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 as decomposition and economic fraud, making the two control systems compatible; an improvement in consumer confidence in seafood cannot 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 most 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 be 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, the statutory provisions that form the basis for these regulations are safety provisions. FDA's application of HACCP is intended for the effective enforcement of sections 402(a) (1) and (a)(4) of the act, which apply to products that contain substances that may render the product injurious to health and to processing conditions that are insanitary and that could render a product injurious to health. Thus, the only real issue is whether the final regulations should retain the recommendations with regard to the application of HACCP to nonsafety matters.

FDA is persuaded by the comments that the proposed recommendations for HACCP controls of nonsafety matters, coupled with the presence of proposed 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 be 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: (1) The cause of the deviation, (2) 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 timely response to the deviation when 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 such action may involve, where 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

trained individual at each processing facility. Those that provided reasons for their support contended that properly trained personnel are essential to the development and effectiveness of HACCP controls, and that training is necessary to ensure consistency of approach.

Those few comments that expressed reservations about the overall HACCP training requirement generally acknowledged the need for a trained individual in the plant but opposed a compulsory training program. Two comments, from State governments, expressed concerns about the financial burden of training on small businesses and questioned the need for making such a provision mandatory.

The overwhelming support in the comments for HACCP training is indicative of the nearly universal view that training is essential to the effective implementation of a HACCP system. As stated in the preamble to the proposed regulations, this view is shared by the NAS based on the success of the training requirement in FDA's HACCP-based regulations for low-acid canned foods at part 113 (Ref. 54). The primary concern expressed about mandatory training is the cost.

The agency is convinced that its efforts with the Alliance will facilitate the development and implementation of a low cost training program. As mentioned above, the Alliance is a cooperative effort between Federal and State food regulatory agencies, academia, and the fish and fishery products industry to provide support to the industry in meeting its needs relative to HACCP training, technical assistance, and research. Presently, the Alliance Steering Committee is comprised of representatives of FDA, the U.S. Department of Agriculture (USDA), NMFS, AFDO and its six regional affiliates, the Sea Grant Colleges, the ISSC, the National Fisheries Institute, and the National Food Processors Association (NFPA).

The goals of the Alliance are to develop: a HACCP training course that will meet the requirements of these regulations, a mechanism for delivering the training to the fish and fishery products industry, a compendium of established methods for controlling hazards in the fish and fishery products industry, and a mechanism for coordinating the research efforts of the participating agencies to facilitate the development of improved methods of hazard identification and control.

The training course materials are in an advanced stage of development and are expected to be publicly available shortly after the publication of these regulations. The AFDO regional affiliates have agreed to work within their regions to identify regulatory and industry training needs and qualified trainers who are interested in participating in the Alliance-sponsored training. They have also agreed to serve as the course coordinators for the Alliance-sponsored training, which will be conducted on a cost-recovery basis.

The Alliance is developing a 3-day course, divided about equally among: (1) The fundamentals of HACCP, based on the recommendations of the NACMCF; (2) the requirements of these regulations and the recommendations of the Guide; and (3) a practical exercise in HACCP plan development.

FDA is sensitive to the concerns expressed about the cost of training but is optimistic that training will not be unnecessarily burdensome on small business, either in actual out- of-pocket expenses or in lost productivity. As was previously mentioned, FDA is working with the Alliance to produce a low cost, 3-day HACCP-training course for the seafood industry, that is intended to meet the requirements of these regulations. Current plans are for the course to be offered through a variety of public institutions, including Sea Grant colleges. As indicated earlier, in this setting the course is expected to be offered on a cost recovery basis. It is likely that the course will also be offered by private institutions, using their own fee structure.

The other cost associated with the training requirement is the lost productivity for the duration of the course. FDA is convinced that, with the flexibility in course structure, described elsewhere in this section, training can be taken at times when it would least affect the operations of the firm (e.g., during an off-season, at night). Moreover, FDA is convinced by the comments that, as a general rule, the benefits of training will significantly outweigh the burden. The agency has concluded that with certain modifications from the proposal as described below, training should remain a feature of these regulations.

The agency has made one modification in response to requests that it modify the training requirement to reduce financial burden, especially on smaller processors. FDA acknowledges that a short course in HACCP has its limitations. For example, a 3-day course might not have anything important to offer to an individual who has significant job experience working with or for an individual who is well-versed in HACCP. In such a situation, if the processor loses the trained individual, it should be able to replace him or her with the individual who has, in effect, apprenticed with the trained individual without having to send the apprentice to a course in HACCP training, assuming, of course, that the apprenticeship has imparted a level of knowledge at least equivalent to that that could be provided by the training. The agency has modified the regulations to provide for this kind of situation by permitting adequate job experience to qualify and individual to perform the functions of the trained individual.

Note that all references in this preamble to a trained individual mean an individual who meets the requirements of § 123.10 through either completion of a course or job experience that provides an equivalent level of knowledge.

2. Who Should Provide Training?

90. A significant number of comments identified organizations or individuals that they considered to be qualified to conduct or develop HACCP-training courses. The majority of the comments, which included remarks from processors, trade associations, and State governments, suggested that FDA should either conduct such training or at least approve the relevant course material. A few of the comments that recommended that FDA conduct the courses also recommended that FDA provide the courses at no cost or financially support the training. The comments that endorsed FDA approved courses asserted that this approach would result in a standardized, comprehensive training program that emphasizes the minimum acceptable HACCP requirements.

Other comments recommended that training programs could be conducted by NFPA or other trade associations, ISSC, Sea Grant colleges and other academic institutions, consultants, and State and local regulatory agencies. The comments acknowledged the cost savings that could be realized with trade association- provided training and through the HACCP training experience already possessed by the NFPA. One comment suggested that allowing many training programs would offer hundreds of professionals the opportunity to contribute to the development of HACCP. A few comments suggested that FDA publish a listing of approved training courses.

A comment from the ISSC cautioned that organization does not support the shifting of public health training in the area of molluscan shellfish away from itself. The comment further stated that the organization would work cooperatively with the Alliance in the development of a HACCP-training

course, which it suggested should be Federally subsidized and ISSC endorsed.

A few comments suggested that the Alliance be permitted to develop the standard for HACCP training, and that the results be shared with all prospective trainers. A few additional comments urged that HACCP training be based on the recommendations of NACMCF, because such efforts would result in a training program that was well defined.

FDA generally agrees with these comments. The agency does not intend to run HACCP-training courses for the industry. Rather, FDA must, of necessity, focus its HACCP training on government investigators. The agency anticipates that industry training will be conducted privately and through academia. This division of labor is based on the model that has worked well for the training requirement for low-acid canned foods.

FDA agrees, moreover, that there should be widespread opportunity for conducting HACCP training. It is not the agency's intent to specify or limit the field of qualified trainers.

The training course that is under development by the Alliance is based on the recommendations of the NACMCF. After reviewing the final draft of the Alliance training materials, FDA intends to publish a notice of availability of the documents in the Federal Register. It is the agency's intent to utilize the Alliance materials as the standard against which other course materials may be judged.

The agency strongly encourages trainers to evaluate their courses, past, present, and future, against the Alliance materials when they become available and to modify or adapt curricula, where necessary, to ensure that they are consistent with, and provide at least an equivalent level of instruction to, the Alliance course. Where previously conducted training fails to meet this standard, it may suffice to provide supplemental materials or instruction so that the cumulative training is at least equivalent to the Alliance course. FDA also encourages the fish and fishery products industry to confirm with past or prospective trainers that a particular course is equivalent to and consistent with the Alliance materials. The agency has no plans to publish a list of ''approved'' courses other than the Alliance course materials.

Finally, it should be noted that FDA resources will not be sufficient to fund the training of all appropriate regulators (i.e., State or local regulators). The agency is confident, however, that Alliance training will provide a low cost opportunity for high quality HACCP training for State or local regulators as well as for processors.

Because FDA will not be approving in advance specific courses other than the Alliance curriculum, and in response to comments, the final regulations have been modified at § 123.10 to require that training courses be ''at least equivalent to the standardized curriculum recognized as adequate by the U.S. Food and Drug Administration.'' FDA had proposed to require that training courses be ''approved by the Food and Drug Administration.''

3. Should Training Be ''Grandfathered?''

91. A large number of comments addressed the question of whether training in HACCP received before the effective date of these regulations should be ''grandfathered'' as fulfilling the training requirement. All of these comments supported the grandfathering of such training. Many of the these comments recommended specific training courses that FDA should grandfather. Approximately half of these comments requested that those trained under NMFS' HACCP training program be grandfathered. Those that provided reasons referenced the large number that had been trained at the time of the writing of the comment (1,310 domestically and 394 overseas) and stressed that NMFS' training was more comprehensive than that which would be necessary under FDA's HACCP approach, especially because the NMFS program covers nonsafety hazards in addition to safety hazards.

Other comments supported grandfathering HACCP courses conducted by NFPA, Sea Grant colleges, State regulatory agencies and those organizations sanctioned by such agencies to provide HACCP training, and Pacific Fisheries Services. One comment suggested that graduation from a Better Process Control School, as required by parts 113 and 114 for processors of acidified and low-acid canned foods, should be considered to meet the requirements of these regulations. Another comment urged that any training program based on the HACCP principles recommended by the NACMCF should be grandfathered.

One comment suggested that, in order to grandfather courses, FDA would need to develop a system to determine the effectiveness of the training that has been conducted. The comment recommended the use of testing or curriculum review as evaluation tools. The comment further encouraged the development of a formal approval process for previously conducted training.

FDA has concluded that it is not in a position to grandfather HACCP training received before the issuance of these regulations. Blanket grandfathering would pose the risk of sanctioning training that does not fully prepare processors for operating under these regulations, and case-by-case grandfathering would be unduly demanding on agency resources.

On the other hand, the agency will not presume that HACCP training received prior to the issuance of these regulations will have to be repeated. FDA will challenge the adequacy of prior training only when a processor's performance demonstrates a lack of understanding of HACCP principles.

Nonetheless, FDA encourages processors to update any prior training to ensure that they have a thorough understanding of the requirements of these regulations. It may well be that many traditional HACCP courses will need only minimal supplementation to accommodate them to the provisions of these regulations, and that there will be no need for a processor to repeat an entire course. As mentioned above, partial, supplemental courses may be offered, or reading materials developed by the course offerer and sent to the processor may suffice. There are numerous possibilities.

FDA is also not in a position to make determinations in advance about the acceptability of courses that will be offered after the issuance of these regulations. FDA agrees with the comment that, in order to do so, the agency would have to develop a system for course evaluation. Review of course materials, auditing of course presentations, testing, and other evaluation tools that FDA might have to employ are labor intensive and are not the most efficient use of agency resources. Rather, the adequacy of courses will have to be evaluated by FDA on a case-by-case basis, when inspectional or other evidence causes the agency to question whether the course meets the requirements of § 123.10.

The ultimate determination of the success of training is whether processors are operating effective HACCP systems. In the initial stages of the program, at least, FDA's primary focus will have to be on whether HACCP plans are adequate, and the systems are being effectively implemented. FDA's interest in the adequacy of training will increase when plans and systems fail to demonstrate an adequate understanding of HACCP and its application to seafood.

Nonetheless, FDA can state that the Better Processing School curriculum for

acidified and low-acid canned foods will not be adequate to meet the training requirement of these regulations. The Better Processing School was developed to instruct acidified and low-acid canned food processors in how to safely process such products to control the hazard of the development of botulinal toxin in accordance with the requirements of parts 113 and 114. The course does not provide instruction in the principles of HACCP or address other hazards (e.g., histamine development) to which these products might also be exposed.

4. Course Curriculum

92. A few comments suggested that the training be divided into a basic HACCP core and interchangeable segments based on the portions of the industry of interest to the students (e.g., vessels, cooked, ready-to-eat fishery products, molluscan shellfish, and smoked fish).

As mentioned previously, the Alliance course includes three segments: A basic HACCP core, the requirements of these regulations, and the development of a HACCP plan. The first two segments are applicable to the entire fish and fishery products industry. The Alliance has acknowledged the need to develop industry-specific features for the third segment. The agency is in agreement with the Alliance and with the comment in this regard and would encourage the development of such directed courses.

93. In response to FDA's invitation to comment on the advisability of alternate training formats, several comments expressed support for the use of video tapes by small processors of low-risk products. A few additional comments did not specifically address video taped training but stated that, while it is desirable to have uniform training, ultimately training should involve ''whatever it takes.'' One comment suggested that home study courses and education via television might be acceptable alternatives to more formal, for-fee training mechanisms. A few comments opposed courses that consist exclusively of video tapes, based on concern for a potential limitation in the level of understanding that could result from this type of noninteractive training method.

FDA agrees with the comments that expressed concern with teaching methods, such as video tapes, that lack instructor/student interaction. However, in the interest of providing flexibility in meeting the training requirement of these regulations, the agency has concluded that any teaching format is acceptable so long as it provides a level of understanding at least equivalent to that provided by the Alliance training program. FDA is aware that video tape training is widely used for a variety of purposes. The agency cannot conclude that video-based HACCP training will not accomplish the purposes of the training requirement. For remote site processors, video-based training may be the only practical method available.

It is unlikely, however, that two or three 2-hour video tapes, as one comment suggested, will provide an equivalent level of training to the 3-day Alliance course under development. On the other hand, a series of video presentations, perhaps in conjunction with a 1-day workshop, may be adequate.

94. A few comments addressed the length of the training course. One suggested that 3 days would be overly burdensome on small businesses because of the loss of manpower during the course. Another suggested that 3 days was not long enough to furnish the needed information. One comment suggested that the length of training should be based on the level of experience of the student and the level of complexity of the processing operation.

FDA has concluded, based, in part, on its participation in the Alliance, that the 3-day Alliance curriculum is the minimum necessary to develop an adequate understanding of HACCP principles and essentials of HACCP plan development. If the curriculum were reduced any further, processors would risk having to take more time later to implement their HACCP systems as a result of trial and error, and as a result, the quality of their HACCP programs would be jeopardized.

Nonetheless, FDA is not specifying in the regulations how long the course must take, only that it be equivalent in terms of curriculum to the standardized curriculum recognized as adequate by the agency. If true equivalency can be achieved in less time, FDA would have no objection. Moreover, depending upon the circumstances, FDA would have no objection to training that can be imparted in segments at convenient times so as to cause only a minimal disruption to the work schedule.

Section 123.10, therefore, states that the training must be ''at least equivalent to the standardized curriculum recognized as adequate by the U.S. Food and Drug Administration.'' This provision will also accommodate the use of food processing experts, who have received training in HACCP that is far more extensive than that planned by the Alliance. FDA recognizes that it would be inappropriate to limit the universe of experts to those who have taken a course based on the Alliance 3-day curriculum. The issue of the use of consultants and other experts will be further discussed later in this section.

5. Do Importers Need Training?

95. A few comments suggested that FDA should provide separate or specialized training aids for importers. Two of these comments noted that importers have not, historically, been involved with the processing of seafood commodities. The comments requested that FDA work with trade associations that represent importers in setting up workshops, developing specialized training materials for importers, and recognizing training provided by foreign institutions.

FDA has reassessed the need for training to accomplish the HACCP functions assigned to importers, especially in light of changes in the imports provisions of these final regulations. These changes are fully discussed in the ''Imports'' section of this preamble. In summary, importers are now required to conduct verification activities but are no longer required to have full HACCP plans of their own unless they also meet the definition of a ''processor.'' FDA has concluded that HACCP training, while desirable, is not essential to the preparation of importers' verification procedures, as specified at § 123.12(a)(2). For this reason, training is not required for importers, and all reference to required training for importer functions has been dropped from § 123.10.

Nonetheless, the agency is aware that importers may be unfamiliar with the technical aspects of fish and fishery product processing and HACCP control procedures. Knowledge about these matters would be helpful for purposes of verification. To meet this need, FDA plans to include in the Guide specific materials relating to importers' verification procedures. In addition, as has traditionally been the case, the agency intends to continue to interact with, and provide information to, the import industry through trade associations and other forums, within the limits of budget constraints. Moreover, importers may want to participate in the training courses that are offered by the Alliance.

Finally, the agency agrees with the comment that suggested that training overseas should be conducted by foreign institutions recognized for their expertise in seafood processing and HACCP control. This issue will be further discussed in the ''Imports'' section of this preamble.

6. Testing and Retraining

96. Several comments supported the mandatory use of testing to assess whether an individual has successfully completed HACCP training. Two comments further recommended that the agency could consider the training requirement to be met if a person successfully passes an examination.

The agency is not opposed to testing at the end of a course but prefers not to mandate that courses include tests. Trainers will be free to include or not include testing as part of their training efforts. The issue of student evaluation is one that is still being debated in the Alliance relative to Alliance-sponsored training courses.

However, testing alone does not provide the kind of exposure to the concepts of HACCP that is necessary to result in company understanding and commitment. The function of training is to prepare industry to meet the requirements of the regulations, not to test competency. The true test will be whether processors are able to implement their HACCP systems. Processors will be judged as plans are reviewed, and plant operations are evaluated, during inspections.

