without requiring predetermined corrective action plans in the processor's HACCP plan. Instead, FDA proposed minimum, generic corrective action procedures for processors to follow. In so doing, FDA was trying to minimize the burden of the mandatory requirements of HACCP, especially for small processors. FDA tentatively concluded that the procedures set out in proposed § 123.7 represented the minimum requirements necessary to ensure that processors respond effectively to deviations that could affect safety, and that if those procedures were followed, specific corrective action plans, although desirable, would not be necessary.

FDA proposed in § 123.7 to require that deviations from CL's trigger a series of actions, including: Segregating and holding the product, making a determination of the acceptability of the product for distribution, taking appropriate remedial action with respect to the product and the cause of the deviation, and documenting the actions taken. In the preamble to the proposed regulations, FDA invited comment on the wisdom of this approach as opposed to requiring that predetermined corrective action plans be made part of the HACCP plan. A large number of comments responded to

that request. Additional comments addressed the specifics of the proposed generic-type requirements in § 123.7.

1. Should Corrective Actions Be Predetermined?

70. Approximately half of the comments supported the corrective action system proposed by the agency or a variation of it, and the other half called for mandatory predetermined corrective action plans. Many of those that supported mandatory corrective action plans urged consistency with the HACCP recommendations of the NACMCF. These comments noted that the NACMCF recommendations are consistent with Codex Alimentarius Commission standards. They predicted that compatibility of the final regulations with such international standards would minimize confusion for processors and importers, smooth international adoption of HACCP principles, and facilitate trade. The comments stressed that predetermining corrective action is an essential component of a processor's HACCP program, with the seven principles being so closely intertwined that overall success is probable only if all are intact.

A number of comments argued that a processor's implementation of a corrective action plan would eliminate indecision and confusion about what corrective action should be taken in the event of a deviation from a CL. For example, one comment pointed out that corrective actions written into the HACCP plan would eliminate the need for employees to substantiate to management the correctness of their response to a deviation, because the corrective action plan would provide the right actions to be taken for each particular deviation. A few comments stated that, if the appropriate corrective actions are detailed in the HACCP plan, responses by employees to CL failures are more likely to be immediate (reducing product losses) and effective (reducing wasted effort). These comments further noted that corrective action plans are particularly necessary when individuals qualified to make product safety evaluations are not readily available.

One comment asserted that the strength of the HACCP system is that it is preventive, and that corrective action plans are fundamental in preventing a product, for which there is a safety concern, from reaching the consumer. The comment further stated that written corrective action plans should provide for the documentation of the following: (a) The cause of the deviation, (b) the action taken to ensure that the deviation does not reoccur, (3) the results of the risk evaluation, and (4) product disposition.

Many comments did not agree that corrective action plans should be required. A few comments argued that developing a corrective action plan is impractical and can be unduly restrictive because of the diversity and complexity of seafood products and of seafood processing operations. One comment noted that many situations exist in which the appropriate response to a CL failure is not apparent until the details of the particular situation are known. Several stated that a corrective action plan is less preferable than having responsible and knowledgeable personnel, adequately trained in HACCP, available to evaluate a deviation from a CL. If such personnel are available, one comment noted, deviations can be handled on a case-by-case basis, with appropriate documentation of the disposition of the affected product.

Several comments argued that the lack of a corrective action plan is not sufficient evidence to demonstrate that a product is adulterated. The comments argued that the proposed requirement that a processor establish CL's and perform and record appropriate corrective actions when these limits are exceeded, provides sufficient demonstration of hazard control.

A number of comments that advocated the concept of predetermined corrective action plans urged that processors be given the option of writing such plans or of following a series of minimum mandatory actions, like those proposed by FDA, when CL failures occur. In the preamble to the proposed regulations the agency did, in fact, encourage processors to predetermine corrective actions as part of the preparation of a HACCP plan.

On this issue, the merits of the various approaches tend to balance. Consequently, FDA agrees with those comments that urged that the regulations provide processors with the option of developing their own corrective action plans as part of their HACCP plans or of following a generic model corrective action plan, provided in the regulations, should a deviation occur.

The agency accepts the view that predetermined plans have the potential to provide processors with benefits, as pointed out by the comments, such as faster action when a deviation occurs, less need to justify to management the appropriateness of the corrective action after it has been taken, and a more [illegible] trained or otherwise qualified individuals are not readily available to make determinations. On the other hand, FDA has not been provided with information on which it can conclude that these benefits—as desirable as they may be—need to be mandated in order to protect the public health. Processors can build them into their HACCP systems if they so choose, but the public health will be protected so long as shipment of the affected product into commerce does not occur until the significance of the deviation has been assessed and appropriately resolved.

This outcome is assured both with specific predetermined corrective action plans and with the minimum generic model that FDA is requiring as an alternative. Without additional evidence from actual experience, which was not provided by the comments, FDA cannot conclude that the overall success of HACCP depends on whether processors have specific predetermined plans for events that might not necessarily occur.

Consequently, FDA has revised § 123.7 to permit, but not to require, processors to include in their HACCP plans any written corrective action plans that they develop. When a deviation from a CL occurs, § 123.7(a) requires that processors either: (1) Follow a corrective action plan that is appropriate for the particular deviation or (2) follow the series of actions provided in § 123.7(c). The steps in § 123.7(c) constitute a minimum generic model for corrective actions and, as will be explained below, closely match those that were contained in the proposed regulations.

The final regulations at § 123.7(b) define an appropriate corrective action plan as one that addresses both the safety of the product that was being processed when the CL failure occurred and the cause of the deviation. In this respect, the contents of the corrective action plan are consistent with the views of the NACMCF (Ref. 34, pp. 199–200). The corrective action must ensure that any unsafe product is not distributed.

FDA advises that action necessary to correct the product may involve any one or more of the following steps: Immediately reprocessing the product, diverting the product to another use where it can be used safely; segregating the product, holding it, and having it evaluated by a competent expert; or destroying the product. In order to ensure that subsequent product is not subjected to the same deviation, the corrective action must be sufficient to bring the process back under control (Ref. 34, pp. 199–200). FDA advises that [illegible] appropriate: adjustments to those process parameters that have an effect

on the relevant CL (e.g., flow rate, temperature, source of raw materials); temporarily diverting product around a point in the process at which problems are being encountered; or temporarily stopping production until the problem can be corrected.

Section 123.7(c) describes the steps that a processor must take whenever there is a deviation from a CL but no corrective action plan to follow. As stated above, these steps constitute a minimum generic-type corrective action plan. The objectives of these steps are the same as those of a preconceived plan: To ensure that adulterated product does not enter commerce and to correct the cause of the deviation. Because it is a generic-type plan that is intended to be applicable to any situation, some of the steps, such as segregating and holding the affected product (§ 123.7(c)(1)), might not be necessary if the corrective action had been predetermined. This aspect of the generic-type plan may provide processors with an incentive to predetermine corrective actions whenever practical.

Another such incentive is the requirement, at § 123.7(c)(5), that the processor reassess the adequacy of its HACCP plan when a deviation occurs. This requirement does not exist where a corrective action plan exists. The reason for the distinction is that, on one hand, if a processor has assessed its process and decided that CL failures are likely to occur from time to time at particular points, those failures, when they occur, do not represent a failure of the plan but a foreseeable occurrence. On the other hand, if the processor has not made such an assessment, and a failure occurs, it is not possible to say what the failure means. The processor must assess whether the deviation is the result of a system-wide problem that is not being properly addressed by the plan or simply a failure that could be expected to occur in the normal course of things. The failure must be fully assessed, and if it represents a failure of the plan, the plan must be modified to reduce the risk of reoccurrence.

The agency is convinced that the corrective action approach contained in the final regulations (i.e., predetermined corrective action plans at the option of the processor) adheres to the principles of HACCP as recommended by NACMCF (Ref. 34, pp. 199–200) and will not result in undue burden, confusion, or trade difficulties. At the same time, these regulations will provide the flexibility needed to accommodate the varying levels of HACCP sophistication within the industry. FDA is satisfied that employee indecision in responding to CL deviations will not result in a public health problem in the absence of corrective action plans because the final regulations contain a set of well defined actions that are to be followed if a deviation occurs and no predetermined plan exists. The actions outlined in § 123.7(d) ensure that no unsafe product will enter commerce, and that a normalization of processing conditions will be effected as quickly as possible. While the agency sees merit in the argument that predetermined corrective action plans will, in many cases, be economically beneficial to a processor (e.g., minimize product loss and wasted effort), such economic factors will, in and of themselves, motivate processors to predetermine appropriate corrective actions, but they do not mean that the agency needs to require the adoption of predetermined plans.

71. A few comments recommended that FDA review corrective action plans for adequacy during, or in advance of, the first regulatory visit. This review, the comments asserted, would help to avoid a situation in which the processor takes a corrective action in conformance with its HACCP plan, but the agency later determines that the action was inadequate.

FDA agrees that these comments reflect a desirable ideal but must acknowledge that such a review ordinarily will not be feasible. If processors complete their HACCP plans, including any corrective action plans that they choose to develop, before the effective date of these regulations, they may be able to obtain a review of those plans as part of a routine FDA inspection.