97. A few comments recommended mandatory retraining or continuing education. The comments stated that as new information about the science of fish and fishery products hazards and the technology of their control becomes available, there will need to be some method for introducing this information to previously trained individuals. One comment, on the other hand, urged that training be limited to a single event and not be subject to periodic renewal.

The primary purpose of the training is to teach the fundamentals of HACCP. These are unlikely to change over time. A comprehensive discussion of seafood hazards and controls is far too extensive for inclusion in a 3-day training session. The agency has concluded that information about the technology that is available to control hazards should be made available to the industry through the Guide, the Alliance Compendium of Established Processes, and other modes of technical assistance. FDA supports the idea of continuing education and will encourage it, but the agency is not prepared to mandate it in these final regulations.

98. A comment suggested that the regulations mandate remedial or enhanced training for a first time violator whose infractions have resulted from a misunderstanding of HACCP principles.

Whenever an infraction occurs, the nature of the remedy that is warranted depends on factors such as the public health significance of the infraction. The agency has administrative warnings and, when necessary, a range of regulatory actions available to it. (See the ''Compliance'' section of this preamble for a more thorough discussion of compliance philosophy under HACCP and available remedies.) Ultimately, however, it will be the processor who will be responsible for correcting the deficiencies in its HACCP system. Part of that responsibility will be determining the most appropriate method of resolving any failure to fully understand HACCP principles, whether through remedial training, hiring a consultant, or taking some other step. So long as an appropriate outcome can be obtained, FDA would prefer not to mandate any particular method of remediation in these regulations. Processors certainly may wish to consider additional education as an option, however.

7. Gradations of Training

99. Several comments addressed whether the HACCP training requirement could be satisfied by different gradations of training, depending on the complexity or size of the operation or on the degree of risks posed by the product being produced. The majority of these comments supported the concept of variable levels of HACCP training. Most did not provide the basis of their support. Those that did suggested that small or large scale processing of low-risk products would not likely require any special training, and that small scale processing of even high-risk products would allow for individual examination of every fish, an option that is not possible in large scale processing. One comment further suggested the use of variances to exclude certain industry members from the training requirement, rather than providing a blanket exemption for a segment of the industry.

A minority of the comments on this subject opposed any variations in the level of training. Several of these comments stated that the necessity for HACCP education and training does not vary based on the size of a company, and that a standard training curriculum should be developed for all companies, regardless of their size. Some of these comments stated that smaller processing operations may be inherently less safe, and that, cumulatively, they represent a large amount of the seafood making its way to the consumer. One comment stated that smaller processing operations may actually have a greater need for employee training, compared to some larger processing operations that may already have trained staff.

The agency agrees with the comments that suggested that the need for HACCP training does not vary solely by the size of the processor. An understanding of the principles of HACCP is essential for the successful implementation of a HACCP program, regardless of establishment size. The agency agrees with the assertion that, in many cases, the training needs of small businesses may, in fact, be greater than those of large firms, because they frequently lack the trained quality control and research and development staffs that are common in large firms. Moreover, small businesses comprise a significant portion of certain high-risk segments of the fish and fishery products industry, such as processors of molluscan shellfish and cooked, ready-to-eat products. Training will be critical to ensure the success of HACCP in these segments.

Although the agency expects that the complexity of HACCP plans will vary with the number and type of hazards associated with a processing operation, an understanding of the basic principles of HACCP, and how to apply those principles to the processor's operations, will remain essential. The curriculum under development by the Alliance is designed to provide a very basic grounding in these matters. As stated earlier, the Alliance has acknowledged a need to tailor part of the course so that it can be directed toward specific industry segments. This approach may be the best way to provide flexibility in the program, so that training can match the degree of complexity and risk that is encountered by the processor. FDA will continue to encourage the development of industry-specific training features.

The agency is not persuaded that the ability of a processor to individually examine all fish because of the small scale of operations will reduce the processor's need to understand the hazards associated with seafood and the specifics of a systematic approach for controlling them. FDA has long taken the position that observing each fish on an assembly line is an inappropriate way to ensure seafood safety (Ref. 208, p. 4146). While matters relating to the quality of the fish can be observed in this manner, safety matters often cannot.

8. Duties of the Trained Individual

100. Several comments suggested that a firm be permitted to hire a consultant, or an outside expert, who is not an employee of the firm, to perform the functions required of a trained individual. Two trade associations

argued that contracting for the development of a HACCP plan by a professional consultant could be more efficient and cost effective, especially for many small companies. Related comments pointed out that some of the proposed functions of the trained individual either did not require a person to be onsite continually (e.g., plan development) or required expertise that could not realistically be obtained in a 3-day course (e.g., making decisions about whether product that has been subject to a deviation is safe to release into commerce).

While the agency considers training employees to be preferable to hiring outside consultants in terms of fostering the appropriate corporate culture and commitment to HACCP, FDA recognizes the importance of ensuring the flexibility that firms, especially small businesses, may need to comply with the regulations in a cost-effective manner. The agency also accepts that for some processors, the expertise that may be needed from time to time could best be provided by an expert consultant. Consequently, the agency is modifying § 123.10 to read as follows: ''* * * the following functions shall be performed by an individual who has successfully completed a course of instruction * * *.'' The requirement that processors employ a trained individual has been eliminated. Moreover, FDA has modified § 123.10(c) to state, ''The trained individual need not be an employee of the processor.''

101. A number of comments asked whether the regulations would require a separate trained individual for each processing location of each company or just one per company.

FDA intends that the functions enumerated in § 123.10 be performed by a trained individual. The number of employees a processor must train, or the consultants that must be hired, in order to ensure that trained individuals perform these functions is left to the judgment of the processor. For some firms, one individual will be sufficient. Others will need to secure the services of more than one such individual, either as employees or as consultants. Whether these individuals are located at each facility, at a corporate headquarters, at a consulting firm, or at some combination of these arrangements is to be determined by each individual processor.

102. A few comments were concerned about the logistics of the routine functions that the agency proposed must be performed by someone with HACCP training (i.e., record review and deviation handling). Specifically, they argued that the proposed requirements would actually require each firm to have more than one trained individual because of work weeks that routinely exceed 40 hours, vacations, illnesses, and employee turnover. The consequence, the comments suggested, would drive up the cost of training.

FDA acknowledges that, for certain situations, these comments may be correct. However, the agency has made three changes in the final regulations to minimize this possibility. First, as stated above, a processor may hire trained consultants on an as-needed basis. Second, as discussed in the ''Verification'' section of the preamble, the regulations do not include the proposed requirement that a trained individual review monitoring records before the product to which the records relate is shipped. These final regulations require only a weekly review. As a result, the need to have a trained individual onsite every day has become substantially reduced. Third, as described below, FDA has decided not to require that the trained individual evaluate CL deviations and corrective actions. This modification reduces still further the need to have a trained individual onsite at all times. In addition, as described previously, the agency is allowing processors to employ individuals whose training has been obtained through on-the-job experience. Thus, for example, a processor that needs the services of two trained individuals could satisfy the requirements of these regulations by employing an individual who has been trained in an adequate course and a second individual who has apprenticed sufficiently with the first individual to have mastered the subject.

As a related matter, the provision in the final regulations that provides for the development of corrective action plans (see the ''Corrective Actions'' section of this preamble) could eliminate the need to bring an expert onto the scene in many instances in which corrective action is necessary. The processor may be able to follow the corrective action plan without having to rely on an expert or trained individual. This procedure could permit further savings.

103. Some comments suggested that there should be different categories of trained individuals, with different responsibilities. These comments, from individuals, processors, and trade associations, asserted that a firm should have one HACCP trained person capable of conducting or overseeing the routine operation of the HACCP program, but that this individual should not necessarily be responsible for designing a firm's HACCP plan or making complex scientific evaluations.

Another comment suggested that it was unrealistic to expect that a training program would provide the level of expertise necessary for a person to make a determination on whether a deviation may have rendered a product injurious to health or otherwise adulterated.

FDA generally agrees with these comments. It was never the agency's intent to limit the processor's use of experts to employees whose training included the course prescribed by these regulations, especially in the areas of HACCP plan development and the evaluation of CL deviations and corrective actions (i.e., making evaluations about whether product that has been subject to a deviation is safe to ship). While FDA is convinced that a short course in HACCP principles is important to the success of the overall program, the agency also recognizes that such a course has its limitations.

FDA has deleted the proposed requirement that the HACCP-trained individual be required to evaluate CL deviations and corrective actions to allow for the use of experts in other appropriate scientific disciplines that have not been trained in accordance with these regulations. For example, the agency does not expect that a processor will be able to determine the public health consequences of every possible deviation without the assistance of experts. The kind of expertise necessary would likely involve disciplines other than HACCP. Moreover, the agency agrees that it is unreasonable to expect that successful completion of a 3-day HACCP course alone would qualify an individual to make determinations about the safety of products involved in a CL failure. HACCP training in such a situation could only reasonably be expected to help ensure that appropriate corrective action measures are taken and recorded from a HACCP perspective. Consistent with this change, FDA has modified § 123.7(c)(2) to state that a determination of acceptability for distribution into commerce of products that may have been affected by a deviation must be made by individuals with the expertise to make such a determination, and that such individuals need not be those who meet the requirements of § 123.10.

Nonetheless, FDA expects that, at a minimum, an individual trained in accordance with these regulations will perform the verification function of reviewing records of corrective actions to ensure that they are complete, and that an appropriate corrective action was taken (i.e., one that was predetermined in the HACCP plan, or

one that was determined by a qualified expert to be sufficient to render the product safe). Section 123.10(c) requires that the trained individual perform certain record reviews associated with the verification principle of HACCP, including reviews of corrective action records (see § 123.8(a)(3)(ii)).

FDA has modified § 123.10 from the proposal to clarify and to conform this section to other features of the regulations. A summary of these modifications follows.

FDA has revised § 123.10(a) to clarify that when a trained individual develops an HACCP plan for a processor, this effort may involve adapting a model or generic-type plan for use by that processor. FDA received a significant number of comments on the pros and cons of model or generic-type HACCP plans. This subject is addressed in various places in the preamble, most notably in the section entitled ''Other Issues.'' In summary, the development of model plans can be of great benefit to the industry, especially small businesses, so long as the model plans are tailored by processors to meet their individual situations and are not simply copied verbatim. The agency is convinced that, in most cases, generic or model plans will need to be modified to some extent to fully accommodate the specifics of the processor's operations.

Section 123.10(b) provides, in part, that the trained individual is responsible for reassessing and modifying the HACCP plan in accordance with corrective action procedures specified in § 123.7(c)(5). This requirement is not new. It should be noted, however, that, unlike the proposal, the final rule requires the trained individual to perform these functions only when the processor does not have a predetermined corrective action plan that addresses the specific deviation. As explained in the ''Corrective Action'' section of this preamble, a review and reassessment of the plan should not ordinarily be necessary when a corrective action was anticipated, as reflected by the existence of a predetermined corrective action plan.

Section 123.10(b) also requires that a trained individual perform the annual reassessment of the processor's HACCP plan as required by § 123.8(a)(1). A new feature of the regulations, this requirement parallels the mandate that each processor engage in verification activities (see § 123.8(a)). It is a logical outgrowth of the principle, central to both the proposal and this final rule, that plan development be performed by individuals who possess the knowledge and skills that are obtained through training in HACCP.

Section 123.10(c) requires that a trained individual perform certain record reviews as enumerated in § 123.8(a)(3). This requirement is not new except for the review of records of end-product testing, if any. End-product testing was not addressed in the proposal but, as explained in the ''Verification'' section of the preamble, has been added as an optional verification activity. The review of end-product testing records by a trained individual is a logical outgrowth of the principle that was reflected in the proposal in § 123.8(b) that a trained individual review all HACCP records for completeness and consistency with written HACCP procedures.

Finally, it should be noted that the requirement in the proposed regulations that trained individuals perform certain functions for importers has been dropped entirely. This deletion is consistent with the changes that FDA is making in the provisions that applied to importers in this final rule. These revisions are described elsewhere in this preamble. In summary, importers are given alternatives to having HACCP plans and are not required to take the kinds of actions for which a trained individual has been determined to be essential.

K. Sanitation

1. Background

FDA proposed to require that processors conduct sanitation inspections at specified frequencies to ensure that each of up to 18 specified sanitation conditions are maintained in the processing facility where they are relevant to the type of processing being performed. The agency also proposed to require that processors maintain sanitation control records, and that they take and document corrective actions when the specified conditions were not met. In addition, FDA encouraged, but did not propose to require, processors to make use of written SSOP's to ensure that the necessary sanitation measures were implemented.

FDA tentatively concluded that sanitation controls are necessary in these regulations because: (1) Sanitation practices directly affect the microbiological safety of seafood products that are not further cooked by the consumer, such as cooked, ready-to-eat products, smoked products, raw molluscan shellfish, and other fish that are consumed raw; (2) sanitation practices are relevant to the microbiological safety of seafood products even where these products are to be cooked by the consumer; (3) sanitation practices directly affect the chemical and physical safety of seafood products; (4) nearly half the consumer complaints relating to seafood that FDA receives in a typical year are related to plant or food hygiene; and (5) inspections conducted by FDA and NMFS demonstrate that a significant portion of seafood processors operate under poor sanitation conditions.

The MSSP, conducted by NMFS, concluded that sanitation controls could be included in HACCP plans without overloading HACCP. Moreover, the FDA/NMFS HACCP-based seafood pilot program included sanitation CCP's. Nonetheless, FDA tentatively concluded that monitoring and recordkeeping for the 18 specific sanitation conditions specified in the proposal should be permitted to occur outside of a processor's HACCP plan so as not to overload it. Because these sanitation controls relate to an entire facility, not just to a limited number of CCP's, FDA felt that they would not all fit well within an HACCP plan.

FDA took this prescriptive approach to sanitation to assist processors so that they would not have to figure out how, or whether, to include sanitation in their HACCP plans and to help them resolve the sanitation problems that the seafood industry has chronically experienced. By requiring a specific, daily sanitation regime that incorporates HACCP-type features (i.e., monitoring and recordkeeping) to help the processor track sanitation in its plant, FDA hoped to foster a culture of, and commitment to, good sanitation practices that has been lacking in a significant portion of the industry.

2. Should the Regulations Deal With Sanitation?

FDA requested comment on whether sanitation control measures should be addressed by processors in accordance with the proposed approach, or whether the regulations should require that processors address sanitation in their HACCP plans.

More than 250 comments addressed various aspects of the proposed sanitation requirements, more comments than addressed any other aspect of the proposed regulations. Approximately 100 of these comments addressed FDA's questions about the approach to sanitation control in these regulations. The remaining comments focused on specific sanitation provisions.

104. Approximately 10 percent of those that responded to the requests supported the proposed approach. These comments were from processors,

consumer advocacy groups, State, Federal, and foreign government agencies, and a trade association. Approximately five percent of the comments, from processors, trade associations, and State government agencies, objected to the inclusion of any explicit sanitation controls in these regulations. It is not clear, however, whether the latter comments were objecting to sanitation controls as part of HACCP where appropriate for safety or to any sanitation approach beyond HACCP. The remaining approximately 85 percent of the comments, principally from processors, trade associations, and State and Federal government agencies, generally acknowledged the need for these regulations to address sanitation in seafood processing plants but objected to one or more of the specifics of the proposal.

Those that supported the proposed approach argued that sanitation controls are a critical component of the regulations because: (1) Addressing the insanitary practices in the seafood processing industry is essential to improved consumer confidence; (2) effective sanitation controls are a prerequisite to the proper functioning of a HACCP system; and (3) sanitation controls are critical to the management of microbiological hazards in both products that will not be cooked by the consumer and those that will be cooked, the latter because of the potential for cross-contamination in the kitchen. The comments suggested that a prescriptive approach to sanitation is warranted because the FDA and NMFS inspection results cited in the preamble to the proposal documented the failure of a significant percentage of the industry to control key sanitation conditions and practices. Moreover, these comments continued, the enumeration of specific controls relieves the industry of the burden of identifying the most significant areas of concern.

Several comments stated that sanitation requirements for seafood processors are necessary because guidelines do not have the force of regulation and therefore are more difficult to enforce. One comment stated that including sanitation requirements in these regulations would simplify compliance for seafood processors because the HACCP and sanitation requirements would be in one place. One comment stated that some processors would be more inclined to implement sanitation control measures if all processors were subject to the same mandatory requirements.

Many of the comments that objected to the manner in which FDA proposed to treat sanitation acknowledged that effective sanitation controls are essential to the proper functioning of a HACCP system. As with comments that supported the proposed approach, a few of these comments identified sanitation as a prerequisite to HACCP.

The comments that objected to the inclusion of any sanitation requirements in these regulations provided reasons that the agency believes are more relevant to the question of how these regulations should address sanitation than to whether they should address the issue. For this reason, the arguments presented in these comments are addressed later in this section.