In any event, the agency intends to review corrective action plans that a processor includes as part of its HACCP plan during routine regulatory inspections. Where the investigator finds a shortcoming in the corrective action plan, the investigator will discuss it with the processor. As with a failure to meet any other provision of these regulations, in determining its response to such a shortcoming, the agency will consider the totality of the situation and the likelihood that the shortcoming will have an adverse impact on the safety of the product. If a corrective action plan has not actually been used as of the time of the investigator's review, and as a consequence of its review the agency advises the processor that the corrective action plan needs to be improved, it is likely that FDA will advise the processor to follow the alternative procedure in these regulations until the upgrade occurs.

2. Assessing the Product for Safety

72. FDA received comments on specific aspects of the generic-type corrective action plan provided in proposed § 123.7(a). A significant number of comments opposed the provision that would have required an "immediate" safety assessment when a CL deviation occurs. One comment stated that, because an appropriately trained individual may not be immediately available to make a determination of the acceptability of the lot, the provision should be modified to require segregation and holding of the affected product until either a timely safety review by a properly trained individual has been completed, or a determination has been made that the appropriate predetermined corrective action plan has been followed. A number of other comments also suggested that the phrase "immediate review" be revised to "timely review." One comment recommended that FDA specify a maximum amount of time in which to evaluate the product, for example within 24 hours. Another comment advised that FDA permit processors to cook or freeze fresh product involved in a CL deviation, until an evaluation can be completed.

FDA agrees that immediate review is not necessary. As long as the review occurs before the product is distributed, the public health will be sufficiently protected. Consequently, while § 123.7(c)(2) requires a review to determine the acceptability of the affected product for distribution, it does not require that the review be immediate, nor does it otherwise specify a timeframe for review. If there is a chance that the product is still fit for commerce, FDA expects that economic considerations will dictate the timing of the review. FDA agrees that, in many cases, it would be advantageous for a processor to cook or freeze a product pending results of a safety evaluation. The agency has no objection to such an action as long as the processor maintains the identity of, and its control over, the lot.

FDA has also modified § 123.7(c)(2) from the proposal to require that the review of the product be conducted by someone with adequate training or experience, although FDA is not tying adequate training to training in HACCP (see § 123.10) as it did in the proposal. FDA made this change because, as comments pointed out, a 3-day course in HACCP would not necessarily qualify someone to make many public health determinations of this nature. The basis for this modification is more fully

described in the "Training" section of this preamble.

3. Documenting Corrective Actions

In § 123.7(d), FDA is retaining the proposed requirement that records of corrective actions be kept. As with the proposal, such records are subject to the general recordkeeping requirements of § 123.9. The records must document the actions taken in following either a predetermined corrective action plan or the corrective action procedures specified in § 123.7(c).

73. One comment suggested that the absence of written corrective action plans would make it more difficult to document a response to a deviation. It went on to explain that, with a plan, the processor could simply note, for example, that "the product was recooked in accordance with 'Section B of the Plan.'" It pointed out that more extensive documentation would be necessary if a processor did not have a predetermined plan.

FDA does not agree with this comment. Section § 123.7(d) requires that the corrective action taken by a processor be fully documented. It is the agency's intent that such documentation provide the specifics about the actions that were taken and not simply refer to a written procedure. In the example given, records of the recooking operation, equivalent to monitoring records for such an operation, i.e., cooking, would be necessary to document that the operation was performed in a manner that would render the product safe. Thus, similar documentation would be necessary whether a plan exists or not.

It is worth noting that § 123.7(d) now states that corrective action records are subject to verification in accordance with § 123.8(a)(3)(ii). This requirement is not new but reflects the fact that record review is deemed to be a verification activity in the final regulations but was not classified as such in the proposal. A further discussion of this matter can be found in the section of this preamble that follows.

G. Verification

1. Overview

Verification is one of the seven commonly recognized principles of HACCP. In the preamble to the proposed regulations, FDA acknowledged and discussed the recommendations of the NACMCF as they relate to verification. According to the NACMCF, verification essentially involves: (1) Verifying that the CL's are adequate to control the hazards; (2) ensuring that the HACCP plan is working properly, e.g., that it is being followed, and that appropriate decisions are being made about corrective actions; and (3) ensuring that there is documented, periodic revalidation of the plan to make sure that it is still relevant to raw materials as well as to conditions and processes in the plant.

2. Need for Verification Requirement in Regulations

In the preamble to the proposed regulations, FDA encouraged processors to adopt verification practices but did not propose to require that a processor's HACCP plan specify the verification procedures. Rather, the agency tentatively concluded that verification of a HACCP plan would effectively occur through: (1) Comparison of the plan to guidance documents such as FDA's draft Guide; (2) technical assistance provided through trade associations, universities, and government agencies; (3) mandatory review of monitoring and corrective action records by trained individuals before product distribution; (4) mandatory reassessment of the adequacy of the HACCP plan as a consequence of CL deviations; (5) reliance on the recommendations in FDA guidelines that processors of cooked, ready-to-eat seafood products use the expertise of "processing authorities," i.e., third-party experts; (6) mandatory training; and (7) investigator review of the entire HACCP system during routine agency inspections. FDA requested comment on whether this approach is adequate to ensure that the verification principle was being properly addressed.

74. A large number of comments responded to this request. Approximately one-third of these comments stated that FDA's proposed approach to HACCP verification was adequate. The other comments argued that verification should be specifically mandated as a part of a firm's HACCP program.

A few of the comments favoring the proposed approach contended that a HACCP plan lacking verification procedures should not be grounds for FDA to consider a product to be adulterated. Several comments stated that processors will engage in verification activities without a requirement, as a natural outgrowth of a HACCP program, because without such activities, HACCP will not work. For this reason, they argued, it is not necessary to mandate that verification procedures be included in processor's HACCP plans.

Of the comments that supported the need for specifically-mandated verification activities, a significant number urged the agency to adopt such a requirement to be consistent with the HACCP recommendations of the NACMCF. These comments noted that the NACMCF recommendations are consistent with Codex Alimentarius Commission standards. They predicted that compatibility of the final regulations with such international standards would minimize confusion for processors and importers, smooth international adoption of HACCP principles, and facilitate trade. The comments stressed that verification is an essential component of a processor's HACCP program, and that the seven principles are so closely intertwined that overall success is probable only if all are intact.

One of the comments stated that verification should involve a continual review and improvement of the HACCP system. The comment added that verification is a primary responsibility of processors, one that is equivalent in importance to plan development. Several comments stated that the benefits of HACCP verification include Assurance that all CCP's are identified assurance that the plan is being followed, a mechanism for third party oversight of the plan development process, a means of measuring the success of a HACCP system, and information on trends in the frequency and reasons for CL deviations. One comment suggested that firms should be required to perform verification activities at least annually.

A few comments stated that although the proposed regulations included some required practices that could be deemed to be verification, such as the calibration of process-monitoring instruments and plan reassessment and modification in response to a CL failure, the entire concept of verification should be addressed more fully in a separate section of the final regulations. One of these comments suggested that the following verification activities be specifically mandated: Calibration of process control instruments, validation of software for computer control systems, and daily review of monitoring records.

One comment stated that, without a requirement for specific verification activities, processors would rely strictly on end-product testing to evaluate the success of the HACCP plan, and that such an approach would diminish the effectiveness of the entire HACCP system. Several comments stated that HACCP plan verification procedures

should include detailed government and industry audits and product analyses.

One comment, from a consumer advocacy organization, challenged whether effective verification would really occur through the measures cited in the preamble. The comment stated that "third-party technical assistance" is not a mandatory part of the HACCP program and, therefore, can not be counted on as a verification procedure. It added that such technical assistance would tend to be performed during plan development, and that verification must be an ongoing procedure. The comment stated that a "review of all HACCP-monitoring records by trained individuals before distribution of product" is not verifiable by the agency because a firm can cut corners by having their employees sign the records without reviewing them. The comment argued that FDA auditing of consumer complaints and mandatory in-process and end-product testing are important verification procedures.

A few comments suggested that FDA should include a requirement that written verification procedures be in place, but that the agency need not prescribe specific verification activities, or should do so only sparingly.

FDA notes that the proposed regulations contained specific provisions identified by many of the comments as appropriate verification steps. For example, the proposed requirement that the HACCP plan adequately address the food safety hazards that are reasonably likely to occur (§ 123.6(c) in this final rule) is a continuing, rather than a one-time requirement. Thus, to continually be in compliance with it, a responsible processor would have to engage in some form of reassessment. Other provisions in the proposal that comments identified as verification steps included: The required calibration of process monitoring instruments; the required validation of computer software; the requirement that consumer complaints be reviewed to assess whether they indicate a problem at a CCP; and the requirement that HACCP-monitoring and corrective action records be reviewed before distribution of the product. FDA now realizes, however, that by not specifically requiring verification as such, the proposal generated considerable confusion about whether FDA intended to include or exclude the principle of verification from processors' HACCP programs. FDA has concluded, therefore, that verification is important enough to be an explicit part of the regulations. FDA has made it such in the final rule at § 123.6(c)(6) and in a new section for verification, § 123.8.

Section 123.6(c)(6) requires that processors include in their HACCP plans a list of the verification procedures that they will use and the frequency of those procedures. This provision is consistent with the view of the NACMCF that a processor's verification procedures should be addressed in the HACCP plan (Ref. 34, pp. 200–202). FDA does not expect that this requirement will be particularly burdensome for the processor for two reasons. First, the requirement that verification procedures be listed in the HACCP plans is really only a variation of the proposal in that FDA proposed to require a number of the activities that it is now designating as verification activities in § 123.6(b)(4) (e.g., calibration of monitoring instruments and review of consumer complaints). Second, a list of the steps that a processor determines are appropriately a part of the annual reassessment of the HACCP plan need not be extensive or detailed. FDA recognizes that, at least initially, much of the annual verification procedure could take the form of meetings and discussion, and may not lend itself well to a detailed listing of steps. FDA believes that the annual verification procedure should be allowed to evolve, and that a requirement that the listing of steps in the plan be detailed before an annual verification ever occurs could adversely affect that evolution.

The new section on verification, § 123.8, describes the minimum components of a processor verification program. Among other things, the agency has consolidated there those aspects of the proposal that, according to comments, should be designated as verification activities. Section § 123.8 contains little in the way of detail that was not included in the proposed regulations. In addition, it is designed to be generally consistent with the verification concepts expressed by the NACMCF, as requested by comments, and at the same time, not unduly burdensome.

3. Verifying the HACCP Plan

Section 123.8(a) requires that processors with HACCP plans verify two aspects of their HACCP systems: (1) That their HACCP plans are adequate to control food safety hazards that are reasonably likely to occur, and (2) that their plans are being effectively implemented. Verifying these two aspects is, essentially, what the NACMCF refers to as the first and second of the four processes of verification (Ref. 34, p. 201).

Second, § 123.8(a)(1) requires that a reassessment of the HACCP plan occur whenever there are any changes of the type listed in these regulations that could alter the plan, or at least annually. The NACMCF takes the view that verification must occur on a periodic, regular basis (Ref. 34, p. 202), although no specific timeframes are suggested. FDA agrees with the NACMCF and the comments that verification of the adequacy of the HACCP plan should be conducted on a regular basis, even in the absence of a recognized change, to ensure that the plan continues to address all of the reasonably likely food safety hazards with appropriate CL's and monitoring procedures. It is essential that processors verify the adequacy of their plans and that this verification occur on a periodic basis. Processors should conduct the review at intervals that are appropriate for their processes. FDA agrees with one of the comments, however, that this interval be no more than a year in order to ensure that the plan remains adequate to address the hazards associated with the species and processes (Ref. 206, p. 1084).

The regulations at § 123.8(a)(1) provide examples of changes that could trigger a reassessment. These include changes in raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. These examples are derived from the NACMCF materials on the "five preliminary steps" that form the basis for the HACCP plan (Ref. 34, pp. 188 and 201). A change in any of these areas could necessitate a change in the plan in order to respond to any new hazards that may have been introduced or to maintain preventive control over existing ones. It is important to recognize that this list is not all inclusive.

Section 123.8(a)(1) requires that the plan reassessment be performed by an individual that has been trained in HACCP in accordance with § 123.10. This requirement is a logical outgrowth of the proposed requirement in § 123.9 that a HACCP-trained individual be responsible for the initial development of, and subsequent modifications to, the HACCP plan. These kinds of activities require an understanding of the principles of HACCP and plan development as obtained through training that is at least equivalent to the course required in § 123.10.

Section 123.8(a)(1) also requires that where a reassessment reveals that the HACCP plan is inadequate, the processor shall immediately modify the

plan. Failure of a processor to immediately modify its HACCP plan after it has determined that the plan is inadequate would result in the processor operating under a plan that is not in conformance with these regulations.

FDA recognizes that the methods that processors will use to verify that the plan is still adequate will vary, based on individual preferences and past experience. FDA agrees with comments that urged the agency to permit maximum flexibility in the development of verification procedures that are tailored to individual operations. Nonetheless, the agency encourages processors to consider the guidance in the March 20, 1992, NACMCF publication, "Hazard Analysis and Critical Control Point System."

Moreover, FDA believes that the best way for the agency to judge the merits of a processor's annual verification will be through its own continuing determinations of whether the processor's overall HACCP system remains appropriate for the circumstances. These determinations will occur as a product of the agency's ongoing inspection program.

On this subject, FDA is sensitive to the comment that the absence of verification procedures from a HACCP plan should not, in and of itself, cause a food to be deemed adulterated under 402(a)(4) of the act. Nonetheless, the absence of verification could jeopardize the likelihood of success of the overall program. For example, monitoring a critical cooking step with a thermometer that has not been calibrated provides little assurance that the CL is actually being met, and failure to review records may allow the absence of monitoring or improper corrective action to go unnoticed for extended periods of time. Should the agency find itself in the position of having to react to the absence of adequate verification procedures in a processor's HACCP plan, in deciding whether to bring regulatory action, the agency will consider the totality of the situation, and the likelihood that it would have an adverse impact on the final food, as it would in considering a processor's failure to meet any specific provision.

4. Verifying the Implementation of the Plan

The regulations at § 123.8(a)(2) and (a)(3) require ongoing verification activities in addition to the annual reassessment. These ongoing activities are in keeping with the NACMCF's view that verification must also take the form of "frequent reviews" (Ref. 34, p. 201). Frequent reviews relate primarily to whether the HACCP plan is functioning effectively on a day-to-day basis. It is important to note that, for the most part, the requirements in these sections were proposed in other parts of the regulations and are now being compiled in § 123.8(a)(2) and (a)(3). Several comments on these provisions pointed out that they were verification steps and should be referred to as such. FDA agrees and has brought them together in this new verification section of the final regulations. Section 123.8(a)(2) requires that processors review consumer complaints (proposed at § 123.6(b)(4)), calibrate process monitoring instruments (proposed at § 123.6(b)(4)), and perform periodic end-product or in-process testing, as appropriate, in accordance with written procedures for these activities in the HACCP plan.

Section II H. of this preamble addresses the review of consumer complaints at some length.

The provision on the calibration of monitoring instruments (§ 123.8(a)(2)(ii)) is brought forward with no substantive change from the proposal. Calibration is an important activity and involves readily defined procedures that can easily be provided in the plan.

Calibration can include the validation of computer hardware and software. FDA proposed to require that the HACCP plan detail the methods of computer software validation to be used by the processor. FDA received a small number of comments both for and against computer software validation as a worthwhile part of verification. Two comments supported the need for consumer software verification. But two comments suggested that computer software verification would be an unnecessary expense because it would result in only marginally improved reliability.

The agency has worked extensively with the low-acid canned food industry to verify computer hardware and software that the industry is now using to operate or control various processing functions. That experience has demonstrated to FDA both the desirability and the feasibility of verifying computer hardware and software. For low-acid canned foods, the industry is using computers to perform several functions, including monitoring compliance with CL's, controlling the processing operations, taking corrective actions, and recordkeeping (Ref. 221).

In a HACCP system such as that being established for seafood by these regulations, FDA is interested in ensuring that hardware and software for computers that monitor compliance with a CL be verified. However, when computers are used as process-monitoring instruments, they must be calibrated in accordance with § 123.8(a)(2)(ii). The other functions that a computer can perform, as listed above, can be verified through procedures required elsewhere in these regulations (e.g., recordkeeping can be verified through the review of records by a trained individual in accordance with § 123.8(a)(3)). Consequently, the agency has concluded that it is not necessary for these final regulations to include a specific requirement for computer validation.

Instead, the agency acknowledges that the proper frequency of equipment calibration is entirely dependent upon the type of instrument and the conditions of its use. Therefore, FDA is not being prescriptive in this regard. FDA has, however, provided guidance on the subject in the draft Guide. Additional guidance should be obtainable from the manufacturer of the instrument. The nature and frequency of the calibration effort should be determined at the time of HACCP plan development and should be included in the plan to ensure that it is regularly and appropriately done. The agency is convinced that without such formalization, calibration, which, for some instruments, may be done as infrequently as once per year, may be overlooked.

5. Product Testing

75. Section 123(8)(a)(2)(iii), which lists the performing of end-product or in-process testing, is a new provision. FDA requested comment on what tests, including or in place of end-product testing, should be used to measure the success of the HACCP program, both in terms of individual firms and the national program as a whole, and how frequently such tests should be administered (Ref. 208 at 4183). A large number of respondents addressed FDA's request for comment. Approximately half of these comments supported the need for an end-product testing requirement. The other half objected to such a requirement or suggested that the need should be determined on a case-by-case basis.

A number of consumer advocacy organizations suggested that end product testing is essential because no other verification mechanism provides public confidence that HACCP programs are actually resulting in a safer product. Several comments stated that regular microbiological testing would help a processor determine whether there are sources of contamination that are not being controlled.

A few comments suggested that such testing should be performed more frequently during plan development and validation, and then reduced to some lower level as part of a firm's verification efforts. Another comment suggested that testing should be performed quarterly by those processors with a poor record of compliance and annually by those with a good record.