FDA accepts the view expressed by the overwhelming majority of comments (i.e., those that advocated the proposed approach and those that advocated other sanitation control mechanisms) that sanitation is relevant to the goals of these regulations and should be addressed in them. The primary source of pathogenic microorganisms for most fish (i.e., wild-caught fish) is the processing plant environment (Ref. 3, p. 267). The control of sanitation in the plant is the most effective way to minimize pathogens, and, for products that are not given a final heat treatment after packaging, it is the only way to minimize them at that stage in the chain of distribution (Refs. 3, p. 10; 7, p. 27; 204; and 205). This situation is nearly the reverse of that for red meat and poultry, where pathogens are likely to have originated from the raw materials before they enter the plant (Refs. 36, p. 197; 209; and 210, p. 1).

A significant body of opinion holds, moreover, that good sanitation is a necessary foundation for HACCP. This view was articulated in comments to this rulemaking and in the proposed rule to establish HACCP and other requirements for the beef and poultry industries issued by USDA (Ref. 211). USDA proposed both SOPs for sanitation as a prerequisite to a HACCP plan and sanitation as part of HACCP where critical for safety (Ref. 211, p. 6789).

FDA concludes, therefore, that these regulations cannot fully address all matters relevant to safety, or significantly contribute to the restoration of consumer confidence in seafood without providing for major improvements in sanitation. Therefore, these regulations address sanitation.

3. Why Isn't Part 110 (21 CFR Part 110) Adequate To Deal With Sanitation Concerns?

105. Some comments asserted that it would be adequate to rely on the existing CGMP's in part 110, which provide guidance of general applicability to all foods. A variation on that concern was the view that the sanitation standards in part 110 need not be codified in these regulations because they are adequately expressed in that part. The NACMCF pointed out that the CGMP's have proven adequate for a wide variety of processed foods under FDA's jurisdiction. Some comments stated that part 110 should be made mandatory for seafood and fully enforced.

Good sanitation is already mandatory for all foods. Section 402(a)(4) of the act deems food to be adulterated if processed under insanitary conditions. The CGMP's in part 110 articulate the kinds of conditions and practices that need to be followed in order to avoid producing an adulterated product under section 402(a)(4) of the act.

Nevertheless, while FDA has been enforcing the sanitation standards contained in part 110 for many years, as indicated earlier, it has not succeeded in developing a culture throughout the seafood industry in which processors assume an operative role in controlling sanitation in their plants. The statistics relating to the incidence of insanitation cited in the preamble to the proposed regulations (Ref. 208 at 4161–4162) clearly demonstrate that such a culture is not adequately in place. The following observation about culture in the preamble to USDA's proposed HACCP rules for beef and poultry is applicable here as well:

> * * * Identification of sanitation requirements has been viewed by some establishment owners and personnel as the inspector's responsibility. Such establishments often fail to take the initiative to find and remedy insanitary conditions, relying instead on the inspector to find deficiencies. (Ref. 211, p. 6788)

Moreover, FDA points out that while the CGMP's state that sanitation controls should occur as frequently as necessary, they are silent with regard to monitoring by the processor to ensure for itself that sanitation controls are being followed.

For these reasons, FDA concludes that part 110 alone has not proven to be adequate for the seafood industry. In order to ensure that firms take full responsibility for sanitation in their plants, which is strongly related to the production of safe and wholesome seafood, FDA has concluded that it is necessary to include sanitation requirements in these regulations.

4. Why Isn't the Proposed Approach Appropriate?

106. Many comments that agreed that sanitation should be addressed in the regulations, as well as some that opposed addressing it, objected that the

proposal was too prescriptive. These comments asserted that: (1) The proposed 18 sanitation controls are overly prescriptive and inflexible and are not appropriate for all processors; (2) the codification of prescriptive sanitation requirements as regulations limits the ability of processors to keep pace with advances in science and technology; (3) the proposed sanitation controls have the effect of establishing eighteen CCP's, which are not always appropriate; and (4) the proposed sanitation provisions duplicate or contradict existing State or NSSP requirements. FDA will respond to these criticisms.

Many comments that argued that the 18 specific sanitation controls that FDA proposed were too prescriptive provided examples of how this approach could deny processors the flexibility necessary to develop and implement sanitation programs that are effective for the specific conditions in which they are to be used. Some of these examples are as follows:

(1) A few comments challenged the proposed ''easily cleanable'' standard for equipment, suggesting that in some applications (e.g., at sea processing and old equipment) this standard may not be attainable and may not be necessary as long as the equipment is, in fact, cleaned;

(2) A large number of comments challenged the proposed 4-hour equipment cleaning frequency, suggesting that it is unwarranted in some situations (e.g., refrigerated processing facilities) because it is inconsistent with actual microbiological growth rates. It is unduly burdensome in other situations (e.g., surimi processing facilities), according to the comments, because it would limit shifts to 4 hours, would interrupt production, and would require hours of equipment breakdown time;

(3) A few comments challenged the proposed ''impermeable'' standard for gloves and outer garments that contact food or food contact surfaces, suggesting that in some instances it was impractical (e.g., filleting fish);

(4) A significant number of comments challenged the proposed 4-hour hand sanitizer strength test frequency, suggesting that replacement of dips rather than checking concentration may be appropriate, as may be the use of automated hand washing and sanitizing systems; and,

(5) A number of comments challenged the proposed requirement that hand washing and sanitizing stations be located in processing areas, suggesting that they need only be easily accessible.

These comments have general merit and have persuaded the agency that a less prescriptive approach is appropriate to ensure that the regulations do not impose impractical, unduly burdensome, or excessively rigid requirements.

107. Another concern with FDA's approach was that codifying specific sanitation control procedures would not enable processors to keep their sanitation programs updated with advances in science and technology. As an example, the NACMCF comment cited recent industry experience with other foods that has shown that the proposed requirement of midshift cleaning and sanitizing in packaging rooms for ready-to-eat foods, may with many current sanitation practices actually be counterproductive to the control of *Listeria monocytogenes*. The NACMCF advised that codification of a midshift cleaning requirement would have prevented these industries from modifying their cleaning procedures to adjust to the new information.

FDA agrees that sanitation requirements should be sufficiently flexible to permit the incorporation of new information and better procedures.

108. A number of the comments, including more than half of those that opposed any new form of sanitation controls, argued that the sanitation control approach proposed by FDA would effectively establish eighteen mandatory sanitation CCP's that may not always be appropriate.

These comments may have been the result of a misunderstanding of the relationship between processor HACCP plans and the proposed sanitation controls. While the proposed controls involved monitoring and recordkeeping, they were not proposed as part of a processor's HACCP system. FDA did not intend to designate them as CCP's. FDA believes that the provisions of these final rules make clear that the necessary sanitary controls need not be considered to be CCP's.

109. A large number of the comments that objected to the manner in which FDA proposed to handle sanitation argued that the proposed sanitation provisions are redundant with State and local regulations and, with respect to molluscan shellfish, with the NSSP.

FDA acknowledges that the NSSP and most State seafood control programs include provisions, much like FDA's CGMP's, that are designed to control processing plant sanitation. These other provisions, like the CGMP's, serve as baseline standards for sanitation. However, the rates of noncompliance with existing CGMP standards, as detailed in the preamble to the proposed regulations (Ref. 208 at 4161–4162), demonstrate a need for a system in which processors are responsible for not only meeting these baseline standards but also routinely auditing their facilities and operations to ensure that they are meeting them. In this way, the sanitation requirements of these regulations build upon existing sanitation requirements, at the Federal, State, and local levels.

The more generalized nature of these final regulations with respect to sanitation should mitigate the concerns of the comments that complained about the conflict between, and duplication with, existing sanitation standards.

As discussed elsewhere in this preamble, FDA encourages adoption of these regulations by State and local regulatory agencies. FDA is convinced that, in many cases, the regulations can be quite easily overlaid on existing State, local, and NSSP requirements.

5. What Is the Appropriate Approach to Sanitation?

Based on its review of the comments, FDA has been convinced that a modification of its approach to sanitation is appropriate. FDA concludes that its approach in the proposal was too inflexible and could have made it more difficult in certain circumstances to incorporate new technologies and information.

The comments argued for one or more of several approaches that they identified as being more appropriate than FDA's proposed approach: (1) Requiring that each processor develop and follow a SSOP that is specifically tailored to a processing operation; (2) including sanitation controls in the HACCP plan where they are critical to product safety; and (3) retaining the general approach of the proposed regulations but somehow reducing the number of specific requirements. Approximately 85 percent of those that opposed the way that sanitation was treated in the proposal advocated one or a combination of the first two of the approaches, with the recommendations evenly split between the two. The small number of comments that objected to including any specific sanitation requirements in the regulations may also have been arguing that sanitation should not be part of HACCP but should be controlled solely through CGMP's.

a. *Inclusion of sanitation controls in HACCP plans.*

110. There was strong support in the comments for the inclusion of sanitation controls in HACCP plans, particularly where the controls are necessary to protect the safety of the product. The comments stated that a processor's

hazard analysis may reveal the need to control certain aspects of sanitation in the HACCP plan, especially to control hazards involving microbiological contamination. One comment noted that sanitation controls are likely to be components of the HACCP plans of molluscan shellfish processors.

Given the strong support that sanitation controls should be included in HACCP plans where they are critical to safety, FDA has no objection to processors including sanitation controls in their HACCP plans. Consequently, these final regulations state in § 123.6(f) and § 123.11(d) that sanitation controls for safety may be included in HACCP plans.

The agency has concerns, however, as to whether including sanitation controls in a HACCP plan will be adequate to ensure that appropriate conditions exist in a plant. The conditions that would be addressed in the HACCP plan will likely be those that are most critically and directly related to product safety. Other situations that are relevant to safety, but in a less direct way, would probably not be controlled through HACCP. For example, following the NACMCF recommendations for hazard analysis and HACCP plan development would likely result in the identification of a number of equipment and hand washing controls at CCP's in the HACCP plan for the processing of a cooked, ready-to-eat product to minimize the risk of microbiological contamination but not in the identification of these same controls in the HACCP plan for a raw finished product that would normally be cooked before consumption. In the latter case, however, attention to sanitation would still be important in the processing plant to prevent contamination of the product, given that the ultimate consumer cook may be inadequate, or that the product, once contaminated, could be a source of cross-contamination to other foods.

Likewise, the potential for contamination of either a cooked, ready-to-eat product or a raw product as a result of rodent activity in a processing plant, or as a result of improper use of pesticides on or near the product, would not likely be identified in a HACCP plan. All of these conditions are relevant to the safety of the product and should be addressed by processors. It is not clear whether HACCP can fully succeed in plants that are not in control of general sanitation practices. The inclusion of sanitation in HACCP—as desirable as it may be—will not fully resolve this problem.

b. *SSOP.*

111. As indicated above, a significant number of comments that addressed alternatives to the prescriptive approach to sanitation in the proposal preferred a SSOP, either alone or in combination with critical sanitation controls in HACCP. Significantly, the NACMCF was among those that made this suggestion. NMFS' comment stated that, in its experience, the development of SSOP's by processors in its voluntary program has been associated with marked improvement in sanitation. Many comments stated that much of the seafood processing industry already has SSOP's, and that those that do not should develop them.

FDA agrees that the development by processors of an SSOP would be a beneficial step. FDA therefore is recommending in § 123.11(a) that:

> Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced.

An SSOP places the primary burden for identifying relevant controls on the food processor. To meet this burden, it will be necessary for the processor to think through each operation and identify where, and how frequently, appropriate sanitation measures are necessary. The process of doing so will foster the type of culture that FDA is trying to promote, in which processors assume an operative role in controlling sanitation in their plants.

FDA is adopting § 123.11 pursuant to sections 402(a)(4) and 701(a) of the act to ensure that seafood is not produced under insanitary conditions whereby it may be rendered injurious to health. It grows directly out of proposed § 123.10, but, as stated above, it reflects the agency's efforts to make the sanitation requirements more flexible.

FDA has not elected to make the development of an SSOP mandatory because it recognizes that some processors may be able to achieve satisfactory sanitation conditions and practices without having to commit their sanitation control procedures to writing. The agency remains convinced however, that such satisfactory conditions are unlikely to be achieved without periodic monitoring of the operations. For this reason the agency has retained at § 123.11(b) the mandatory sanitation monitoring requirements proposed at § 123.10(c). Sanitation monitoring will be further discussed in the next section of this preamble.

Where a processor elects to develop an SSOP it should specify how it will meet those sanitation conditions and practices that are to be monitored in accordance with § 123.11(b). These conditions and practices will also be discussed in the next section.

Both § 123.11(d) and § 123.6(f) provide that sanitation controls that are monitored in accordance with § 123.11(b) need not be included in the HACCP plan and vice versa. The purpose of these provisions is to allow processors to incorporate those sanitation controls into their HACCP plans that they believe are appropriately addressed through HACCP, without having to duplicate those controls in a separate sanitation program.

6. Monitoring and Corrective Actions

The regulations no longer contain specific monitoring frequencies to ensure that proper sanitation conditions are being met, as was proposed at § 123.10(c). In keeping with the agency's decision to reduce the prescriptive nature of the sanitation requirements, § 123.11(b) now requires that each processor monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with certain key sanitation conditions and practices as specified in part 110.

112. The agency arrived at this approach in response to the comments. As part of the agency's efforts to achieve flexibility, it examined the 18 sanitation controls that it proposed at § 123.10(a) in light of the comments that argued that they were overly prescriptive. FDA proposed the 18 sanitation controls to ensure that, where relevant to the processing operation, important areas of concern were addressed in each plant. The preamble addressed at some length why each of them was significant and relevant to safety. Moreover, although considerable comment was received that challenged the manner in which a particular processor should address these sanitation conditions and the situations in which they should be considered applicable, only two comments challenged the significance of these conditions or the need for them to be controlled when they are determined to be germane, and neither comment provided a basis for doubting the significance of these controls.

FDA concludes that, where relevant to a processor's operation, the processor should monitor sanitation conditions and practices relating to the general subject areas reflected by the 18 specific sanitation controls because they are important for ensuring the safety of the product. As in the proposal, each processor will be responsible for determining which of the subject areas are relevant to its plant and process. However, unlike the proposal, the

processor will be free to tailor the sanitation controls to the circumstances of its operation, as long as it does so in a manner that ensures the effectiveness of those controls. The regulations do not specify the manner in which control must be achieved. FDA will provide guidance on how to ensure appropriate sanitation control in the Guide. FDA is deferring consideration of the comments that it received on the specific sanitation control measures that it described in the proposal until it prepares the Guide.

In order to ensure that processors monitor the general subject areas reflected by the 18 specific sanitation controls listed in the proposal, FDA has concluded that it is appropriate to list in the regulations the sanitation controls that should be considered. This list will ensure that the most significant sanitation controls are considered by the processor in formulating the measures that it will institute in its plant.

The controls that FDA is listing in § 123.11(b) no longer contain sanitation standards that are beyond part 110 or repeat specific standards that are contained in that part. Instead, § 123.11(b) now states that the processor shall ensure that actions are taken to ensure that those sanitary conditions that are contained in part 110 and that are relevant to the plant are maintained in eight general areas:

(1) The safety of the water that comes into contact with food or food contact surfaces or is used in the manufacture of ice (§ 123.11(b)(1)). This control derives from proposed § 123.10 (a)(1) and (a)(2) relating to water quality and treatment and to cross connections between potable and nonpotable water systems.

Water is used in virtually all seafood processing facilities for washing product, equipment, and employees' hands, for transporting fish in flumes, and as an ingredient. Contaminated water can serve as a vehicle for contamination of the product, both directly and indirectly (Refs. 63; 64; 65, p. 49; 66; 67; and 68, pp. 1 and 2). Cross connections, which include situations that allow for back siphonage into a potable system from a nonpotable system under negative pressure conditions, can result in the chemical or microbiological contamination of the potable water system (Refs. 64; 65, pp. 50 and 51; 68; 71; and 72).

This matter was one of the two, as indicated above, about which FDA received a comment that challenged the need for a sanitation control. A comment suggested that the safety of the water supply is within the jurisdiction of local health authorities, and that a processor should not have to deal with that issue.

FDA acknowledges that many State and local jurisdictions exercise control over both public and private water supplies. In the case of private wells, they often permit and inspect the construction of the well and collect periodic water samples for microbiological and chemical attributes. Where such is the case, it may be reasonable for the processor to rely upon these measures. However, in the absence of appropriate controls by a public authority, FDA has concluded that the processor must exercise whatever control is necessary to ensure that the water supply is safe. To do otherwise would be to subject the product to an unacceptable safety risk from the contaminants that may be introduced by the water.

(2) The condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments (§ 123.11(b)(2)). This control derives from proposed § 123.10 (a)(3) through (a)(5) relating to the design, workmanship, materials, and maintenance of food contact surfaces; the cleaning and sanitizing of these surfaces, including the frequency of cleaning and sanitizing; the impermeability of gloves and outer garments that contact food; and the maintenance of gloves and outer garments.