Several comments suggested that the need for and frequency of product analysis should be established as part of the HACCP plan development process. One of these comments noted that the frequency of testing may fluctuate depending, in part, upon changes in personnel, raw materials, equipment, and product formulation.

A number of comments stated that end-product testing is a questionable method for measuring the success of a HACCP system. One of these comments stated that end-product testing measures the effectiveness of the plan for a small, finite portion of production and has limited value in measuring the success of the HACCP plan overall.

One comment stressed that finished product testing is contrary to the concept of HACCP, i.e., a reliance upon preventive controls at critical points throughout the system. Another comment contended that mandatory microbiological analysis of foods would be inappropriate because: (1) Statistically valid sampling programs for pathogens are not economically feasible because of the low incidence of pathogens in most foods; (2) the use of indicator organisms to predict the presence of pathogens is not always reliable and, where it is not, can become merely a test for aesthetics; and (3) microbiological analysis of foods is often costly, imprecise, and slow, and, therefore, not suitable for real time data generation.

The agency acknowledges the shortcomings of product testing, especially microbiological testing, used for process control as pointed out by the comments. The NACMCF, in its comments in response to FDA's questions about product testing, reiterated its view that, while verification is essential to the success of HACCP, end-product testing has limited value for measuring the success of a HACCP system. Comments also noted that in-process or finished product testing should not normally be a prerequisite for lot release under a HACCP program.

However, FDA recognizes that many processors will find that product testing has a role to play in the verification of HACCP systems, and the agency wishes to encourage incorporation of testing into HACCP plans, where appropriate. Consequently, the regulations at § 123.8(a)(2)(iii) list end-product and in-process testing as a verification activity at the option of the processor.

The agency provided guidance concerning appropriate attributes for product testing in the draft Guide and intends to elaborate on it in the first edition of the Guide.

6. Records Review

Section § 123.8(a)(3) requires that a trained individual review all records that document monitoring of CCP's, the taking of corrective actions, the calibrating of any process control instruments, and the performing of any end-product or in-process testing. The review of HACCP records by a trained individual was included in the proposed regulations at § 123.8(b). In response to comments that urged consistency with the recommendations of the NACMCF, FDA has designated this review a verification function for purposes of the final regulations and has included it in the section on verification. Specifically, the proposed regulations provided that a HACCP-trained individual review the monitoring records, sanitation control records, and corrective action records before distribution of the product to which the records relate. Under the proposal, the individual's review would include records of process monitoring instrument calibration, because the agency characterized these records as monitoring records.

The comments that FDA received on these provisions focused on the proposed requirement that the review by the trained individual occur before the product could be shipped. Several comments objected, stating that such a review before shipment was unnecessary, because under the corrective action provisions of the proposed regulation, any CL deviation caught by the observer/operator would necessitate the segregation and holding of the affected product before shipment until the safety of the product could be assured. One comment further stated that linking lot release to record review before shipment underestimates the level of control attainable through the monitoring and corrective action principles of HACCP.

Comments from several processors and trade associations stated that, for some processors, it would be impractical to withhold the shipment of every lot until HACCP records could be verified and signed. These comments noted that, with the use of today's high speed processing lines, it is normal practice for some processors to begin shipping products before the end of the shift (lot). Several comments also stated that holding a product until the HACCP records could be reviewed could result in a product being subjected to unfavorable conditions during storage, which could compromise both quality and safety.

Several comments urged that processors be permitted to review the HACCP records at the end of the day or at the end of the shift, even if this review occurred after distribution. Others suggested that record review should be performed within a "reasonable time" of production of the record.

The agency remains convinced that the coupling of lot release with verification-type record review provides a valuable added level of safety assurance. This kind of record review before shipment is a regulatory requirement for low-acid canned foods and acidified foods. FDA's experience with these industries is that record review before distribution has been instrumental in preventing the introduction of potentially hazardous foods into commerce (Ref. 221). The agency encourages processors to institute such a program whenever possible.

However, FDA accepts from the comments that the proposed requirement would cause certain processors to delay shipping perishable products and thus present an unacceptable burden to them. The agency therefore is not requiring that record review occur before shipment.

Uncoupling record review from lot release leaves as the primary purpose for record review the periodic verification that the HACCP plan is appropriate and is being properly implemented. Record review needs to occur with sufficient frequency so as to ensure that any problems in the design and implementation of the HACCP plan are uncovered promptly and to facilitate prompt modifications. The concept is roughly that of a "feedback loop," with information coming out of the record review process in such a timely manner that it can have impact on the production of subsequent lots of the product.

FDA is convinced that a weekly review of HACCP monitoring and corrective action records would provide the industry with the necessary flexibility to handle highly perishable commodities without interruption, while still facilitating speedy feedback of information. FDA is reluctant to allow the level of flexibility provided by such language as "reasonable time," out of concern for the confusion that it

would generate. FDA's experience with low-acid canned foods and acidified foods has demonstrated that review of these kinds of records is a critical verification tool. FDA is, therefore, adopting the proposed provision as § 123.8(a)(3) with one revision. As set out in the final rule, it requires that the HACCP-trained individual review the monitoring records of CCP's and the records that document the taking of corrective actions within 1 week of the making of the records, rather than before shipment, as a part of a processor's verification activities (§ 123.8(a)(3) (i) and (ii)).

FDA agrees, on the other hand, that this principle need not apply to the review of records of such verification activities as process control instrument calibration and product testing. The frequency of these activities will be variable and dependent upon the HACCP plan development process. Consequently, setting a specific review frequency for these records is not warranted. Section 123.8(a)(3)(iii) reflects this conclusion. It requires that the HACCP-trained individual review the calibration records within a reasonable time after the records are made, rather than before any additional products are shipped. It also applies the same "reasonable time" standard to any end-product testing records that are made.

The proposed regulations did not address the review of end-product testing records by a trained individual. The requirement in these final regulations for a review of such records reflects the principle contained in the proposal that there be a verification-type review by a trained individual of the HACCP records that are being created by the processor. In this respect, the responsibilities of the trained individual are unchanged from those that were contemplated in the proposal, although details relating to those responsibilities have been modified based on the comments.

Section § 123.8(b) requires that processors take appropriate corrective action whenever a review of a consumer complaint, or any other verification procedure, reveals the need to do so. This provision is essentially a restatement of the proposal regarding consumer complaints, expanded to include the results of verification procedures for purposes of emphasis. Verification was not specifically included in the proposal. FDA is including a reference to it here to remind processors not to preclude the possibility that information obtained through verification could lead to the taking of a corrective action. This possibility exists even though, more often than not, verification will not provide the kind of immediate feedback that the processor will receive from monitoring. Corrective actions based on information received through verification will be exceptions to the rule. However, processors should be mindful of the possibility.

7. Verifying the Hazard Analysis

Section 123.8(c) requires that, whenever a processor does not have a HACCP plan because a hazard analysis has not revealed any food safety hazards that are reasonably likely to occur and that can be controlled through HACCP, the processor must reassess the hazard analysis whenever a change occurs that could reasonably affect whether such a hazard exists. FDA has included examples of such changes in § 123.8(c). The list is identical to that provided in § 123.8(a)(1), for when a plan must be reassessed. Consequently, any change in these factors should warrant a reassessment to be certain that a plan is still not needed.

FDA has concluded that, under a mandatory HACCP system, the principle of verification applies equally to a decision that a HACCP plan is not necessary as it does to a decision that the plan continues to be adequate. Circumstances change, and processors must be alert to whether the exemption from the requirement to have a plan continues to apply to them.

Section 123.8(d) requires that processors document calibration and product testing in records that are subject to the recordkeeping requirements of the regulations at § 123.9. The requirement that records be kept of process monitoring instrument calibration was included in the proposed regulations at § 123.6(b)(5). The requirement that records of end-product testing be kept is consistent with the general recordkeeping principles of HACCP. The one exception is that FDA is not requiring records that document the review of consumer complaints. The agency is satisfied that the requirement for a processor to review consumer complaints relating to potential safety concerns will be sufficient for this kind of verification activity. Moreover, as explained in the discussion of consumer complaints elsewhere in this preamble, FDA is persuaded that most consumer complaints will involve matters unrelated to the mandatory HACCP system.

H. Consumer Complaints

1. Background

In the proposed regulations, FDA tentatively concluded that each processor's HACCP system had to utilize any consumer complaints that the processor receives that allege a problem with product safety. Several provisions described how consumer complaints were to be used. In one, FDA proposed to require that a processor's monitoring efforts include the use of consumer complaints, and that its HACCP plan reflect how they will be used. In a second provision, FDA proposed to require that, when a processor receives a consumer complaint that may be related to the performance of a CCP or that may reflect a CL deviation, the processor determine whether a corrective action is warranted, and, if so, take one in accordance with the specified corrective action procedures. FDA also proposed to require that the taking of such corrective actions be fully documented in records. Finally, FDA proposed to require that consumer complaints that relate to the operation of a CCP or to a possible CL deviation be included as part of the processor's HACCP records and be available for agency review and copying.

FDA's rationale for proposing these requirements was that consumer complaints may be the first alert that a processor has that problems are occurring that are not being detected or prevented by the processor's HACCP controls. While the goal of a HACCP system is to prevent all likely hazards from occurring, no system is foolproof. The agency tentatively concluded,therefore, that each HACCP system should take advantage of consumer complaints as they relate to the operation of CCP's. FDA also tentatively concluded that it might be necessary for the agency to review those complaints in order to be able to verify whether a processor is taking necessary steps to review its HACCP controls and take corrective actions as necessary in response to consumer complaints. The agency emphasized that it was referring solely to complaints relating to the operation of the HACCP CCP's (i.e., those that allege a problem with human food safety) and not to consumer complaints generally.

2. Consumer Complaints as Verification Tools

76. FDA received a large number of comments on the advisability of handling consumer complaints in the manner that the agency proposed. Generally speaking, the comments

addressed two broad issues: Whether consumer complaints are relevant to a HACCP system, and if they are relevant, how they should be used. The question of whether FDA should have access to consumer complaints was a significant concern that comments found germane to both issues. Approximately one-fifth of the comments supported the proposed system or a variant of the system (i.e., they believed that consumer complaints are relevant to a HACCP system). Some of those who voiced general support urged more comprehensive agency access to consumer complaints, and others urged that some restriction on agency access be put in place. The remaining approximately four-fifths of the comments, principally from seafood and other food processors and trade associations, argued that consumer complaints have no place in a HACCP system.

Those comments that opposed the mandatory use of consumer complaints in a HACCP system provided a variety of reasons. The comments argued that consumer complaints are generally: (1) Unrelated to the safety of the product; (2) not received in a timely manner that would facilitate control of the process and are, in this way, akin to finished product testing; (3) erroneous and sometimes exaggerated or fraudulent; (4) vague; (5) subjective and nonscientific; (6) associated with hazards that develop during transportation, storage, and retail marketing, rather than processing, if they identify food safety hazards of any kind; (7) not traceable to a specific processing plant or lot of product; and (8) not readily associated with a specific CCP or CL failure, even where it is likely that they are the result of a problem during processing. These comments asserted that, therefore, consumer complaints are not an appropriate monitoring tool.

A number of these comments suggested that, given the problems listed above, sorting through the large volume of consumer complaints that are received by most large firms to identify those few that might be able to be linked to the performance of a specific CCP would be a waste of both the processor's and the agency's time. These comments stated that such a review of consumer complaints would divert their efforts from more productive tasks.

Several comments raised additional questions about consumer complaints as a HACCP verification tool. They suggested that there are better, more effective means of verifying that the HACCP plan is working properly. These suggestions are covered in the "Verification" section of this preamble. These comments further argued that consumer complaints are not identified in the NACMCF recommendations as a useful verification tool.

A relatively small, diverse group of comments, including those from a seafood processor, a seafood trade association, a State regulatory agency, an individual, and a professional organization, supported the handling of consumer complaints as proposed. One of these comments suggested that consumer complaints could be useful in FDA's efforts to verify that processors' HACCP programs are effective.

Another group of comments, from consumer advocacy organizations and a State regulatory agency, agreed that consumer complaints are an appropriate part of HACCP. One of the comments noted that the consumer performs the final quality control check, and that if a consumer finds a problem egregious enough to take the time to write a letter, the information contained in that letter should be considered in any evaluation of the adequacy of the relevant HACCP plan. The comment further argued that consumer complaints could bring to light unidentified CCP's. This benefit, the comment contended, would not be possible under the proposed regulations because the agency limited consumer complaints in a HACCP system to those that may be related to a CL deviation at an existing CCP. Finally, one of the comments noted that the inclusion of consumer complaint access in the proposed regulations is the one area in which the agency delivers on its "water to table" commitment.

FDA is persuaded that consumer complaints generally will not make an effective monitoring tool in a HACCP system, primarily because they tend not to provide the kind of immediate, reliable feedback expected of a HACCP-monitoring system. FDA agrees with the comments that suggested that monitoring procedures under HACCP must provide the processor with immediate feedback on whether the process is under control and be scientifically sound.

FDA is not persuaded, however, that consumer complaints are irrelevant to HACCP systems. The agency received no comments that were able to demonstrate that outside sources of information should not, where appropriate, supplement a processor's own monitoring as a way of determining whether the process is in control. Moreover, a number of comments stated that they go to some lengths to examine the consumer complaints that they receive. The question, then, is whether consumer complaints can serve some legitimate verification purpose in a HACCP system.

While consumer complaints are not specifically addressed in the NACMCF HACCP recommendations, the verification portion of that document states, in part, that verification inspections should be conducted, "When foods produced have been implicated as a vehicle of foodborne disease." This statement is a recognition that information from sources outside the processing plant can and should be considered in the verification of a HACCP plan. In fact, it is FDA's experience that consumer injury or illness complaints to the agency occasionally point out problems traceable to defective controls at the food processing facility (Ref. 207). Where information that has potential relevance to food safety is available to a processor as a result of its own consumer complaint system, it is entirely appropriate for the processor to consider that information in assessing the adequacy of its HACCP program. FDA accepts the possibility that many, if not most, consumer complaints that a processor receives will not be germane to safety, that many will turn out not to be valid, and that others will relate to events at retail or that are otherwise beyond the ability of the processor to control. Nonetheless, FDA strongly believes—and the comments support this view—that a responsible processor will at least review consumer complaints to determine their potential value and take steps to correct the product or the process, when such stops are warranted.

FDA has concluded, therefore, that processors should evaluate the consumer complaints that they receive to determine whether the complaints relate to the performance of CCP's, or reveal the existence of unidentified CCP's, as part of their HACCP verification procedures. The agency acknowledges that the absence of consumer complaints does not, by itself, verify the adequacy of a HACCP system. However, after taking into account all the concerns raised by the comments, the agency is of the view that those consumer complaints that a processor does receive, and that allege a safety problem, can be of value as a verification tool and should serve that purpose. This conclusion is reflected in the requirements of § 123.8 of these final regulations (see discussion in the "Verification" section of this preamble), which lists the review of consumer complaints as an appropriate verification activity (§ 123.8(a)(2)(i)).

As explained earlier in this preamble, because the agency regards consumer

complaints as a verification tool rather than a monitoring tool, FDA has modified § 123.6(c)(4) to eliminate the proposal requirement that the HACCP plan describe how consumer complaints will be used in the monitoring of CCP's. The agency has also modified § 123.6(c)(7) to eliminate the proposed requirement that consumer complaints be part of a processor's HACCP-monitoring records.

FDA has concluded that when a review of a consumer complaint reveals a need for the processor to take corrective action (e.g., recall, destruction, or reprocessing of the product or modification of the process to reduce the risk of reoccurrence of the problem), such action must be taken in conformance with the applicable corrective action procedures of these regulations. This conclusion is reflected in of § 123.8(b) which states that processors shall immediately follow the procedures in § 123.7 whenever a review of a consumer complaint, or any other verification procedure, reveals the need to take a corrective action. The corrective action provisions are discussed in the "Corrective Actions" section of this preamble.

As suggested by several of the comments, records of corrective action relative to consumer complaints need not include the original consumer complaint. However, it is unlikely that a comprehensive record of the corrective action taken could be generated without at least the critical information contained in the complaint, such as the nature of the complaint and identification of the product in question. Identification of the complainant is not likely to be critical.

3. Agency Access to Consumer Complaints

77. Many comments questioned whether FDA should have access to consumer complaints. Several comments argued that no other food industry is required to provide access to consumer complaints. A few specifically cited the absence of such a requirement in the low-acid canned foods regulations (part 113).

One comment noted that FDA has methods other than access to a company's consumer complaint file to obtain information about product defects that affect safety, including direct calls from consumers and health professionals, MedWatch, and reporting to the Center for Disease Control and Prevention (CDC). Another comment suggested that it would be more efficient to devise a system whereby consumers are encouraged to submit complaints about product safety directly to FDA rather than to mandate access to corporate files.

Several comments suggested that consumer complaint files should remain a private company matter, and that open access to these files is likely to result in regulatory abuse. A few comments further argued that, by mandating complaint file access, the agency would penalize those firms with good consumer complaint gathering systems and possibly deter others from developing such systems.

A relatively small, diverse group of comments, including seafood processors, a seafood trade association, and a Federal government agency, submitted that, while it is appropriate for FDA to mandate that processors utilize consumer complaints in assessing the effectiveness of their HACCP program, it is not necessary for the agency to have direct access to the firms' complaint files. The comments suggested two alternatives to providing direct access to complaint files: (1) Allowing processors to prepare Notices of Unusual Occurrence and Corrective Action (NUOCA) that described the action taken in response to consumer complaints that relate to product safety; or (2) allowing processors to prepare a matrix of complaints, as is currently used in the voluntary, fee-for-service HACCP program being operated by NMFS.

Others in this group suggested that FDA have access only to written complaints, or only to consumer complaints, as opposed to trade complaints, which the comment argued are often submitted for commercial advantage only. One comment noted that it would be impossible for processing vessels to retain consumer complaints on board the vessel, and that provision should be made for these to be stored at the corporate office. Other comments urged that FDA access to consumer complaints not include the right to copy them, or that, in some other way, they be protected from public disclosure.