Utensils, equipment, aprons, gloves, outer garments, and other food contact surfaces can be vehicles for microbial contamination of both the raw and finished products. Food contact surfaces that contain breaks, pits, cuts, or grooves, or that are porous or corroded, may harbor pathogenic microorganisms that can migrate to the product and contaminate it. These kinds of surfaces are difficult to clean (Refs. 65, pp. 20, and 36–48; 72, pp. 166–167; 73; and 83). Where food contact surfaces are constructed of toxic materials, the product may be directly contaminated (Ref. 74). Inadequately cleaned food contact surfaces can serve as a reservoir for pathogenic microorganisms, especially if biofilms are allowed to form, in which microorganisms can be entrapped and shielded from the action of cleaning and sanitizing compounds.

(3) The prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product (§ 123.11(b)(3)). This control derives from proposed § 123.10 (a)(6), (a)(7), (a)(13), and (a)(18), relating to employee practices to prevent contamination, to physical separation of raw and cooked product, and to plant design to prevent contamination.

Employees and food contact surfaces can serve as vectors in the transmission of pathogenic microorganisms to the food. These microorganisms can be introduced to the product from outside areas, rest rooms, contaminated raw materials, waste or waste receptacles, floors, and other insanitary objects. In the processing of cooked products, the raw material may also serve as a reservoir of pathogenic microorganisms. Employees or equipment that touch the raw material can transmit these microorganisms to the cooked product (Refs. 7, 63, 64, 73, 74, 84, and 85). Finally, proper construction of the processing plant is essential if other sanitary measures are to be successful. For example, incompatible operations, such as handling of raw materials and handling of cooked product, should be isolated (Refs. 71, 74, 87, and 88).

(4) The maintenance of hand washing, hand sanitizing, and toilet facilities (§ 123.11(b)(4)). This control derives from proposed § 123.10 (a)(8) and (a)(16), relating to the location and maintenance of hand washing and sanitizing facilities, and toilet facilities.

Employee's hands can serve as a vector for the transmission of pathogenic microorganisms to the food. Hand washing and sanitizing, when performed using suitable preparations are effective means of preventing such transmission. Toilet facilities eliminate from the processing environment pathogenic microorganisms shed in fecal material (Refs. 63, 64, 73, 74, 84, and 85).

(5) The protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants (§ 123.11(b)(5)). This control derives from proposed § 123.10(a)(9), (a)(11), and (a)(12), relating to the protection of food from various microbiological, chemical, and physical contaminants.

The use of toxic compounds (e.g., pesticides, cleaning and sanitizing agents, and lubricants) is frequently necessary in the processing environment. Food and food packaging materials should be protected or removed from areas where pesticides are used, and caustic cleaning compounds should be thoroughly removed from food contact surfaces before processing begins (Ref. 74). Condensate which forms on an insanitary surface and then falls on the

product may carry with it pathogenic microorganisms (Ref. 65, pp. 24–25).

This measure is the second about which FDA received a comment that challenged the value of having a sanitation control. A comment suggested that preventing the formation of condensate on ceilings above processing is, in some situations, physically impossible. The comment did not suggest that condensate is irrelevant to safety.

FDA reasserts that condensate is relevant but acknowledges that there are instances in which it may be impractical for it to be fully eliminated. In these instances, after taking all reasonable measures to minimize the development of condensate, the processor will need to take steps to protect the product from the dripping condensate or to ensure that the surface from which it is dripping is sanitary. The development of a written SSOP processor should tailor its sanitation controls to its particular situation in order to accomplish this objective.

(6) The proper labeling, storage, and use of toxic compounds (§ 123.11(b)(6)). This control derives from proposed § 123.10(a)(10), relating to the overall handling of toxic compounds to protect against contamination of food. Improper use of toxic compounds is a frequent cause of product adulteration throughout the food industry. Proper labeling, storage, and use of the compounds is necessary to minimize the risk of occurrence of such incidents (Ref. 74).

(7) The control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces (§ 123.11(a)(7)). This control derives from proposed § 123.10(a)(15), relating to the exclusion of persons who appear to have an illness, wound, or other affliction that could be a source of microbial contamination.

Employees can serve as a reservoir of diseases, such as salmonellosis, shigellosis, and hepatitis, that can be transmitted to consumers by foods. Additionally, open sores, boils, or infected wounds present the potential for contamination of the food with such pathogenic microorganisms as *Staphylococcus aureus* (Refs. 22, 74, and 84).

(8) Exclusion of pests from the food plant (§ 123.11(b)(8)). This control derives from the proposed requirements at § 123.10(a)(17). Pests, such as rodents, birds, and insects carry a variety of human disease agents, which they can introduce to the processing environment (Refs. 63, 64, 73, and 84).

113. FDA proposed at § 123.10(a)(14) that, ''Refrigeration units that store raw materials, in-process, or finished fish or fishery products that are cooked, ready-to-eat, smoked, or made in whole or in part from scombroid toxin forming species shall be operated at a temperature of 40 °F (4.4 °C) or below.'' The purpose of the proposed requirement was to ensure that processors control the microbiological hazards associated with refrigerated storage for these particularly susceptible products. A significant number of comments argued the control of temperature in refrigerated storage is a processing hazard rather than a sanitation issue, and should be covered by a firm's HACCP plan.

FDA agrees with these comments and has not included a provision on refrigeration in the sanitation section of these regulations. A large number of comments were received relative to the appropriateness of a 40 °F (4.4 °C) limit. These comments are no longer relevant to these regulations but will be addressed in the redrafting of the Guide.

FDA has also incorporated the corrective action requirement relative to sanitation conditions proposed at § 123.10(d) in § 123.11(b). Section 123.11(b) the processor shall, correct in a timely manner those sanitation conditions and practices that are not met. The phrase ''in a timely manner'' did not appear in the language of proposed § 123.10(d). However, it was implicit that corrections should be made as quickly as possible so as not to subject subsequently processed product to conditions that could both jeopardize their safety and render them adulterated. FDA has added the phrase for clarity.

Note that the other corrective action requirements in these regulations, i.e., those in § 123.7, do not apply to sanitation controls that are exclusively addressed in § 123.11. The controls in § 123.7 apply to a processor's HACCP system only.

7. Records

114. FDA received approximately 20 comments that addressed the issue of sanitation records. Many others discussed recordkeeping in general but did not specifically mention records of sanitation controls. These latter comments have already been addressed in the ''Records'' section of this preamble.

Of those that commented specifically on sanitation records, approximately three-fifths, from processors and trade associations, objected to the proposed requirement that processors maintain records that demonstrate compliance with the appropriate sanitation standards. In fact, a number of comments listed this issue as a significant reason for their objection to the overall proposed approach to sanitation control. The comments suggested that sanitation recordkeeping is costly and has not been demonstrated to be effective. None of these comments provided any data in support of their statements. Some argued that, while they accepted the notion of records for CCP monitoring, they opposed records of sanitation monitoring.

The remaining comments that addressed the issue of sanitation records, from consumer advocacy groups, an individual, a Federal government agency, a trade association, and a seafood broker, supported the need for such records. These comments argued that sanitation records are essential to ensure that processors adhere to established sanitary standards, and that they need not be extensive.

FDA does not find the arguments against the requirement for sanitation control records to be compelling. The agency concludes that the burden will be minimal. Checklist type or simple notation records will suffice in most instances. Creating them should be incidental to monitoring. Monitoring to ensure that sanitation is under control is the responsibility of all processors.

Monitoring and recording of sanitation conditions is as much a key to the success in improving those conditions, and, hence, to increasing consumer confidence in the seafood processing industry, as is the development by a processor of an SSOP. As in the case of HACCP records, sanitation records require that processors engage in systematic monitoring of their own sanitation practices and conditions. It enables them to see trends. Moreover, participation in recordkeeping helps empower the work force and foster responsibility. It also allows the regulator to assess a processor's compliance over a period of time, not just at the time of an inspection.

FDA believes that the records bearing on the monitoring of relevant sanitation conditions and practices and FDA's access to such records are all essential if § 123.11 is to be an effective regulatory strategy. Therefore, FDA has concluded that the recordkeeping requirement proposed at § 123.10(b) will be retained. To reflect other modifications in this section, § 123.11(c) has been modified to read, ''Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b)

of this section. These records are subject to the requirements of § 123.9.''

Additionally, FDA has moved the requirement that sanitation corrections be documented from proposed § 123.10 (d) to § 123.11 (b).

Finally, FDA notes that § 123.11 does not contain any mention of importers. The lack of a mention of importers in this section reflects the position that the agency is taking in these regulations that, to the extent that importers are also processors, they would be subject to the sanitation requirements in this section. To the extent that they serve as importers only, the sanitation provisions are not relevant to their operations.

L. Imports

1. Background

The majority of seafood consumed in the United States is imported. FDA's surveillance system for imports largely consists of reviewing the customs entries for fish and fishery products being offered for entry into the United States, engaging in wharf examinations and sample collections for laboratory analysis, and placing products with a history of problems on automatic detention. As with domestic inspections, this method is basically a ''snapshot'' approach that places a significant burden on the government to uncover problems. It has failed to result in full compliance or consumer confidence in the safety of imported seafood. Consequently, the agency tentatively concluded that HACCP controls should apply to imported fish and fishery products as well as to domestic products. Among other things, FDA proposed that the definition of ''processor'' explicitly include those who process seafood in foreign countries.

In addition, FDA tentatively concluded that the importer should share some responsibility with the foreign processor for safety. More often than not, it is an U.S. importer, rather than the foreign processor, who actually offers imported fish and fishery products for entry into the United States. The preamble noted that, while many importers are conscientious about the safety of the products that they import, others have little understanding of the potential hazards associated with their products. Thus, the agency tentatively concluded that the existing system of import controls had not promoted a sense of responsibility in the import industry.

Therefore, in addition to proposing to require that foreign processors that export to the United States comply with part 123, FDA proposed that importers of fish and fishery products take steps to ensure that their shipments are obtained from such processors. Specifically, FDA proposed that importers: (1) Have and implement a HACCP plan that describes how the product will be processed while under their control; (2) maintain a copy of the foreign processor's HACCP plan; and (3) take affirmative steps to ensure that the imported fish or fishery product was produced in conformance with the foreign processor's HACCP plan and with the proposed sanitation requirements. The agency also proposed that importers need not take affirmative steps if the fish or fishery product was imported from a country with which FDA has a MOU documenting the equivalency of the foreign inspection system with the U.S. system.

2. Should Imports Be Subject to These Regulations?

115. Approximately 70 comments addressed various aspects of the proposed requirements for imports. Approximately half of the comments that addressed the import provisions argued that it is necessary to subject imported products to the same regulatory requirements as domestically processed products. These comments were submitted by processors, trade associations, State and foreign government agencies, professional associations, and individuals. Many of these comments argued that exempting foreign processors from the requirements of these regulations would put the domestic industry at an unfair economic disadvantage. Other comments stated that the import requirements would increase consumer confidence in seafood because they would ensure that imported fishery products have been produced under the same HACCP requirements and held to the same sanitation standards as domestically produced product. A few comments suggested that imported products are more likely to present safety hazards than domestically-produced products because of a lack of understanding of CGMP's on the part of foreign processors. One comment asserted that a number of countries, including Canada, the EU, Iceland, and Thailand are in varying stages of establishing HACCP programs for their own domestic seafood processors.

Most of the remaining comments (approximately one-half) did not comment on whether HACCP controls should be required for imported fish and fishery products but discussed aspects of the agency's proposed approach. These comments will be addressed later in this section.

FDA did not receive any comments that persuaded it that imports should be exempt from the requirements of these regulations. On the contrary, the comments reflect a nearly universal recognition that the safety of seafood cannot be adequately ensured if the majority of products (that is, imports) are not subject to the same controls as domestic products.

Therefore, the agency has not modified the regulations' basic approach for imports.

116. Only two comments objected to the concept that imported fish or fishery products should meet the same requirements as those for domestic products. One of these comments argued that FDA should be tolerant of a foreign processor that may not have the knowledge or time to develop a HACCP plan before its product is ready for export and urged the agency to develop a temporary waiver system to accommodate such firms.

FDA is convinced that a 2-year implementation period, as discussed in the ''Effective Date and Compliance'' section of this preamble, will provide sufficient time for processors, both within and outside the United States, to develop and implement HACCP plans and otherwise come into compliance with the provisions of these regulations. The comment provided no basis for treating foreign processors any differently than domestic processors in this regard.

117. Another comment suggested that raw material fish and fishery products imported for further processing in the United States should be exempt from the requirements of the regulations but provided no reason to support that position.

The exemption requested by the comment would make it difficult, if not impossible, to control environmental hazards that may be associated with these products. This preamble and the preamble to the proposed regulations fully discuss the conclusions of the NAS, which identified raw material hazards, such as microbiological contamination in molluscan shellfish and natural toxins in both shellfish and finfish, as among the most pressing problems that must be addressed to ensure seafood safety. For the most part, these hazards are best addressed at the time of harvest and by primary processors, through HACCP, at the time of receipt. In many cases, there is little opportunity for control beyond the latter point. Raw material fish and fishery products for further processing comprise a substantial portion of fish

and fishery products imported into the United States (Ref. 212, p. 49). Thus, to exempt foreign processing of such products from the requirements of these regulations would be to greatly diminish the scope and, therefore, the overall effectiveness of these regulations.

118. One comment that supported the need for equitable treatment of imported and domestically produced products urged the agency to provide the same opportunities for processors abroad to familiarize themselves with the requirements of these regulations as it does the domestic industry. The comment argued that just printing the regulations in the Federal Register would not fulfill that responsibility. The comment further suggested that FDA send copies of guidance materials to all known foreign seafood processors, preferably in their native language.

FDA acknowledges the difficulty in reaching foreign processors with information about the requirements of these regulations. However, mass mailings to, and multiple translations of, these regulations and the Guide for all foreign seafood processors that export to the United States would not be practicable for FDA.

The agency intends to reach foreign processors primarily by briefing foreign embassy staffs and by communicating with U.S. importers during public and trade association meetings. Based on experience in disseminating information about U.S. requirements to the import community, the agency expects that these two groups will provide the necessary information and guidance materials (in the appropriate languages) to the foreign processors that they represent. This same approach was used in disseminating information about the proposed regulations. In fact, FDA became aware of a Japanese translation of the proposal shortly after it issued.

In addition, FDA traditionally has provided training and technical assistance for foreign processors and government officials on a variety of food control topics, within the constraints of budget and manpower. These projects have principally been conducted in developing countries, often those in which the agency has become aware of a particular problem that threatens the safety of products offered for entry into the United States. FDA anticipates that these kinds of projects will continue, and that they will focus more closely on HACCP. FDA also expects that HACCP training, performed in accordance with the standardized training materials under development by the Alliance (see the ''Training'' section of this preamble), will provide further opportunity for foreign processors to be exposed to the requirements of these regulations.

3. Should Importers Be Subject to These Regulations?

119. Approximately half of those who commented on the import provisions addressed whether the importer should be required to take steps to ensure that its shipment originates from a foreign processor that operates under HACCP. Approximately half of these comments favored the concept and half opposed it, with both groups being diverse in their representation.

Of those who opposed it, many argued that these requirements should be the responsibility of the government, and that FDA should not require that importers enforce them. A number of these comments further argued that equivalent foreign government inspection systems cannot be presumed to be in place, and that the only way to achieve a ''level playing field'' is for FDA to perform inspections of foreign processors at the same frequency, and using the same standards, that the agency applies to domestic processors. One comment suggested that it may be necessary to obtain legislative authority to perform foreign inspections, as a condition of importation. Another comment suggested that FDA auditing of foreign processor compliance would give importers assurance that the products that they obtain from such sources had been produced in accordance with appropriate U.S. standards.

One comment, while not opposed to mandatory importer responsibilities, nonetheless argued that FDA should spend as much time and effort inspecting foreign processors as it does on domestic processors because over 50 percent of the seafood consumed in the United States is imported. The comment continued that, ''to do any less would be an unfair burden to domestic processors and would not accomplish the stated goal to significantly improve the safety of seafood consumed in the U.S.''

One comment argued that there is no real cost savings in assigning importers the responsibility of verifying foreign processor compliance rather than assigning that responsibility to FDA, because importers will merely pass along the additional costs to the consumer. Another comment noted that many small importers obtain products from over 25 countries, and that they cannot afford to provide the surveillance necessary to ensure compliance.

Another comment argued that many importers function simply as brokers, connecting a buyer with a seller, and that they lack the expertise, manpower, and facilities to evaluate the adequacy of a processor's HACCP controls. One comment stated, ''Many of the people involved in importing never see the product and know nothing about fish—these are people in a small room with a battery of phones!'' Another comment argued against placing reliance for assuring the safety of imported seafood on persons who have a financial interest in the product but lack the required knowledge about seafood safety.

One comment argued that requiring importers to exercise control over their suppliers has no parallel in the proposed domestic HACCP scheme. The comment stated that domestic processors must control the hazards that are introduced during their processing operations but need not be involved in verifying the control of those hazards associated with their supplier's operations. Some comments argued that the responsibility for controlling hazards that are reasonably likely to occur should be assigned to the foreign processor, while others argued that it should be assigned to the U.S. processor to whom the importer sells the product. One comment asserted that importers are not in a position to exercise control over the processing of products in foreign plants any more than they are in a position to exercise control over how the products are handled by their customers.