Another group of comments, composed of consumer advocacy organizations and a State regulatory agency, urged that all consumer complaints, regardless of their potential relationship to product safety, be included in a processor's HACCP records and be available for FDA review. These comments suggested that the FDA investigator should make the determination of which complaints are relevant for follow up rather than the firm. They further suggested that the investigator can ignore any complaints that are not relevant to safety controls at the processing facility.

Unquestionably, FDA has an essential role to play as a regulatory verifier of HACCP. As described earlier, the agency received a number of comments that raised concerns about the veracity of a mandatory HACCP system in the absence of adequate regulatory review. Moreover, FDA has concluded that this role cannot be carried out without the ability to review HACCP plans and a narrow category of processor's records (i.e., those that relate to how a processor is controlling the critical safety aspects of its operations). The agency is not interested in expanding this access beyond those records that are the minimum necessary to carry out this responsibility.

With regard to consumer complaints, FDA is persuaded by the comments that, especially when used as HACCP verification records rather than HACCP-monitoring records as originally proposed, the public health benefits that may accrue from agency access to these kinds of records would probably be minimal and are outweighed by the concerns that have been expressed.

FDA is satisfied that agency review of a processor's overall verification scheme, plus access to records that document any corrective actions that were taken as a result of information obtained through consumer complaints, review of those complaints that consumers regularly send to the agency, the ability to conduct unannounced inspections, and access to monitoring records and plans, should be enough for FDA to adequately verify processor's HACCP systems.

FDA also accepts that the burden on processors if they had to segregate complaints that have a potential relationship to product safety from those that relate to product quality, economic issues, customer satisfaction, and other nonsafety issues, would be great and is not warranted by any potential gain in product safety. Many firms would have to take this step to make safety-related complaints available to FDA. Similarly, the agency recognizes that a significant burden would be placed upon its inspectional force if it had to verify that a processor had properly categorized its complaints.

The alternative of FDA having access to all consumer complaints and making its own determinations about which relate to safety, as some comments suggested, is simply not practicable. In addition, it is not the desire of FDA to penalize those firms that have large, expensive complaint gathering systems, by mandating that they provide all information so gathered for agency review, or to discourage others from developing such systems.

In the preamble to the proposed regulations, FDA stated that more than half of the seafood-related consumer complaints that it receives relate to product quality, filth, and economic deception concerns. Access to all consumer complaints is, therefore, unnecessary to ensure product safety.

FDA has, therefore, removed from what is now § 123.9(c) the requirement that consumer complaints relating to safety be available to the agency. The agency reiterates, however, that processors should utilize all available information as they evaluate the adequacy of their HACCP plans and their implementation. Consumer complaints are one potential source of information, and a significant group of comments recognized the value of consumer complaints in the verification process.

I. Records

FDA proposed that records required by the regulations: (1) Contain certain information, (2) be completed at the time of the activity, (3) be signed by the operator or observer, (4) be reviewed for completeness and compliance with the HACCP plan and signed and dated by the reviewer, (5) be retained for specified periods of time, and (6) be available for review and copying by FDA.

FDA received a large number of comments that addressed these proposed recordkeeping requirements. These comments were from a diverse group of commenters, including large and small processors, trade associations, individuals, Federal, State, and foreign government agencies, consumer advocacy groups, professional societies, and academics. Several comments provided arguments that support the need in a mandatory HACCP program for records in general, and none specifically argued in opposition to that concept. Most of the comments addressed specific issues that relate to recordkeeping.

Those comments that supported the need for records stated that recordkeeping is a key component of HACCP. One processor's comment noted that HACCP records must be kept in good order so that problems can be easily tracked to their root cause. One comment stated that HACCP records facilitate an evaluation of safety conditions over time, rather than through a "snap shot" inspection. Another processor noted that HACCP recordkeeping is not overly burdensome, and that the proposed regulations would not require it to maintain any records in addition to those that it already maintains.

1. Details and Signatures

78. FDA proposed that all HACCP-monitoring records (including records of process-monitoring instrument calibration), sanitation control records, and corrective action records identify the date of the activity that the record reflects. One comment recommended that the final regulations should also require that the time of each observation be recorded, to make it easier to link records to specific lots of product. A comment from a trade association requested that the records be required to identify the establishment where the activity occurred to reduce the potential for confusion in firms with multiple processing facilities.

FDA agrees with both comments that the date and time on records will help to connect information on the records to specific lots of product, and that the name and location of the processor will help link information to a specific processing facility.

The agency has, therefore, modified § 123.9(a)(1) and (a)(2) to state, in part, that the required records must include: "(1) The name and location of the processor or importer; (2) The date and time of the activity that the record reflects."

79. FDA proposed to require that HACCP-monitoring records (including records of process-monitoring instrument calibration) and sanitation control records be signed by the observer/operator. A few comments supported the proposed requirement on the grounds that it fosters accuracy and accountability in the recordkeeping process. One comment opposed the proposed requirement, raising concern about the legal liability that it imposed upon the workers that sign the records. A few comments suggested that the observer/operator be allowed to initial, instead of sign, the records.

FDA agrees with the comments that suggested that a signature on monitoring and sanitation control records is necessary to ensure accountability in the recordkeeping process. FDA also hopes that it will enhance workers' sense of responsibility and pride in their participation in the HACCP system of preventive controls. Regarding worker liability, those that deliberately falsify records are liable whether they sign the records or not. In any event, the falsification of records cannot be condoned and should not be tolerated by processors.

FDA further agrees that the purpose for the observer/ operator's signature is achieved if the observer/operator either signs or initials the monitoring records. FDA proposed to require the signature of the observer/operator on all records involving observations or measurements made during processing or related activities. This specification of the kinds of records in which signatures were required would have had the effect of exempting consumer complaints, which were considered to be monitoring records in the proposal from this requirement. However, the use of consumer complaints as monitoring records has not been carried forward to these final regulations. Consequently, limiting the records that must be signed to involving observations or measurements is no longer necessary, and FDA has deleted it for purposes of clarification (see § 123.9(a)).

FDA has also deleted the proposed provision that the observer/operator need not sign corrective action records. The agency proposed to require that only a trained individual sign these records. FDA is requiring the signature or initials of the observer/operator on corrective action records in order to be consistent with the corrective action provisions of these regulations. In § 123.7, for example, processors may now predetermine their corrective actions in ways that empower observer/operators to take corrective measures, especially in the absence of a trained individual. The likelihood that a trained individual might not be present at the moment when a corrective action must be initiated is enhanced by the fact that such an individual need not be an employee of the processor (see § 123.10). Conversely, the presence of a trained individual during the initiation of a corrective action need not preclude the observer/operator from taking corrective steps, as appropriate. Finally, the agency has concluded that the burden imposed by requiring the signature or initials of the observer/operator whenever that individual participates in the making of a corrective action record is inconsequential.

80. Several comments questioned whether the proposed requirement that monitoring records include the "identity of the product, product code * * *," meant that all fish and fishery products were required to bear a product code.

It was not the intent of the agency to require product codes on such products, only to require that they be listed on appropriate records when they are used. The purpose of the proposed requirement was to facilitate linkage between records and product. To clarify this point, FDA has modified what is now § 123.9(a)(4) to read, "(4) Where

appropriate, the identity of the product and the production code, if any."

81. Several comments suggested that FDA not specify the components of required records. These comments argued that many processors have existing forms that can appropriately be used as HACCP records.

It is not FDA's intent in § 123.9(a) to specify record format or content, beyond certain minimum, essential components. Processor's are encouraged to use existing records, making modifications only as necessary to meet the previously described requirements.

2. Retention and Storage

FDA proposed to require that processors retain monitoring (including process monitoring instrument calibration), sanitation control, and corrective action records for 1 year after the date that they were prepared for refrigerated products and for 2 years for frozen or preserved products. FDA also proposed that records used to substantiate the adequacy of equipment or processes be retained for 2 years after the date that they apply to products being processed.

82. Several comments stated that these proposed retention times were too long. Most of these comments suggested record retention times of from 90 days to 1 year for refrigerated products and from 6 months to 1 year for frozen products. One comment argued that 1 year is a sufficient period for record retention unless the records relate to a CL deviation, in which case they should be held for 3 years. Another comment urged that the agency not mandate record retention times but require processors to identify appropriate retention time requirements in their HACCP plans.

FDA rejects those comments that requested a reduction in the proposed mandatory record retention period. While it may be true that most refrigerated products will be unusable within 90 days, as suggested by one of the comments, retention times of less than 1 year do not provide for sufficient access for the processor's or FDA's verification activities. (See revised § 123.8(a)(1) and the accompanying preamble discussion of the minimum 1-year frequency of plan reassessment.) No new, substantive comment was provided relative to record retention times for frozen or preserved products that would warrant a reduction for those products.

Thus, FDA has made no changes to § 123.9(b).

83. FDA proposed that, in the case of processing facilities that close between seasonal packs, records could be transferred to another accessible location between seasonal packs, as long as they were returned during the next active season. Comments from several processors and trade associations urged the agency to modify the requirement to: (a) Allow for permanent transfer from the facility and (b) include both remote processing sites and processing vessels regardless of whether they close seasonally. Comments from operators of processing vessels and remote processing sites and from a trade association requested that FDA allow HACCP records to be kept on the processing vessel or remote site for a period of time and then be transferred permanently to the processor's corporate, or closest business office. The comments argued that the records in those locations would be more easily stored, safer, and more readily accessible to regulators than they would be at remote sites and on processing vessels. Additionally, they argued that corporate verification activities often would be performed at the land-based facilities. Transfer of the records to these facilities would promote verification in these circumstances. Comments opposing the requirement that the records be returned to a seasonally closed facility once the facilities reopened expressed concern that return of the records to the reopened locations could result in lost records.

FDA has been persuaded to accommodate the difficulties associated with record storage on processing vessels and remote processing sites by allowing HACCP records to be moved from such facilities to another reasonably accessible location at the end of the seasonal pack without requiring that the records all be returned for the following season (§ 123.9(b)(3)). Additionally, the agency will, as proposed, allow HACCP records from any facility that is closed between seasonal packs to be permanently transferred to another reasonably accessible location. However, FDA points out that, in most instances, the agency will need to examine processing records onsite in order to conduct an effective verification inspection. For this reason, records must be so stored that they can be promptly returned to the processing facility upon demand by FDA. In order to maintain inspectional efficiency, the time period between an FDA request for the records and their arrival should not ordinarily exceed 24 hours.

84. Several comments urged FDA to provide for the use of computers to maintain HACCP records.

It was not the intent of the agency to preclude such records. To make this fact clear, FDA has added a new paragraph, § 123.9(f), to the final regulation, which reads, "(f) *Records maintained on computers.* The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures."

In the **Federal Register** of August 31, 1994 (59 FR 45160), FDA proposed separate regulations at 21 CFR 11 that, if adopted, will become the standard for determining what constitutes appropriate controls for electronic records, electronic signatures, and handwritten signatures executed to electronic records. In the interim, processors are encouraged to look to industry standards for guidance.

3. Confidentiality of Records

85. In the preamble to the proposed regulation, FDA stated that, as a preliminary matter, HACCP plans and monitoring records appear to fall within the bounds of trade secret or commercial confidential information and would, therefore, be protected from public disclosure by section 301(j) of the act (21 U.S.C. 331) and by the Freedom of Information Act (FOIA) and the Department of Health and Human Services (DHHS) and FDA regulations promulgated pursuant to these laws. FDA specifically invited comment on the issue of public disclosure of HACCP records and on whether FDA has any discretion about the releasability of any HACCP records that it may eventually have in its possession. A large number of comments responded to FDA's request for comment, especially in the context of the provision in the regulations (§ 123.9(c) in this final rule), that provides that all required records and plans must be available for review and copying.

A large number of comments, from processors, trade associations, professional associations, State and Federal agencies, and individuals, contended that HACCP records and plans are trade secrets and should under no circumstances be released to the public. Comments from several consumer advocacy groups countered that in many cases HACCP records and plans will not contain trade secret information or will contain only limited trade secret information, and that the nonsecret parts (i.e., most of their contents) should, therefore, be available to the public.

Many of the comments that supported protection from public disclosure urged that the final regulations contain controls over the agency's access to, and

copying of, HACCP plans and records as the only guaranteed way to ensure confidentiality. The comments argued that the potential harm from exposure of HACCP plans and records to competitors or to the public is considerable and carries the threat of increased costs, misuse, and damage to the integrity of a firm and its products.

Several comments contended that HACCP records will be trade secret because they will be process-specific and, therefore, will contain such information as processing times and temperatures. They stated that these processing parameters may differ from company to company based on product formulas.

A few comments argued that there is no precedent for public access to industry-generated records. Some of these comments stated that processing records are regarded as trade secret under the LACF regulations, and they noted that § 108.35(d)(3)(ii) deems processing information submitted to FDA to be trade secret within the meaning of 301(j) of the act and within the meaning of the FOIA. Other comments asked that FDA protect HACCP plans and records in the same way that the agency protects processing and quality control data that are submitted to FDA under cooperative quality assurance agreements (i.e., manufacturing methods or processes, including quality control procedures, are deemed not to be releasable unless the information that they contain has already been released or is otherwise no longer trade secret or confidential commercial per §§ 20.111(d)(2) and 20.114 (21 CFR 20.111(d)(2) and 20.114)).

Several comments suggested that FDA specifically declare that: (1) HACCP plans and records are trade secrets; (2) section 301(j) of the act and the FOIA prohibit disclosure of trade secret or confidential commercial information and give the agency no discretion whether to release these types of records; and (3) § 20.81 provides for disclosure of trade secret or confidential commercial information only if the information has been previously disclosed to the public.

One comment proposed that, if FDA felt obliged to release some HACCP-related information pursuant to FOIA requests, reports of regular inspections be released instead of HACCP plans and records, because such reports are likely to contain less sensitive information. Another comment suggested that, to avoid releasing proprietary information, the agency should describe or explain information that is contained in HACCP plans and records in general terms rather than release the records themselves. The comment asserted that this step would serve to inform consumers about the relative safety of the product and the effectiveness of the HACCP system, while not divulging specific process parameters that are trade secret or confidential commercial.

Conversely, comments from consumer advocacy groups argued that, for the most part, HACCP plans and records are not trade secret or confidential commercial. The comments asserted that much of the information contained in these plans and records involves the application of basic sanitary engineering and is already in the public domain, as evidenced by the draft FDA Guide.

The consumer advocacy groups argued that, given the limited resources that FDA can devote to monitoring HACCP compliance, public access to HACCP records should be as broad as allowed under the law, so that consumer confidence in, and understanding of, the seafood supply can be fostered. One comment asserted that the public's right and need to know about matters involving public health should be the basis from which the agency formulates public access policy. Another comment stated that consumers are the intended beneficiaries of the HACCP seafood proposal and therefore should have the right to determine through record inspection whether processors are properly implementing the HACCP requirements. These comments urged FDA to routinely collect HACCP plans and records from processors to facilitate agency verification activities and public review of the effectiveness of the HACCP system. One comment from a consumer advocacy group asserted that *Public Citizen Health Research Group* v. *FDA*, 704 F.2d 1280 (D.C. Cir. 1983) narrowly defined trade secrets in such a way that HACCP plans and the records at issue in this rulemaking could not be considered trade secret.

Unquestionably, adoption of a mandatory HACCP system will place significant documentation requirements on seafood processors. As a result, they will produce records that reflect processing designs and equipment and certain types of day-to-day operations. They will be available to FDA. FDA strongly believes that it is in the public interest to require that these records be maintained, and that the agency have access to them. Such records and access are necessary to effectuate a mandatory system of preventive controls for safety. As stated in the preamble to the proposed regulations, FDA expects to take possession of records on a case-by-case basis, and only when there is a specific need to do so. The agency categorically rejects the view that FDA should be a collection point for HACCP records and plans so that they may be made publicly available. Nevertheless, the apprehension expressed by many comments about the consequences of public disclosure of these new types of records is certainly understandable.

FDA agrees with the views expressed by consumer advocacy organizations that the public needs ways to be able to judge how and whether it is benefiting from a HACCP system. Neither the agency nor the industry can reasonably expect that the public will simply take the government's word for it. It remains to be seen, however, whether public access to information about processors that processors have traditionally held as protected is the only way, or the best way, to provide the public with information about this system.

FDA is considering how meaningful data can be extracted from the inspectional process and prepared in such a manner that it could be released without jeopardizing trade secret and confidential commercial information and yet be useful to both FDA and the public in evaluating this program. FDA is considering developing standardized reports that would be completed by investigators at the conclusion of routine HACCP-based inspections and become part of agency files. As presently conceived, these reports would contain a summary of the status of the HACCP program in effect at the firm, similar to the suggestion of two of the comments.

Nonetheless, the question is whether, as FDA preliminarily concluded, most plans and records to be generated under this program will be subject to protection under existing law and FOIA regulations. FDA's experience in seafood processing plants, its experience with HACCP, and its understanding from the cost-benefit modeling that has been done in the preparation of these regulations is that HACCP plans will take each processor some time and money to develop. Thus, the agency concludes that HACCP plans generally will meet the definition of trade secret, including the court's definition in *Public Citizen Health Research Group* v. *FDA, supra*. Plans that incorporate unique time-temperature regimens to achieve product safety, or other parameters that are processor-specific and that are the result of considerable research and effort, will surely meet this definition.

Moreover, there is value in a plan to a company that produces it for no other reason than that it took work to write. The equity in such a product is not

readily given away to competitors. FDA knows from its own experience that plant configurations tend to be unique to individual processors, or at least have unique features (Ref. 222). While generic plans will have great utility in many circumstances, they serve primarily as starting points for processors to develop their own plans. FDA expects that its Guide will help serve that purpose, but firms will still need to expend time and money to tailor HACCP to their individual circumstances.

Additionally, the agency has come to the conclusion, as a matter of policy, that records and plans should be protected to the extent possible in order to promote the implementation of HACCP across the seafood industry. FDA has concluded that the public will benefit from the protection of records because it will actually strengthen the HACCP system. So long as the legitimate public need to be able to evaluate the system can be met through other means, the confidentiality of HACCP records and plans generally will foster the industry's acceptance of HACCP. Even though HACCP may be mandatory under these regulations, in order for it to succeed, processors must be committed to it because they see value in it for themselves. Fear of public disclosure of matters that have long been regarded as confidential business matters could significantly undermine that commitment. FDA concludes, therefore, that it is in the public interest to foster tailored HACCP plans that demonstrate understanding and thought, rather than promote the use of rote plans and minimally acceptable standards due to fear of public disclosure.