Most of those comments that supported the concept of importer responsibility provided no reason. However, one comment stated that requirements on importers would ensure that someone in the United States would be legally responsible for the safety and wholesomeness of each imported product.

FDA recognizes that requiring importers to take steps to ensure that foreign processors from whom they purchase seafood products are in compliance with these regulations could necessitate significant changes in the operations of importers who have limited their activities to matching buyers with sellers based on product specifications that may have had little to do with safety. However, for two reasons, FDA cannot agree that responsibility with regard to safety is inappropriate for importers.

First, it has always been the importer's responsibility to offer for entry into this country products that are not adulterated under U.S. law. It is a prohibited act, under section 301(a) of the act, to introduce into interstate commerce an adulterated food. Thus, an importer would be committing a prohibited act if it failed to ensure that

the food that it is offering for import into the United States is not adulterated under section 402 of the act, including section 402(a)(4), one of the principal provisions on which these regulations are based.

Currently, however, the importer is not required to operate in a proactive manner to ensure that it is meeting this responsibility. Rather, the importer need only offer products for entry into commerce and thereby place the burden on the government to find a problem. Many importers traditionally have purchased ''FDA rejection insurance'' to hedge against that possibility. The government can shift the burden to the importer by placing the importer's products on automatic detention if it finds problems that warrant such a step, but in most instances the burden remains on the government.

Second, responsible importers understand the issues related to the safety of the seafood products that they import and customarily require that foreign suppliers conform to their product specifications and applicable U.S. regulations relating to safety. These importers take various measures to ensure that a foreign processor can comply with their specifications and safety requirements before they agree to purchase products from the foreign processor.

Thus, it is feasible for importers to take steps to ensure that they are not offering adulterated products for entry into U.S. commerce. Requiring such measures will not be a significant added burden for many importers, particularly as HACCP principles become more widely used and understood in international commerce. Foreign processors that want to participate in the export market, not only to the United States but to the EU, Canada, and an increasing number of other countries, will implement HACCP and sanitation control programs and will be prepared to address an importer's needs for verification.

FDA does not agree that there is no parallel in the domestic scheme to the importer's responsibility to ensure that the goods it is offering were produced under HACCP. Domestic processors, like importers must work with their suppliers (e.g., fishermen) to ensure that all reasonably likely hazards (e.g. natural toxins and agricultural and industrial chemical contaminants) are controlled. FDA is confident that importers, like processors, will realize that ensuring that foreign processors institute preventive control systems is a cost effective means of ensuring that the products that they offer for entry into the United States will consistently meet FDA's entry requirements and will be safe for consumption. FDA also disagrees with those comments that suggested that a requirement that importers take steps to ensure that the products they offer for entry have been produced under a HACCP plan is an abrogation of FDA's responsibilities. As stated previously, the industry has a responsibility to ensure that the food that it introduces into interstate commerce is not adulterated. FDA has a responsibility to verify that industry is meeting its obligation and to take remedial action if industry fails to do so. Importers, who are usually the owners of the products that they are offering into commerce, are a part of that industry. FDA cannot accept that importers have no responsibility to ensure that their products are not adulterated.

The agency recognizes that probably the most effective way for a regulatory agency to evaluate a processor's compliance with the HACCP and sanitation requirements is through onsite inspection of facilities, practices, and records. FDA has performed a limited number of inspections of foreign processors and, within its budgetary limitations, will continue to do so to enforce these regulations. However, such inspections are costly, and any attempt to significantly increase their number would require additional resources.

FDA will continue its traditional import surveillance role, utilizing entry document review, wharf examinations, sample collections, and automatic detentions as screening tools. These tools indirectly evaluate the adequacy of HACCP and sanitation controls and will continue to be useful in detecting significant problems. While end-product testing and evaluation are not adequate substitutes for preventive controls in ensuring the safety of a product, they can provide verification where appropriate (Ref. 34, pp. 201–202).

FDA has concluded that requiring HACCP controls, together with import surveillance and periodic inspections of importers to ensure their compliance with the requirements of § 123.12, will better ensure the safety of imports than the current system.

In a related matter, § 123.3(g) makes clear that, under ordinary circumstances, freight forwarders, custom house brokers, carriers, or steamship representatives will not be required to fulfill the obligations of an importer. It is possible, although FDA has no way to know with any certainty, that some of those that objected to being required to fulfill those obligations would, as a result of these clarifications, find that they would not be expected to do so.

4. Memoranda of Understanding (MOU's)

120. Many of the comments that objected to the importer responsibility provisions of the proposal on the grounds that the government is the appropriate entity to ensure foreign processor compliance, stated that the most effective means of ensuring such compliance would be for FDA to enter into MOU's with the governments of exporting nations. Approximately one-third of those that commented in any way on the importer provisions urged FDA make the negotiation of MOU's a high priority. Only one comment objected to the development of MOU's.

Several comments argued that FDA should develop MOU's with all countries from which seafood is imported. One of these comments pointed out that to do otherwise would unfairly cause the obligations of importers to vary considerably. A few comments argued that the existence of an MOU should be a prerequisite for the importation of seafood products from a country. One of these comments stated that mandatory MOU's would reduce the complexity of the present import surveillance situation, reduce the number of countries exporting seafood to the United States, and encourage the development of improved food safety programs in exporting countries. Another comment asserted that MOU development is appropriate because government-to-government relationships and audits can be free of influence from packers and importers, whereas foreign suppliers may be prone to provide false assurances about their programs to prospective importers.

One comment urged FDA to fully describe the process and criteria for developing and evaluating MOU's and expressed concern about the process because of the varying level of sophistication of foreign seafood control programs. One comment stated that the foreign government should be responsible for evaluating the foreign processor's HACCP plan, inspecting the foreign processor, periodically analyzing products produced by the foreign processor, and issuing health certificates. A few comments stated that FDA should monitor the effectiveness of the foreign government's control program in a manner that is authorized in the MOU. These comments stated that, under the MOU's, the foreign government should provide FDA with periodic lists of processors that meet the requirements of these regulations, or, alternately, that all seafood processors

in the country would be required to meet the requirements.

One comment urged FDA to publish periodic reports on the status of MOU's on seafood products and to make them available to all importers. This comment and others argued that it should be FDA's responsibility to notify importers about changes in the status of MOU's, rather than be the responsibility of the importer to find out about any changes. One of these comments noted that, because a change in the status of an MOU could be very detrimental to importers, there must be sufficient lead time to allow importers to develop alternate verification procedures when changes do occur.

Another comment urged FDA to coordinate with U.S. importers and exporters in developing a schedule for MOU development. The same comment urged FDA to assign more resources to the development of MOU's.

On the other hand, one comment stated that the MOU development process is overly open-ended and could result in inconsistencies between domestic and foreign requirements. The comment argued that this inconsistency could result in an economic disadvantage for domestic processors.

FDA agrees with those comments that urged that the agency give high priority to the establishment of MOU's with U.S. seafood trading partners. In the absence of significant numbers of agency inspections of foreign processing facilities, FDA acknowledges that an MOU can be the most efficient and effective mechanism for ensuring that foreign processing plants are operating in compliance with the requirements of these regulations. FDA also agrees that the potential for signing an MOU with FDA is likely to serve as an incentive for the improvement of regulatory food control programs and processing conditions in seafood exporting countries, especially where the existence of an MOU serves to excuse the importer of products from that country from certain verification activities.

FDA has concluded that the development of MOU's or similar agreements with foreign regulatory agencies is an appropriate method for ensuring that foreign processors that export to the United States are in compliance with the requirements of these regulations. Moreover, as suggested by several comments, the agency has determined that, where an MOU exists, there is no need for the importer to perform any independent verification procedures for purposes of these regulations. In this situation, the importer should be able to rely upon the foreign regulatory authority to ensure compliance by foreign processors.

FDA is therefore retaining the provision on MOU's from the proposal but modifying it to provide that, where an importer elects to obtain a fish or fishery product from a country with which FDA has an active MOU or other similar agreement, the importer need not engage in any independent verification activities.

The agency has developed an internal protocol for developing MOU's and is negotiating agreements with several countries. FDA is committed to negotiating as many MOU's as possible. Also in the Federal Register of June 15, 1995 (60 FR 31485), FDA published the notice of availability of a new Compliance Policy Guide on MOU's.

However, it is not reasonable to expect that an agreement could be reached with all countries from which seafood is imported into the United States. The barriers to achieving such a result include the inadequacy of foreign regulatory programs and the lack of interest on the part of some foreign governments in entering into an agreement. The availability of FDA resources also can affect at least how long it takes FDA to enter into a particular MOU.

For these reasons, the existence of an MOU or similar agreement as a requirement of entry of fish or fishery products into the United States would result in an enormous negative economic impact to a major segment of the U.S. seafood industry. Moreover, such a restriction is not warranted from a public health perspective given the alternative means of verifying the existence of HACCP controls that are provided in these regulations.

Experience obtained in part in the international portion of the FDA/NMFS seafood HACCP pilot project has demonstrated that foreign seafood regulatory programs vary considerably, both in their capabilities and in their structures. Likewise, foreign seafood processing conditions are highly variable. Thus, FDA cannot simply follow a boiler plate format in negotiating MOU's. Rather, they must be tailored to the specifics of the situation presented by a particular country. It is possible that some agreements can provide simply for the submission of lists of approved processors to FDA at regular intervals; others may require much more extensive FDA involvement before and after goods flow under the agreement. Some agreements may cover all of a country's seafood processors, while others may be targeted to specific species or product forms, depending on factors such as the capability of the foreign regulatory authority.

In any case, all agreements can be expected to provide for FDA verification of the effectiveness of the foreign programs, including onsite visits. FDA is principally interested in two- way agreements, that is, agreements that acknowledge the acceptability of the U.S. regulatory system to the foreign government as well as the acceptability of the foreign regulatory system to the U.S. government.

The agency will make every reasonable effort to communicate with the industry about changes in the status of MOU's through Federal Register notifications and other means. FDA is open to suggestions about the best ways to communicate in this regard.

Nevertheless, it will ultimately be the importer's responsibility to keep appraised of any changes in the status of MOU's.

The agency is also receptive to the views of the seafood industry and others about how countries should be prioritized for the purpose of negotiating MOU's. Any information that the agency receives on this topic will be coupled with existing information concerning the likelihood of negotiation success and the types and quantity of products typically offered for entry from the country in question.

5. Importer Verification Procedures

121. The remaining comments discussed specific aspects of the proposed importer requirements. Some of these comments argued that the responsibilities that were proposed for importers are onerous, unworkable, and inefficient but offered nothing in support of these assertions.

A number of comments objected to the proposed requirement that all importers have and implement a HACCP plan. Several of these comments contended that an importer's plan can only address the hazards that occur during the time that products are under the importer's control (i.e., from the time the importer takes possession of the product until it is shipped to its customer), and that requiring that the plan cover this point is inconsistent with the principles of HACCP. One comment agreed that an importer should be required to develop a plan if it also processes the product, as in the case of an importer who stores the product. The comment asserted that, in such a case, however, the importer's HACCP plan would be minimal. The comment further asserted that the foreign processor should be the party responsible for developing a HACCP plan that addresses the hazards

introduced during processing in the foreign plant. The comment recommended that, as an alternative to having a HACCP plan, an importer should be able to develop SOP's that outline the steps that it will take to determine whether to purchase the product from a foreign supplier.

A number of comments supported the proposed requirement for importer HACCP plans but provided no reasons for their support.

The agency agrees that it would be inappropriate to require that importers have and implement a HACCP plan regardless of whether they process the products they import. As stated elsewhere in this preamble, HACCP is a system that provides immediate feedback, through the monitoring of CCP's, as to whether a process is under control. Unless an importer is also a processor, there are no CCP's in the classic sense for the importer to monitor, and from which to obtain real-time feedback. Consequently, only where importers also process in accordance with the definition of that term at § 123.3(k) will they be required to have and implement a HACCP plan that meets the requirements of § 123.6. Those food safety hazards that can be controlled by the foreign processor must be addressed in the foreign processor's HACCP plan in accordance with § 123.6.

Consequently, FDA has revised the regulations to limit the responsibilities of importers. Instead of having to maintain their own HACCP plan, under § 123.12(a), in the absence of an MOU or similar agreement, importers only need to maintain and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States have been processed in accordance with the requirements of these regulations. The only exception to this rule would be if the importer itself engages in processing, such as holding food, in which case the importer would, as stated above, also be a processor and subject to § 123.6.

122. In determining the nature of the verification procedures that an importer must have and implement, FDA considered the comments that addressed the appropriate functions and existing procedures of importers. Several comments noted that importers routinely purchase products according to specifications and observed that these specifications could be the basis for reasonable control measures for importers. The NACMCF recommended that importers be required to maintain product specifications that are relevant to product safety for fish and fishery products that they import. The NACMCF listed water activity, pH, histamine content, and, perhaps, pathogen limits as examples of specifications that importers might set in an effort to ensure product safety.

The agency agrees with the comments that product specifications can be useful tools with which importers can exercise some control over the products that they purchase and offer for entry into the United States. In fact, FDA stated in the preamble to the proposed regulations that the purpose of an importer's plan was, in part, to include criteria for how the importer will decide to purchase seafood. FDA is also encouraged by the fact that the comments generally agreed that having product specifications would not constitute a new burden for many importers.

For these reasons, the agency in § 123.12(a)(2)(i), is requiring that the importer's written verification procedures include product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions. These are the adulteration sections that relate to the safety of fish.

In many cases, importers will find existing Federal food safety standards, including tolerances and guidelines, to be useful specifications. In other cases, specifications may need to be tailored to the circumstances. For example, the importer might need to ensure that the temperature of a modified atmosphere packaged product, when it comes off a ship, is 38 °F (in such foods there is a risk of *C. botulinum* type E growth and toxin development which can occur at temperatures as low as 38 °F), although the CGMP's at § 110.80(b)(3)(i) state only that refrigerated foods should be stored at 45 °F or below. The importer is encouraged to seek the advice of qualified experts, as needed, in setting specifications. The same resources available to help domestic processors in setting CL's are available to importers, including the Guide; Sea Grant Institution and other academics; Federal, State, and local food safety regulatory agencies; consultants; the Alliance and other training courses; and published literature.

6. Affirmative Steps: General

As a second part of the importer's verification procedure, FDA is essentially retaining from the proposal, in § 123.12(a)(2)(ii), the requirement that the importer take affirmative steps to ensure that the products being offered for entry are actually being produced under controls that meet the requirements of these regulations. In order for product specifications to be meaningful, importers must take steps to establish that their suppliers are in fact operating in a manner that can reasonably be expected to produce a product that meets those specifications. Effective verification involves scrutinizing the standard, much like evaluating whether the HACCP plan continues to be appropriate, and scrutinizing performance to determine whether the standard is consistently reached, much like reviewing monitoring records (Ref. 34, p. 201). FDA is adopting this approach in § 123.12(a)(2)(ii).

Among the affirmative steps that FDA proposed that a processor take were: (1) Obtaining the foreign processor's HACCP-monitoring records; (2) obtaining a certificate from a foreign government inspection authority certifying that the firm is operating under a valid HACCP plan or certification on a lot-by-lot basis; (3) regularly inspecting a supplier's facilities; (4) periodic end-product testing by the importer or a private laboratory hired by the importer; or (5) other such verification measures as appropriate. FDA listed these affirmative steps as examples of the types of measures that would be acceptable to the agency. FDA does not wish to predetermine all the possible ways that an importer could perform affirmative steps.

123. A number of comments objected to each of the affirmative steps that FDA listed in the proposed regulations, and a few expressed support for each. However, few of the comments provided any reasons for their positions.

One comment suggested that the best means by which an importer can ensure that the conditions at a foreign processing facility are at least equivalent to those required of domestic processors is for the importer to verify the adequacy and implementation of the foreign processor's HACCP plan during a visit to the facility. Another comment stated that, ''without both audits and HACCP records, foreign plants (possibly domestic facilities too) will not adhere to the letter of the FDA regulation and assure safe product in the market.''

Conversely, a number of comments argued that it would be unworkable for importers to conduct inspections of foreign processors. One of these comments stated that to justify the expense of such an undertaking would necessitate that a highly trained, competent individual perform the function.

As stated earlier, FDA remains convinced that importers must exercise

sufficient control over the fish and fishery products that they offer for entry into their country to ensure that the products are produced pursuant to the requirements of these regulations. The agency recognizes that any one of the affirmative steps may not be appropriate or feasible for a particular importer or foreign processor. The regulations allow importers to select an affirmative step that is workable for their circumstances and to develop appropriate affirmative steps other than those listed in the regulations (see § 123.12(a)(2)(ii)(F)). However, such measures must provide at least an equivalent level of assurance of foreign processor compliance as that provided by the listed affirmative steps.

Additionally, FDA has modified the importer requirements to allow for the performance of any of the affirmative steps by a competent third party (§ 123.12(b)). This provision provides even greater flexibility to importers in meeting the requirements of these regulations.

Thus, FDA is not persuaded that the affirmative steps are not feasible or appropriate and has included them in these final regulations.

124. A comment argued that government certificates should not be acceptable unless they are issued by countries with which FDA has signed an MOU or similar agreement. The comment asserted that, especially in developing countries, there may be different interpretations of the regulations, and differences in competency, credibility, infrastructure, intent, and uniformity that might bring the utility of such certificates into question.

FDA acknowledges that it is likely to have a higher level of confidence in certificates received from a government entity with which it has signed an agreement than with one with which no agreement exists. However, as discussed above, it is unlikely that the agency will be able to negotiate an MOU with every country that exports seafood to the United States. Thus, there may be countries that have excellent certification programs with which FDA, for a variety of reasons, simply does not have an opportunity to enter into an agreement. Moreover, if the agency learns, either through its own routine surveillance activities, consumer complaints, or other means, that there is evidence that a country is routinely issuing certificates inappropriately, the agency will try to inform firms that import fish or fishery products from that country that it will expect them to use other means of verification if they want to avoid the appearance that those products are adulterated under section 402(a)(4) of the act (see § 123.12(d)).

125. One comment urged that certification be permitted on a continuing basis rather than requiring lot-by-lot certification.

FDA agrees that continuing certification is appropriate and notes that the language and intent of the proposed regulations would have allowed for it. Nonetheless, in an effort to further clarify this situation, the agency provided in § 123.12(a)(2)(ii)(B) that: ''Obtaining either a continuing or lot-by-lot certificate * * *'' will be one way to satisfy the requirement that an importer take affirmative steps to ensure that the product is produced in accordance with the requirements of this part.

7. Foreign Processor HACCP Plans

126. Approximately 15 comments addressed whether importers should be required to have on file copies of the HACCP plans of each of their foreign processors. Approximately half of these comments supported such a requirement, although for the most part they provided no reasons for their support. The other half objected to the requirement. One of these comments argued that possession of a foreign processor's HACCP plan would be cumbersome for the importer and would provide no assurance that product shipped by that processor was processed in accordance with the plan. One comment cautioned that it would be unrealistic to expect that importers could make any but a rudimentary judgment as to the adequacy of foreign processors' HACCP plans. Such judgments, these comments asserted, should be reserved for the regulator when the plans are assessed during inspections of importers' records.

One comment cited the possibility of breaches in confidentiality because commercially sensitive material would be supplied to importers. A related comment suggested that, to solve the confidentiality problem, the foreign processors' HACCP plans should be filed directly with FDA rather than with importers.

Although the agency continues to believe that a foreign processor's HACCP plan provides a useful basis for verification, FDA is persuaded by the comments that there are logistical and other issues that could render the retention of HACCP plans by importers unmanageable in some cases. FDA has also concluded that, in most cases, affirmative steps such as those listed in § 123.12(a)(2)(ii) (e.g., onsite inspection by the importer and certification by a foreign government agency) will be adequate to enable an importer to verify that the products being imported are safe in accordance with the requirements of these regulations.

As described previously, the NACMCF recommendations describe two primary goals of verification: (1) Ensure that the plan is adequate to address the hazards that are likely to affect the product; and (2) ensure that the plan is being consistently implemented. The affirmative steps listed in § 123.12(a)(2)(ii) are designed to address both of these functions. For example, obtaining HACCP and sanitation monitoring records from the foreign processor (§ 123.12(a)(2)(ii)(A)) enables the importer to confirm that the foreign processor has addressed the relevant hazards and sanitation concerns (i.e., those for which there are monitoring records), and that it is monitoring to ensure that these concerns are under control during the production of lots that are shipped to the importer. Similarly, obtaining governmental or third party certification of foreign processor compliance with the requirements of these regulations (§ 123.12(a)(2)(ii)(B)) or inspecting the foreign processor directly (§ 123.12(a)(2)(ii)(C)) enables the importer to confirm that the foreign processor has an adequate HACCP plan and SSOP, and that the relevant sanitation and safety concerns are being controlled for those lots that are shipped to the importer. The affirmative step options provided for by § 123.12(a)(2)(ii)(D) and (a)(2)(ii)(E) are discussed later in this section.

Consequently, FDA has not included a requirement that importers of fish and fishery products have on file the HACCP plans of each of their foreign suppliers in these final regulations.

Nonetheless, FDA points out that maintaining copies of these plans could be one of several measures that an importer could incorporate into its affirmative steps. Therefore, these final regulations in § 123.12(a)(2)(ii)(D) incorporate the concept as one of the affirmative steps that an importer may choose to use for verification purposes.

127. One comment noted that the plans of foreign processors would normally be prepared in the native language of the country of origin and asked whether FDA would require that these documents be translated into English. On the other hand, another comment recommended that HACCP plans be maintained in both the language of the native country and in English.

FDA agrees with the comment that argued that a copy of a processor's HACCP plan would not, by itself,

provide adequate assurance that a given shipment of imported product was processed in compliance with that HACCP plan or that the sanitation requirements of § 123.11 were met. One additional thing is needed to provide such assurance: a written guarantee from the foreign processor that the products shipped to the importer are processed in accordance with these regulations. The guarantee is necessary to demonstrate that the HACCP and sanitation control systems are being implemented for products shipped to the importer. An importer should be able to make a reasonable judgement about the validity of the guarantee through a rudimentary review of the plan, as described below. Therefore, FDA is including these requirements in § 123.12(a)(2)(ii)(D).

FDA is also providing in § 123.12(a)(2)(ii)(D) that the foreign processors' HACCP plans that are maintained by importers be written in English, so that they will be meaningful to the importer and will allow for regulatory review.

128. As stated above, one comment cautioned the agency about the ability of many importers to evaluate the adequacy of HACCP plans that they might retain.

FDA acknowledges that many importers may not have the technical expertise to evaluate the adequacy of seafood HACCP plans. However, the agency is convinced that, as a result of the importers' assessment of the food safety hazards that are reasonably likely to be presented by the product, the importer should have developed some general expectations about the content of the HACCP plan (e.g., which hazards should be addressed). The importer should be able to spot any obvious shortcomings and to discuss them with the foreign processor. It is not enough that importers simply file away the documents upon receipt. Importers may find it advantageous to make a judgment about the likelihood that their product specifications will be met and to insist that they be given a guarantee that contains assurances that the specifications will be met.

129. Regarding the comment that complained about the potential loss of confidentiality of foreign processor HACCP plans that are provided to importers, since the agency has eliminated the requirement that all importers retain copies of foreign processor plans, the significance of this issue has been minimized. In the case where a foreign processor does not wish to share its plan with the importer, the processor and the importer would need to agree upon another means of providing for importer verification.

130. Regarding the comment that suggested that all foreign processors file their plans with FDA, the resource demands on the agency that would come with such an undertaking would be prohibitive. FDA cannot accept this suggestion.

8. Other Affirmative Steps

As a related matter, FDA has determined that, in the absence of a requirement that importers maintain a copy of the foreign processor's HACCP plan, finished product tests alone are insufficient as an importer affirmative step to ensure that the foreign processor is operating in accordance with these regulations. Finished product testing alone has a small statistical likelihood of detecting defects in a product, especially when the occurrence of such a defect is an uncommon event, as is the case with most seafood hazards (Ref. 213). The proposed requirement for the importer to obtain a copy of the foreign processor's HACCP plan, in addition to performing finished product testing, would have provided indirect evidence that HACCP controls are in place and would have lent support to a conclusion, based upon the analytical findings, that the relevant hazards are under control. In the absence of such evidence, the importer cannot reasonably conclude that the hazards are being controlled based solely on a negative analytical finding. For this reason FDA has required in § 123.12(a)(2)(ii)(E) that such sampling be accompanied by a written guarantee from the foreign processor that products being shipped to the importer are processed in a manner consistent with the requirements of these regulations. The guarantee provides the importer with reasonable assurance that HACCP and sanitation controls are in place and are being implemented, in a manner similar to the way that the foreign processor's HACCP plan would have under the requirements of the proposed regulations. Under this alternative, the importer would not have to maintain a copy of the HACCP plan.

For clarification and consistency within the document, FDA has revised the language of two of the affirmative steps to include reference to the sanitation provisions of the regulations. In both the proposed regulations and these final regulations the stated purpose of the affirmative steps is to enable the importer to verify that the fish or fishery product was processed under conditions that meet both the HACCP and sanitation requirements of these regulations. However, the formulations of two of the affirmative steps in the proposal did not make specific reference to sanitation. To avoid confusion over what the affirmative steps should cover, § 123.12(a)(2)(ii)(A) now reads ''Obtaining from the foreign processor the HACCP and sanitation monitoring records * * *'' and § 123.12(a)(2)(ii)(B) reads ''* * * certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part.''

131. Several comments asked the agency to specify the frequency with which the importer affirmative steps must be taken. A few comments suggested that the frequency should be no greater than the frequency of equivalent FDA verification activities.

It would not be practical for the agency to specify frequencies for affirmative steps that would be appropriate in all circumstances. Consistent with the frequency of monitoring by processors, importers should take affirmative steps to monitor their suppliers with sufficient frequency to accomplish its purpose—that is, to provide the importer with reasonable assurance that the foreign processor is operating in compliance with these regulations.

It would be inappropriate to tie importer affirmative step frequencies to average FDA sampling and inspection frequencies. FDA sample collection and inspection frequencies are determined, in part, by the compliance history of individual firms, agency priorities, and overall agency resources, not simply on a desired average minimum rate of verification. Thus, FDA's rate of inspection has no bearing on how frequently an importer should monitor a supplier.

132. A number of comments urged that the agency permit importers to contract with third parties to perform verification activities on their behalf. Two comments opposed such a provision but did not provide reasons for their position.

Several comments urged that certificates by nongovernmental third parties be accepted as an affirmative step. One of these comments, from a trade association, suggested that an equivalent arrangement has been accepted by FDA in controlling the importation of canned mushrooms from the Peoples Republic of China. This same comment argued that a system where individual importers inspect each of their suppliers is highly inefficient. The comment suggested that a single, technically competent party should perform the inspections. The trade association offered to serve as a

clearinghouse for the reports of such inspections. Likewise, the association offered to serve as a clearinghouse for finished product sample results for imported products, reducing the number of samples needed when the same product is imported by a number of importers. The comment further suggested that the association be permitted to hold foreign processor HACCP plans for its members, and perhaps for nonmembers. The comment argued that acceptance of this suggestion would reduce the number of duplicate records for the same product stored by various importers.

The agency accepts that third party verification can be an appropriate and efficient control mechanism. Such a system is consistent with the use of third parties by processors for plan development, record review, and CL deviation evaluation. Therefore, FDA has added a new provision at § 123.12(b), that reads, ''An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.'' It is worth pointing out that where an importer uses the services of a third party, the importer remains responsible for the verification procedures that are performed. The importers must be able to demonstrate that appropriate verification measures have been performed. This step may involve providing an FDA investigator with a copy of the foreign processor's HACCP plan, results of end-product sampling, results of an onsite inspection, the foreign processor's monitoring records, or the foreign processor's written guarantee. Third parties must, of course, be competent to perform the duties in question, and FDA reserves the right to challenge such competency. The agency has no objection to the use of clearinghouses for importer verification activities, as long as the forgoing requirements are met.

9. Importer Records

As previously mentioned, the proposed regulations would have required that importers develop and implement a HACCP plan. One effect of such a requirement would have been that importers would have had to maintain appropriate records. As has been explained, FDA is adopting only those essential components of the proposed approach that the agency considers to be practicable for importers. One such component is recordkeeping. Recordkeeping is essential in documenting for the benefit of importers and the agency the affirmative steps of importers, in the same way that it is essential in documenting the monitoring, corrective action, and verification activities of processors. For this reason, the agency has retained the recordkeeping aspect of the proposal for importers, in a manner that is consistent with the overall approach for importers in these final regulations. Section 123.12(c), which treats importer records identically to processor records, reads, ''The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 123.9.''

133. FDA proposed that importers encourage foreign processors to obtain HACCP training. A few comments urged the agency to make it clear that foreign processors must comply with the same training requirements as are applicable to domestic processors. One comment urged the agency to permit HACCP-training courses for foreign processors to be conducted in the country of origin by ''an official agency.''

FDA agrees that the need for training is the same for foreign processors as it is for domestic processors. The intended benefits of the training requirements are fully discussed in the ''Training'' section of this preamble. Nonetheless, the agency finds that the proposed requirement that importers encourage foreign processors to obtain training is unnecessary. Foreign processors that ship seafood products to the United States are advised of the training requirement of these regulations in the same way that they are advised of the other requirements of these regulations, through publication of the regulations. In addition, as mentioned elsewhere in this preamble, FDA intends to provide the embassies of seafood exporting countries with information concerning these regulations in order that they may in turn provide it to the processors in their countries. Consequently, FDA is not adopting this provision.

FDA has no objection to HACCP training being performed in the country of origin by ''an official agency'' or other entity, as long as the course of instruction is at least equivalent to that provided by the standardized course under development by the Alliance.

10. Determination of Compliance

FDA proposed to require that there be evidence that imported fish and fishery products were processed under conditions that comply with the requirements of these regulations, and that if assurances that this was the case did not exist, the product would appear to be adulterated and would be denied entry. This section of the proposed regulations provided five types of evidence that the agency would consider as adequate to provide such assurance.

134. A few comments supported these provisions. However, a few comments suggested that, if the importer is unable to provide assurance that a HACCP system is in place, the importer should be permitted to conduct finished product testing rather than having the product denied entry. One comment urged that importers be held only to a ''best efforts'' standard in determining whether their suppliers are in compliance with these regulations. This comment suggested that if an importer cannot determine that such compliance exists after using its best efforts, the importer's product should not be banned from the United States.

The purpose of these regulations is to cause processors of fish and fishery products, both domestic and foreign, to develop and implement HACCP systems of preventive controls to ensure the safety of their products. The importer requirements are designed to impose an obligation on importers to ensure that, like domestic products, the products that they are importing are not adulterated within the meaning of section 402(a)(4) of the act. This requirement means that importers must be able to satisfy themselves, and ultimately FDA, that the fish and fishery products that they are offering for import were produced subject to a HACCP system and sanitation controls designed to prevent insanitary processing conditions that may render the food injurious to health. If an importer does not have evidence that shows that the products were produced subject to such controls, it should not offer the product for import into this country. The lack of such evidence creates the appearance of adulteration that cannot be overcome by the collection and analysis of a finished product sample by an importer. Given the problems that can arise in seafood processing if HACCP and sanitation controls are not in place, under sections 402(a)(4), 701(a), and 801(a) of the act, FDA is adopting § 123.12(d), which provides that if evidence does not exist that an imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors, the product will appear to be adulterated.

Section 123.12(d) derives from proposed § 123.12 (a) and (b). FDA has combined these provisions and, as

suggested by a comment, has used terminology consistent with the rest of the regulation in § 123.12(d). While proposed § 123.12 (a)(1) through (a)(5), which described the types of evidence that could be used to demonstrate compliance with the proposed regulations, reflected important principles for the importation of fish, based on the comments, FDA finds that these provisions were causing confusion, and that the statute can appropriately be implemented without including them in the final rule. For this reason, FDA has not adopted these provisions.

135. One comment asked what documents, if any, would have to be presented to FDA at the time of entry concerning the status of the foreign processor. Another comment suggested that importers should note on the entry documents that a HACCP plan is available for the foreign processor. This comment stated that FDA would have an opportunity to review the plan as part of its determination of whether to allow entry of the product.

FDA is not requiring that evidence of the importers' affirmative steps be presented along with the existing U.S. Customs Service entry documents as a matter of routine practice. It is possible that, in some circumstances, such a step will be necessary (e.g., where the agency has reason to believe that inappropriate conditions exist in the foreign processing facility). However, typically, the importer will be able to retain such evidence in its files and to make it available to the agency when FDA performs an inspection at the importer's place of business. Such a system is necessary because of the time that is necessary for the agency to properly review the importer's documentation of its affirmative steps and of the foreign processors' HACCP plans. Nonetheless, the agency is willing to explore alternate methods of implementing the import requirements of these regulations, such as that suggested by the comment. FDA welcomes a continuing public dialog about this matter.

136. One comment asked whether FDA would maintain an approved list of foreign processors.

The agency has no plans to maintain such a list, nor is it apparent upon what basis such a list would be prepared. A possible exception would be as part of an MOU arrangement, where the foreign country would agree to provide a list of ''approved'' firms to FDA. In such a situation, FDA would use reasonable means to inform the import industry of the purpose and contents of the list and update them as rapidly as possible when changes are made.

137. One comment expressed concern that the same foreign processor HACCP plan might be reviewed by different FDA investigators in different ports of entry, and that these investigators might reach different conclusions as to its adequacy. The comment urged that the agency coordinate such reviews, as well as reviews of importers' affirmative steps, in a way that would minimize inconsistencies.

FDA acknowledges that the situation might well arise where different investigators review the same foreign processor HACCP plan as a part of different importer inspections. To minimize inconsistencies in such reviews, the agency intends to train its inspectional staff in the requirements of these regulations and the application of HACCP principles to seafood processing, including training on the Guide. The agency also intends to develop guidance relative to importer verification activities.