FDA understands that it cannot make promises of confidentiality that exceed the permissible boundaries established under FOIA, nor does the agency wish to do so in this case. The agency still does not expect that it will be in possession of a large volume of plans and records at any given moment. However, given the significant interest in this subject as conveyed by the comments, FDA has concluded that the final regulations should reflect the fact that the HACCP plans and records that do come into FDA's possession will generally meet the definition of either trade secret or commercial confidential materials. A statement to this effect in the final regulations will help to make this fact as widely understood as possible and will clarify the agency's position on this matter. This fact is codified at § 123.9(d)(1), which reads as follows:

(d) *Public disclosure.* (1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter, or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.

The agency acknowledges that there could be exceptions to this general rule. The nature of information in HACCP plans and records varies. Some of it could be generally available processing methodology or procedures, based on generic or model HACCP plans or guidelines developed by the agency or some other public source, that is sufficiently reflective of an industry standard that it has little if any proprietary value. In such a case, in response to an FOIA request, there may not be a valid reason for protecting this information. The agency has concluded that there should be a provision that makes clear that it will make information available in appropriate circumstances. Consequently, the final regulations in § 123.9(d)(2), state:

(2) However, these records and plans may be subject to disclosure to the extent that they involve materials that are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

There is precedent for describing in regulations the records that have protected status. The low-acid canned food regulations at § 108.35(l) provide that, except under certain limited situations, filed scheduled processes submitted to FDA are not available for public disclosure. Additionally, § 108.35(d) provides that data submitted to the agency to support these processes are to be treated as trade secret. These materials are analogous to HACCP plans, and their treatment is consistent with the agency's views relative to the protected status of HACCP plans. The comments that suggested that the low-acid canned foods regulations grant trade secret status to the monitoring records that are required to be kept by part 113 are incorrect. These records are not provided any special status in those regulations.

4. Agency Access to Records

86. Several comments suggested that the final regulations should require processors to provide access by FDA to HACCP records only after the submission by the agency of a written request for specific records it deems necessary to review. The comments noted that this approach would be similar to § 108.35(h) in the LACF regulations, because processors are familiar and satisfied with such procedures.

FDA remains convinced that access to HACCP documents is essential to the agency's verification of a firm's HACCP system. A key feature of the HACCP verification process is access by government investigators to the HACCP plan, to monitoring records kept according to the plan, and to records of corrective actions that were taken in response to CL deviations. Examination of HACCP records enables an investigator to see how the processing facility or the importer operates over time rather than how it is functioning at one particular moment in time. Additionally, it will enable the regulator to review the adequacy of the processor's or the importer's preventive control system itself.

FDA rejects the idea of being required to request in writing access to HACCP plans and records. The agency is convinced that it has sufficiently limited its access to those records and plans that are minimally necessary to adequately evaluate the adequacy of a firm's HACCP system. Section 123.9(c) has been modified slightly to clarify to which records FDA is required to be granted access.

The comments are correct that the emergency permit regulations for low-acid canned foods at § 108.35 require that FDA issue a written request for access to monitoring records. However, the written request has proven to be merely a mechanical exercise. It has not in any way served to affect the outcome of FDA access to records, nor is it associated with any managerial control over the activities of FDA investigators, with respect to the kind or numbers of records to which they seek access. Moreover, the bottled water regulations at § 129.80(h), promulgated subsequent to the low-acid canned food regulations, do not contain a requirement for the issuance of a written request for records. FDA is not aware of any undue concerns expressed by the bottled water industry relative to agency abuse of its records access authority as a result of the lack of a written request requirement in those regulations. FDA further notes that its investigators are required to present a written notice of inspection to management of the firm at the start of each inspection. The notice explains the authority of the investigator to conduct an inspection of the facility. The agency has concluded that there is no need to further encumber the efficient enforcement of these regulations with a

written request for those records to which it is entitled to have access. It has chosen to use the more recent regulations, bottled water, as the model for these regulations with respect to records access.

5. Agency Copying of Records

87. A large number of comments opposed the provision in the proposal that provided for FDA copying of HACCP plans and records, mostly because of concern about public disclosure. Several comments stated that the agency should be permitted to obtain copies only to support a regulatory action and only after FDA has obtained a subpoena. Several other comments suggested that FDA be permitted to copy only those records that relate to a CL failure.

Several comments requested that FDA provide safeguards to control potentially abusive regulatory practices by establishing rules to be followed when copying records. The comments stated that the rules should accomplish the following: Identify investigators authorized to copy records, limit copying to records pertaining directly to CCP's, require prior written authorization for copying from the investigator's supervisor, require that the authorization identify the specific records to be copied and the reason that they are needed, require that a responsible company executive receive each request before any copying is permitted, and permit the company to question the purpose for the request before records are copied.

Comments from several consumer advocacy groups, on the other hand, supported the agency's need to copy records.

There are two primary reasons for the agency to copy HACCP plans and records: (1) To facilitate expert review of such issues as the identification of appropriate hazards and CL's in HACCP plans and the evaluation of the adequacy of corrective actions taken in response to CL failures; and (2) to document suspected inadequacies of the HACCP plan or the firm's implementation of the plan for possible regulatory followup.

Limiting the copying of records to those situations in which regulatory action is contemplated or in which a subpoena could be obtained would serve neither the needs of the industry nor the agency. Resolution of differences in food safety control strategies through scientific review and dialog, where possible, is superior to reliance solely upon the legal system for such resolution. Similarly, limiting the copying of records to instances involving CL deviations would inappropriately restrict the agency's ability to evaluate potential problems in the identification of CCP's, the establishment of CL's, and other scientific issues, which, in some cases, may be beyond the expertise of agency investigators.

Industry comments have expressed considerable concern, as discussed in the "Compliance" section of this preamble, that there will be no mechanism for dialog with the agency if a firm disagrees with an investigator's findings with regard to the sufficiency of HACCP plans and records. The agency is strongly committed to dialog whenever possible. Provision of a means by which senior reviewers at agency headquarters will have access to HACCP plans and records will facilitate that process.

FDA has concluded that the restrictions on copying of records suggested by the comments would significantly interfere with that access. It would be highly inefficient for FDA to identify a special class of investigators that are permitted to copy HACCP records and plans. FDA investigators are responsible for conducting inspections and investigations to enforce a wide array of regulations, and FDA field managers need the flexibility to assign work in an efficient and effective manner. Copying, like record access, is limited to the records specified in § 123.9(c). It would be highly impractical for supervisory preapproval to be accorded to an investigator for the copying of specific records. Until an investigator has evaluated a HACCP plan and validated the operations of the plant, it is not likely that the investigator will know with any certainty what HACCP records are appropriate for review. Additionally, inspections are often done in remote locations and under highly flexible itineraries that preclude close contact between the investigator and particular supervisor. Certainly, FDA investigators will make every effort to obtain HACCP plans and records from responsible individuals of the firm and will, if necessary, explain the relevance of the requested records to the recordkeeping requirements of these regulations.

The agency is unconvinced of the need to modify § 123.9(c) in response to the aforementioned comments, except that reference to consumer complaints in this section has been eliminated as discussed in the "Consumer Complaints" section of this preamble.

88. Several comments questioned the phrase "duly authorized officers and employees" used in this section. Some felt that it referred, at least in part, to employees of the firm, and others felt that it excluded officials of State regulatory agencies that may adopt these regulations by reference.

The intent of the proposed regulations was to grant records access to regulatory agency officers and employees, not officers or employees of a firm. The language was intended to be flexible enough to cover State officials if their agency adopted the regulations by reference. FDA has changed the wording of the regulations to address these concerns.

The modified paragraph in § 123.9(c) reads:

(c) *Official review.* All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

J. Training

A large number of comments addressed the proposed training requirements. FDA proposed to require that each processor and importer employ at least one individual who has successfully completed a training course that has been approved by FDA on the application of HACCP to fish and fishery products processing. FDA also proposed that the trained person or persons be responsible for, at a minimum, developing and modifying the HACCP plan, evaluating the adequacy of corrective actions taken in response to CL deviations, and reviewing monitoring records before shipment.

In the preamble to the proposed regulations, FDA specifically requested comment on: (1) Whether the need for training could be satisfied by different gradations of training (e.g., based on complexity or size of operation or on the degree of risk posed by the products being produced); (2) whether other training formats, such as video tapes, might be effective, at least under some circumstances (e.g., a small business whose processing involved few hazards); (3) whether, assuming the regulations are adopted by FDA, training in HACCP received before they are effective should be "grandfathered" as fulfilling the training requirement; and (4) whether some or all of the training requirements should be deleted or modified as a means of reducing the burden on the industry.

1. The Need for Mandatory Training

89. Most of the comments that addressed the question of whether there should be a mandatory training requirement expressed support for it. A significant portion of these comments acknowledged the need for at least one