M. Guidelines or Regulations?

1. Background

FDA recognizes that many processors will need guidance in the preparation of HACCP plans, and that HACCP plans will vary in complexity. The agency is committed to providing the industry with technical assistance that includes general guidelines for HACCP plans and the contents of plans for specific types of products and processes.

As part of FDA's seafood HACCP proposal, the agency included guidelines, in the form of appendices, on how processors of cooked, ready-to-eat products and products involving scombrotoxin-forming species could meet various provisions of the proposed regulations relating to the development and implementation of HACCP plans. FDA regards these products as being high-risk relative to other seafoods. They involve special considerations or special hazards for which additional guidance would likely be useful.

Cooked, ready-to-eat fishery products present an elevated risk of a microbiological hazard compared to most other seafood products. They are cooked as part of processing and might not receive additional cooking by consumers before consumption. Consequently, to be safe, these products must not contain pathogens at a level that will cause disease and must not be subjected to time-temperature abuse that would allow any existing pathogens to grow to unacceptable levels.

Scombrotoxin-forming species are fish that can form a toxin if exposed after death for significant periods to temperatures that permit the growth of certain bacteria. Scombrotoxin can result in a mild to severe allergic response in humans.

The guidelines for these products contained advice about hazards that are reasonably likely to occur and on details for HACCP plans for the control of these hazards. In addition to asking for comments on the substance of the guidelines, the agency asked for comment on whether these guidelines should remain as guidelines, or whether some or all of them should be adopted as regulations. As regulations, they would, essentially, tell processors that certain hazards must be controlled in their HACCP plans, identify in advance critical points in the processing of these products that processors must control to minimize these hazards, and tell processors what they would have to do, at a minimum, to maintain proper control of those critical points.

In another appendix to the proposed regulations, FDA published excerpts from the draft Guide, mentioned earlier in this preamble, for the stated purposes of publicizing the existence of that draft Guide and of providing processors with information about the types of guidance that the agency expected would be available in it.

One of the excerpts that FDA published was guidance on the processing of smoked and smoke-flavored fish. These products represent a significant hazard relative to contamination with *C. botulinum*, especially when packaged in reduced oxygen atmosphere packaging. FDA requested comment on whether this guidance should remain solely within the Guide, whether it should be provided an appendix to the regulations, or whether it should be adopted as regulations. The effect of adopting these materials as regulations would be the same as for the appendices described above.

If these materials remained in the form of guidelines, processors would be free to adopt them or not, so long as measures that provide an equivalent or superior degree of safety are implemented.

138. Approximately 55 comments responded to FDA's request for comment on whether these materials should remain as guidelines or be adopted as regulations. The majority of comments preferred guidelines. A few comments suggested that FDA initially issue guidelines, then possibly convert them to regulations after gaining experience with them as adjuncts to a functioning HACCP system or after pilot testing them. A few comments preferred to retain some of the materials as

guidelines and convert others to regulations.

Over one-third of those who commented on this subject supported guidelines in general, without distinguishing among the three guidelines. They argued that guidelines are in keeping with the general philosophy of HACCP that processors assume responsibility for the safety of their products. Some stated that detailed regulations for processors to follow would not provide an adequate incentive to processors to develop a full understanding of the hazards associated with their products or processes. The result could be the development of rote HACCP plans that might be inadequate for safety in specific situations.

Some comments pointed out that, while guidelines can assist processors to identify controls, guidelines probably could never properly identify the CCP's and limits for all processors given the uniqueness of individual processing methods. In the case of regulations, processors would be obliged to adhere to the presented limits regardless of their appropriateness to the operation. Many of these comments preferred the flexibility that guidelines provide in permitting HACCP controls to evolve with a changing knowledge base and new technologies. Some expressed concern that if the guidelines were adopted as regulations, the industry would bear an unnecessary burden of having to petition FDA for amendments in order to accommodate new products or processes. Modifications to the regulations could take considerable time.

Several comments specifically objected to adopting either the guidelines for cooked, ready-to-eat products or the guidelines for scombroid toxin-forming species, or both, as regulations. The reasons were generally the same as those given by those comments that supported the use of guidelines generally.

One comment did express the concern that adopting the scombroid guideline as regulations would have the effect of adopting a policy action level for histamine as a defacto regulation without a formal notice and comment rulemaking.

Several comments requested that guidelines only appear in the Guide, and not in appendices to the regulations, to alleviate confusion.

However, FDA did receive a number of comments that urged the agency to adopt these guidelines as regulations. These comments cited a need for minimum enforceable standards for these products to ensure the protection of the public health. The comments argued that minimum standards would avoid confusion about what is enforceable, and what is not. They pointed out that as regulations, these provisions could be more readily enforced.

FDA believes that all of these comments have merit. Guidelines can provide flexibility that regulations sometimes lack. Moreover, because they are advisory in nature, guidelines are less likely to be followed by rote.

FDA thus agrees that, ideally, HACCP should serve as a catalyst for processors to develop a full understanding of the relationships between their products and processes and human food safety and to devise controls for ensuring safety. There may well be more than one way to reach an appropriate safety endpoint. Regulations might not always take such alternatives into account.

On the other hand, in those cases involving high-risk products where adherence to scientifically established minimum standards or procedures is necessary to ensure a safe product by design, and those minimums are not likely to change, there is good reason to make those minimums something more than advisories. In those types of situations, it makes no sense to act as if the work that scientifically established the minimum processing conditions had not been done.

2. Cooked, Ready-To-Eat Products and Scombroid Species

These, then, are the considerations that FDA has weighed. In the case of cooked, ready-to-eat products and products made in whole or in part from scombroid toxin-forming species, FDA is persuaded that the guidelines should remain as guidelines, at least until there is enough experience with them to determine whether a change to regulations is warranted. The agency has concluded that processors should be given maximum flexibility, at least initially, to identify the reasonably likely hazards and the CCP's and CL's for those hazards that are most appropriate for their manufacturing processes. FDA will examine over time whether processors are achieving an adequate degree of preventive control for these products under the guidelines, and whether they are doing so by following the guidelines exactly or partially or by relying on alternative approaches.

FDA acknowledges that many comments objected to the details of the appendices. These comments will be addressed when the first edition of the Guide is published. FDA recognizes that these materials will be more easily modified and improved if they remain as guidelines, at least for the time being.

FDA agrees that all of these guidelines should appear solely in the Guide. There are no appendices to these final regulations.

3. Smoked and Smoke-Flavored Fishery Products

The guidance for smoked and smoke-flavored fish contained specific processing parameters (i.e., time and temperature of smoking and finished product salt and nitrite concentrations) to be met in the processing of such products, and control mechanisms for ensuring that they are met. *C. botulinum* toxin production is prevented in smoked and smoke-flavored fish by controlling these interrelated variables, as well as by controlling the temperature of the product throughout the chain of distribution.

139. Approximately 25 comments addressed whether these materials should be regulations or guidelines. About half of the comments, representing State and Federal regulatory agencies, professional associations, and others, urged that the materials be codified as regulations. The remainder, representing processors and trade associations, requested that the guidelines remain as guidelines.

A number of the comments that urged that the smoked and smoke-flavored fish guidelines be issued as regulations asserted that regulations are more easily enforceable, would provide clear direction to the industry, and would provide much needed nationwide uniformity in the processing of smoked fish. One comment from a State regulatory agency observed that processors are not adhering to existing guidelines, such as the 1991 recommendations for these products by AFDO, and are unlikely to change their operations in response to another guideline. Several comments argued that the States need Federal regulations to support their own efforts to regulate the industry and to foster uniformity among the various existing State requirements. One of these comments also stated that such regulations are needed to ensure the safety of smoked fish, because the product has a history of involvement in botulism outbreaks, is handled more than most other products, increasing the risk of microbiological contamination, and is frequently not cooked prior to consumption. One comment suggested that the guidelines be tested in pilot programs before making them mandatory, and that research information on smoked fish be disseminated to industry through

technical bulletins, workshops, and meetings.

Several of the comments that suggested that the proposed guidelines remain as guidelines argued that FDA has not demonstrated that present practices in the smoked fish industry are causing risks that would justify regulations, and that there have been no recent incidents of botulism attributable to smoked fish. Several comments stated that most of the problems with smoked fish in the past have resulted from abuse of the product at retail or by the consumer.

A few comments objected to FDA's contention that large portions of the industry do not conduct final product testing and to the inference that all smoked fish processors do not monitor the composition of their products. The comments stated that responsible companies do conduct product testing on a regular and routine schedule, have scheduled processes, and are aware of what they are doing.

Other comments recommended that FDA enforcement of the current CGMP's, coupled with State and local enforcement of the Food Code for smoked products that are produced in restaurants, retail, and food service establishments, would make it unnecessary to treat smoked fish products any differently than other products under these HACCP regulations. One comment suggested that guidelines would have the same impact as regulations because HACCP plans would be rejected by FDA if they do not contain the recommended controls, and because States would adopt the guidelines as regulations.

One comment argued that the issuance of prescriptive regulations would eliminate the diversity in the types of smoked fish products available and result in a ''homogeneous'' market. Another comment counseled that the issuance of a regulation would cause Alaskan native salmon processors to abandon their traditional trade.

The agency remains convinced that smoked and smoke-flavored fish is a potentially hazardous food. While cases of botulism have not been attributed to commercially prepared smoked or smoke-flavored fish in over 30 years, the outbreaks of the 1960's clearly demonstrate the potential for such occurrence. Virtually all the research that has been conducted establish that processors need to control time, temperature, and salinity (T-T-S) parameters and other matters for these products in order to provide adequate barriers to toxin production (Ref. 214).

As the preamble to the proposed regulations pointed out, FDA and a number of States have longstanding concerns that the actions of a significant portion of the smoked fish industry do not demonstrate a full appreciation for the nature of the risks. FDA and New York State surveys of the smoked fish industry in the late 1980's, for example, showed that many processors did not routinely control their T-T-S parameters.

The comments have not persuaded FDA that, even without regulations, processors will employ preventive controls to ensure the safety of these products as a matter of design and not of chance. Botulism derives from one of the most dangerous toxins known to exist. Controls to prevent the formation of this toxin cannot be left to chance. HACCP controls for this hazard are highly appropriate because HACCP requires that the processor analyze its operation to determine how hazards affecting its product can arise, and that it institute specific controls to prevent those hazards. The majority of comments that addressed smoked and smoke flavored fish products either supported the concept of HACCP controls or did not argue against them.

140. The question, therefore, is whether, in addition to requiring HACCP plans for these products, FDA should mandate specific CCP's, minimum CL's, monitoring frequencies, and other matters that processors would have to include in their HACCP plans. If the agency were to codify draft guidelines as regulations, the agency would be answering that question in the affirmative. The preamble to the proposed regulations identified the T-T-S parameters in the draft guidelines as being scientifically established minimums for ensuring that toxin produced by *C. botulinum* will not be produced over the shelf life of the product under refrigerated conditions and under conditions of moderate temperature abuse. FDA has been urged for years to mandate such T-T-S parameters for these products. In 1988 and 1989, for example, AFDO passed resolutions asking FDA to expedite the development of regulations for the safe processing of smoked fish. The comments to this rulemaking that supported regulations over guidelines support the mandating of specific T-T-S parameters.

However, a significant number of other comments challenged whether some of the parameters in the guidelines were actually minimums, as FDA had contended. They specifically objected to the minimum water-phase salt levels in the draft guidelines for air packaged smoked and smoke-flavored fish. Generally, these comments stated that there is little safety concern with air-packaged smoked or smoke-flavored fish (hot or cold smoked) containing as little as 2.5 percent water phase salt (less than the minimum stated in the guidelines), and requested that FDA reexamine the existing scientific data. A few comments stated that air-packaged smoked fish has a limited shelf life in the refrigerated state and that NMFS research has shown that spoilage occurs before toxin production. One comment stated that NMFS, New York State Department of Agriculture and Markets, and AFDO all consider a minimum water-phase salt content of 2.5 percent to be acceptable for air-packaged products.

A few comments suggested that an alternative to specifying T-T-S parameters would be to require that all processors have a scheduled process for air-packaged products. The comment stated that this requirement has been successful in the State of New York and has enabled industry to produce products with water-phase salt concentrations that are lower than those proposed by FDA. A few comments suggested that the high salt levels proposed by FDA for smoked and smoke-flavored products would be counterproductive to those government programs aimed at reducing salt in the human diet and would be unacceptable, or only marginally acceptable, to consumers. Other comments suggested that the necessary minimum salt levels for smoked and smoke-flavored fish might be reduced by shortening the shelf life of the product or by storing and distributing the product frozen.

The comments have persuaded FDA that it may be possible for processors to use parameters other than those in FDA's draft guidelines and still produce a safe product. Moreover, the NACMCF has recently endorsed AFDO's recommended parameters for smoked and smoke-flavored fish. Most notably, these recommendations differ from those in FDA's draft guidelines in that they provide for a minimum finished product water phase salt content in air-packed product of 2.5 percent, whereas the FDA proposal provided for a range of minimum values of from 2.5 percent to 3.5 percent, depending upon other processing parameters.

The agency acknowledges, therefore, that some recommended T-T-S parameters differ from those in FDA's draft guidelines. FDA acknowledges the possibility that other safe T-T-S parameters exist as well. It is reasonable to suppose that there is more to be learned about how the development of *C. botulinum* toxin is controlled in these products, given the lack of reported illnesses in recent years. Thus, while

FDA strongly believes that the T-T-S parameters in its draft guidelines provide effective controls for botulism, the agency accepts that they are not necessarily the only effective controls, or that all effective controls have been identified.

Consequently, the agency has concluded that, at least for now, the most appropriate place for such guidance on T-T-S parameters and related matters is the Guide, and that it would not be appropriate to adopt specific parameters for the processing of smoked fish by regulation. However, because of the extreme nature of the hazard, and in response to comments, FDA has chosen to codify a rudimentary performance standard for the control of botulism in these products from the draft guidelines (item number 11). As incorporated at subpart B, § 123.16, the performance standard reads:

> In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *C. botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

This requirement responds in part to the comments that proposed that FDA require that all processors scientifically establish scheduled processes for smoked and smoke-flavored fish, rather that mandate specific T-T-S parameters and other matters. It requires processors to establish CL's that are both appropriate to their operation and scientifically sound. Because botulism is undoubtedly a hazard that must be controlled in the production of these products, subpart B of part 123 does not impose a requirement that would not exist in its absence. It has been included for emphasis and as a reminder to processors. The Guide will provide processors with assistance with regard to specific T-T-S parameters and related matters.

141. FDA proposed that, with certain exceptions, fish to be smoked or salted be eviscerated and free of residual viscera. The preamble to the proposed regulations explained that salted or smoked uneviscerated fish present a potential hazard for the development of *C. botulinum* toxin production. The viscera of fish contain the majority of *C. botulinum* normally present.

One comment argued that the entire evisceration provision should be moved to the Guide. Another comment suggested that specific evisceration requirements be codified but not as part of sanitation.

These regulations require in subpart B of part 123 that the processors of smoked and smoke-flavored fish describe in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *C. botulinum*. Specific types of controls will be provided in the Guide. Because evisceration is one form of control for this toxin, it will be covered in the Guide as well and need not be included in the regulations. Consequently, FDA has not included this proposed provision in these final regulations.

N. Molluscan Shellfish

1. Background

In addition to the general HACCP provisions in subpart A of part 123, FDA proposed subpart C of part 123—''Raw Molluscan Shellfish,'' which set forth specific requirements for the processing of fresh or frozen molluscan shellfish. Proposed subpart C of part 123 described certain types of controls that processors of these products must include in their HACCP plans in order to meet the requirements of subpart A of part 123.

Specifically, FDA proposed to require that processors of raw molluscan shellfish identify in their HACCP plans how they are controlling the origin of the molluscan shellfish that they process. FDA proposed to require that these controls include accepting only molluscan shellfish that originated from growing waters that are approved by a shellfish control authority, that are from harvesters that are licensed or from processors that are certified by a shellfish control authority, and that are properly tagged or labeled. In addition, FDA proposed to require that processors maintain records to document that each lot of raw molluscan shellfish meets these requirements. FDA also proposed to amend § 1240.60 (21 CFR 1240.60) to provide for a system of tagging for shellstock and labeling for shucked molluscan shellfish as a means of source identification.

It is important to note that shellfish control authorities in the United States are generally agencies of State governments, and that the tagging of molluscan shellfish is an important aspect of State shellfish control programs. As discussed below, reference to aspects of existing State programs in these Federal regulations is not intended to supplant or override the State programs in any way. Rather, these provisions are intended to strengthen the Federal system in ways that will complement, and thereby better support, State programs.

Molluscan shellfish consumed raw or partially cooked pose unique public health risks. As the preamble to the proposed regulations noted, they probably cause the majority of all seafood-related illnesses in the United States. This situation is not unexpected, given the nature of the product and the way that it is consumed. The preamble documented a relationship between the microbiological quality of molluscan shellfish growing waters and the incidence of molluscan shellfish-borne disease. It also noted that naturally occurring toxins may accumulate in molluscan shellfish because they are filter-feeding animals.

The NSSP was established as a cooperative program among FDA, State regulatory agencies, and the molluscan shellfish industry, relying on section 361 of the PHS Act (42 U.S.C. 264), to provide for the classification and patrol of shellfish growing waters and the inspection and certification of shellfish processors. The preamble to the proposal reaffirmed FDA's support for the NSSP but noted the difficulties that are associated with ensuring the safety of these uncooked products. As the preamble stated, FDA tentatively determined that it could strengthen and provide additional support for the cooperative program through these regulations.

2. Should There Be Specific Requirements for Raw Molluscan Shellfish?

FDA received approximately 45 comments about the proposed requirements for raw molluscan shellfish. The responses were from processors, trade associations, State and Federal government agencies, individuals, consumer advocacy groups, and a foreign country. Approximately half of these comments urged FDA to eliminate proposed subpart C of part 123 and the proposed amendment to § 1240.60, while the other half acknowledged the advisability of including these kinds of provisions but commented on, or questioned, various specifics of them.

The comments that generally supported the need for specific requirements for raw molluscan shellfish were from trade associations, molluscan shellfish industry members, consumer advocacy groups, Federal and State government agencies, individuals, and a professional organization. A number of comments noted that special requirements for molluscan shellfish are warranted because of the association of these products with illness. One

comment in particular stated that, with respect to seafood, molluscan shellfish ''serve as the primary source of illness due to ingestion.'' One comment noted that Federal regulations relating to source of origin controls for raw molluscan shellfish would enable FDA to lend support to the States in the administration of the NSSP. Another comment suggested that the proposed regulations would improve FDA's regulatory effectiveness with regard to molluscan shellfish control. The comment from the ISSC stated that ''The Conference has long recognized and supported expansion of FDA authority to assist States in assuring the safety of molluscan shellfish.''

The comments that suggested that subpart C of part 123 and the amendment to § 1240.60 be deleted were from State government agencies and seafood processors. A number of the comments that suggested deletion of the proposed provisions stated that the tagging and labeling requirements of the NSSP are designed not to serve as a control to prevent harvesting from closed areas but to assist States in tracing shellfish that are implicated in illness outbreaks back to the harvest area. The comments went on to state that harvesters who illegally harvest from closed waters do not identify the shellfish as originating from the closed area. The comments maintained that preventing illegal harvesting is the key to reducing the incidence of illness, and that the only known method to achieve this goal is through effective law enforcement, including the patrol of closed waters.

A number of these comments argued that increased FDA funding and support for State molluscan shellfish control and patrol efforts would do more than the proposed rule to deter illegal harvesting, to increase States' compliance with the NSSP, and reduce the number of illnesses caused by molluscan shellfish. The comments went on to state that the proposed regulations unnecessarily duplicate the requirements now in place in the Manual of Operations for the NSSP. They contended that formal adoption of NSSP requirements into Federal regulations would release State agencies from their cooperative relationship with FDA under the NSSP.

One comment noted that the weaknesses in State molluscan shellfish control programs are in areas not addressed by the proposed regulations, such as improperly classified growing waters; the ability of State growing water classification programs to respond to breakdowns at waste water treatment facilities or unexpected climatic events that affect the quality of molluscan shellfish growing waters; and improper handling by caterers and consumers. The comment concluded that the proposed HACCP provisions for molluscan shellfish will, therefore, not reduce the incidence of illness attributable to such products.

As previously mentioned, FDA is a partner with State and foreign regulatory authorities and with industry in the NSSP. The NSSP Manual of Operations provides the standards for State and foreign molluscan shellfish regulatory programs that belong to the cooperative program, as well as for processors. The participating States routinely adopt those standards as law or regulations, but the NSSP itself has neither Federal nor State regulatory stature.

Each participating State and foreign nation classifies and monitors its molluscan shellfish growing waters, controls harvesting, inspects molluscan shellfish processors, and issues certificates for those that meet the shellfish control authority's criteria. FDA evaluates State and foreign molluscan shellfish control programs and publishes monthly the ''Interstate Certified Shellfish Shippers List,'' which lists the molluscan shellfish processors that are certified under the cooperative program. States that are in the program are not willing to receive shellfish from noncertified shippers.

FDA disagrees with the comments that suggest that establishment of the proposed source controls in Federal regulations would supplant the similar and, in some cases more stringent, requirements of participating States and foreign nations or the standards set forth in the NSSP. Rather, the agency is convinced that they will reinforce and support these requirements and standards.

The molluscan shellfish industry is subject to significant regulatory oversight in those States that participate in the NSSP. However, the quality and effectiveness of State laws and enforcement activities can vary considerably as a function of the financial and administrative support available to the responsible State units (Ref. 7, p. 15). For example, FDA documented discrepancies in State enforcement practices during its 1994 evaluation of State programs to determine compliance with the NSSP standards (Ref. 215). Moreover, although all harvesting States participate in the NSSP, many other States do not.

Based on these factors, FDA proposed, and is now adopting, subpart C of part 123 and amendments to § 1240.60 to support and strengthen the shellfish program in two ways. First, these provisions will complement the efforts of the States. FDA recognizes that while States are making significant and important efforts to ensure that all shellfish harvested in their jurisdiction are taken only from open waters and then properly tagged, some shellfish that do not meet these requirements inevitably escape State control. The new provisions will allow FDA to take action against shellfish that are not harvested from open waters or that are not properly tagged if it encounters such shellfish in interstate commerce and make the gravamen of such action the origination from unopen waters or the lack of proper tagging itself, rather than evidence that the shellfish are injurious to health.

Second, the regulations require that processors only use shellfish that originate from growing waters that have been approved for harvesting and that have been properly tagged. Failure to do so can result in Federal regulatory action against the product or against the processor itself. This fact should provide a significant incentive to processors to ensure that they are not receiving shellfish that do not meet these requirements.

Taken as a whole, rather than diminishing in any way the importance of State programs, FDA's regulations elevate the importance of those programs. These regulations make proper origin and tagging—concepts that derive directly from the NSSP—keys to the unimpeded movement of shellfish in interstate, as well as intrastate, commerce.

Moreover, these requirements extend these control measures to imported products, enabling FDA to more efficiently and effectively ensure the safety of imported raw molluscan shellfish. At present, the agency must resort to advising State regulatory authorities of the prospective entry of raw molluscan shellfish from an uncertified source (Ref. 216, part V, p. 5). While States normally take action against uncertified imported raw molluscan shellfish, FDA is aware that uncertified imports enter interstate commerce (Ref. 107).

FDA acknowledges that uniform Federal tagging and record-keeping requirements will not completely eliminate illegal harvesting. The agency agrees with the comments that rigorous enforcement of closed area restrictions by State regulatory agencies will always be needed. Unquestionably, increased funding would help State efforts to classify and patrol growing areas. However, FDA does not have resources for this purpose. Nonetheless, the agency remains convinced that there are

significant, positive steps that can be taken to strengthen source controls as part of HACCP, and thereby to support the cooperative program.

A processor's most significant safety control for raw molluscan shellfish is at the point of receipt. If processors refuse to accept molluscan shellfish for which there is no assurance that they have been legally harvested, the incentive for illegal harvesting would be eliminated. FDA participation in a number of covert investigations into illegal molluscan shellfish harvesting in recent years has convinced the agency that, in many cases, processors are aware of the illegal harvesting activity of their suppliers (Ref. 217). If the provisions of these regulations can help foster a culture change in that respect, shellfish safety will be significantly enhanced.

Based on these considerations, the agency proposed that, as a universal aspect of the HACCP plans for these products, molluscan shellfish processors engage in certain activities to ensure that the products that they receive originate only from waters that have been approved by a shellfish control authority (e.g., checking tags on containers of shellstock, licenses of fishermen, and certification of suppliers). Molluscan shellfish that are clearly improperly tagged or from questionable sources must be rejected by processors as a requirement of their HACCP plans. It is reasonable to conclude that, as more processors adopt HACCP and exercise greater control over their suppliers, the amount of illegally harvested shellfish offered for sale will decrease, because the market for such product will decline.

While it is true that the tagging requirements of the NSSP were primarily designed as a means of tracing back molluscan shellfish involved in incidences of illness to their harvest area, they have also served as a key component in efforts by FDA and State regulators and industry to ensure that molluscan shellfish that are placed in commerce originate from areas that are approved by a shellfish control authority. It is certainly true that the tags on containers of molluscan shellfish that are harvested from closed waters are often falsified to disguise their true origin. However, such falsification carries potential Federal and State penalties and is a focus of current molluscan shellfish control programs.

Regarding the comments that pointed to weaknesses in State programs, at retail, in the classification of molluscan shellfish growing waters, and elsewhere, which are not directly addressed by these regulations, the agency acknowledges that HACCP plans and specific source control requirements cannot serve as a substitute for improvements in the food safety system that directly address these weaknesses. Regulatory systems will always have their strengths and weaknesses, and research to better understand and control hazards will always be needed. Nonetheless, these comments provide no reason for FDA to abandon its efforts to remedy existing agency weaknesses and, in particular, to lend support to the States in those areas to which these regulations do relate.

141. One comment stated that references cited in the preamble to the proposed regulations in support of the tagging requirements (Refs. 102 through 109) do not provide convincing evidence of a need for such a measure. The comment stated that, for the most part, the references that FDA cited document corrective actions taken by State regulatory agencies that would likely be the same measures that FDA officials would take under the proposed regulations. In addition, the comment stated that a failure to have properly tagged shellfish does not always mean that the shellfish were harvested illegally. The comment pointed out that the absence of a tag could mean simply that the tag was lost.

The references in the question contain examples of problems associated with molluscan shellfish tagging, recordkeeping, and harvesting. FDA cited these references to demonstrate that, in some cases, the deterrent effect of existing State tagging requirements and sanctions is inadequate to prevent problems from arising (Refs. 102, 103, and 109). The problems documented in the references helped persuade FDA to propose Federal source control requirements to help deter the interstate shipment of shellfish from unapproved harvest areas. FDA did not intend to imply that the State actions that were documented in these references were incorrect, or that FDA would have responded in a different manner. FDA continues to believe that the references are relevant and supportive to its intended assertion.

A few comments maintained that a better strategy for decreasing illness from the consumption of molluscan shellfish would be to increase the education efforts of FDA and of the ISSC that are directed toward consumers and the medical community to alert susceptible individuals to the risks associated with the consumption of raw molluscan shellfish.

The agency agrees that consumer education can play a vital role in reducing illnesses associated with the consumption of raw molluscan shellfish, particularly in medically compromised individuals. During the period of 1984 through 1994, the agency expended nearly $1 million to alert the public to the risks of raw molluscan shellfish consumption by distributing brochures to consumer groups, groups that represent those with special medical conditions, and consumers; developing a video news release; issuing press releases; and establishing the toll-free, FDA Seafood Hotline. Included in this expenditure is the agency's efforts to inform the medical community about the illnesses associated with the consumption of raw molluscan shellfish by providing informative articles to medical bulletins and journals and by mailing brochures and news articles to target professional groups. The agency will continue its consumer education efforts, but such efforts alone will be insufficient to address the hazards posed by the consumption of raw molluscan shellfish harvested from unapproved growing waters. The existing and planned consumer education efforts are geared toward individuals in high-risk consumer groups, advising them to avoid molluscan shellfish that have not been fully cooked. The risks posed by viruses, toxins, and many bacteria are to the population as a whole. There is little advice that the agency could provide that would enable consumers to protect themselves from these kinds of hazards in molluscan shellfish.

143. Several comments questioned the validity of FDA's statement that molluscan shellfish consumed raw or partially cooked pose unique public health risks and probably cause the majority of all seafood-related illnesses in the United States.

The comments provided no data upon which to conclude that either the NAS or FDA is wrong in this regard. FDA remains convinced that the statements made in the preamble to the proposed regulations are valid, and that the references support these statements.

3. Cooked Versus Raw Molluscan Shellfish

144. Comments from a number of State agencies, trade associations, seafood processors, and the ISSC objected to the use of the terms ''raw'' and ''fresh or frozen'' in the title of part 123 subpart C and the text of the proposed regulations on shellfish. These comments were concerned because these terms would have the effect of exempting canned and any other heat-processed molluscan shellfish from the source control, recordkeeping, and

tagging provisions of subpart C of part 123 and § 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 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. Other comments requested that FDA clarify whether canned shellfish were included in subpart C of part 123 but did not suggest that canned and other heat-processed shellfish be included.

FDA has responded to these comments generally in response to comment 34, *supra.* The agency adds the following points:

It is important to recognize that foreign processors who export cooked molluscan shellfish to the United States now will have to have HACCP systems through which they identify and control hazards that are reasonably likely to occur. These hazards include heat stable toxins and chemical contaminants that would cause these products to be adulterated under U.S. law.

To further clarify that the requirements of subpart C of part 123 apply only to the processing of molluscan shellfish that are not heat treated or treated in some other manner by the processor to eliminate microorganisms of public health concern, FDA has modified the language at § 123.20 to read, ''This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.''

4. Shellfish Control Authorities

FDA proposed to require that processors only process molluscan shellfish that originate from waters approved for harvesting by a shellfish control authority. The term ''shellfish control authority'' is defined at § 123.3(o) to include foreign government health authorities that are legally responsible for the administration of a program that includes classification of molluscan shellfish growing areas.

145. Two trade associations questioned how a processor could evaluate the competency of a foreign shellfish control authority. They stated that FDA should require that a foreign country that exports shellfish to the United States have an agreement with the agency that establishes that a competent shellfish control authority exists in that country, and that the foreign shellfish program meets NSSP standards. One comment from a seafood processor argued that it would be unreasonable to require processors to verify that molluscan shellfish from all over the world are caught or cultivated in waters that meet NSSP standards. The comment stated, moreover, that a processor could not keep abreast of which countries have current shellfish agreements with FDA and which countries do not.

FDA acknowledges the merits of requiring that a foreign country that exports shellfish to the United States have an agreement with the agency but has concluded that, given the significance of such a requirement and the agency's failure to raise the possibility of imposing it in the proposal, it is beyond the scope of this rulemaking. Even though FDA is not imposing such a requirement, it is the case that the only means by which a processor can ensure that the molluscan shellfish of foreign origin that it receives are in compliance with the requirements of subpart C of part 123 of these regulations is by determining whether the foreign shellfish control authority is formally recognized by FDA. It is not likely that the processor could employ any other process that would give it assurance that molluscan shellfish harvesting waters that are approved by the shellfish control authority are properly classified. Such a determination is appropriately performed through government to government audit.

5. Shellfish From Federal Waters

146. Comments from a significant number of trade associations and seafood processors stated that a requirement that shellfish originate only in waters ''approved for harvesting by a shellfish control authority'' would preclude harvesting in Federal waters unless the Federal government introduced a formal approval process for waters under its purview through a Federal shellfish control authority.

Under the current system, State agencies are responsible for approving molluscan shellfish growing waters. However, State jurisdiction extends only to waters that are within three miles of the shore. Waters beyond that point but up to 200 miles offshore are under the jurisdiction of the Federal government. The comments pointed out that the harvesting of molluscan shellfish is permitted in all of the oceanic waters under Federal control unless there is a specific Federal action to declare an area unsafe under the provisions of the Magnuson Fishery Conservation and Management Act. The comments further noted that large volumes of molluscan shellfish are harvested in Federal waters.

How Federal waters will be classified, and by whom, has not been fully resolved. The comments are correct that the proposed requirement, if incorporated into the final rule, would pose significant problems for molluscan shellfish processors who receive product harvested from Federal waters. Therefore, FDA has modified § 123.28(b) to allow for the receipt of molluscan shellfish that are harvested in U.S. Federal waters except where such waters are specifically closed to harvesting by an agency of the Federal government. This provision is consistent with the provisions of the Magnuson Act.

It is worth noting that, by allowing Federal waters to be open unless they are specifically closed, this system is the opposite of the State system, under which waters are closed unless they are affirmatively classified so as to be open. This difference is reasonable from a public health standpoint because there is less likelihood that Federal waters will be affected by pollution than will near shore State waters.

Furthermore, because there is no Federal authority to license shellfish harvesters who fish in Federal waters, FDA has modified § 123.28(c) to require only that a harvester be in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish, rather than specifically requiring licensure.

6. Tagging and Recordkeeping Requirements

147. FDA proposed recordkeeping requirements for processors to follow with respect to shellstock and shucked molluscan shellfish in § 123.28 and requirements for the information to be included on the shellstock tag in § 1240.60. A few comments stated that

the proposed molluscan shellfish tag and record requirements were too specific, and that placing such requirements in the form of regulations would make it difficult to make timely changes to these requirements as future needs may dictate. The comments asserted that FDA or the ISSC may wish to modify the content or form of molluscan shellfish tags or records to improve product traceability. They suggested that FDA write the tagging and recordkeeping requirements at § 123.28 and § 1240.60 in general terms and allow the specific form and information required on the tags to be addressed by the NSSP. The comments went on to urge that, if the agency were determined to include specific tagging and recordkeeping requirements as part of the final regulations, they should be fully consistent with current NSSP guidelines.

It is not the agency's intent that the provisions of § 123.28 and § 1240.60 would preclude the ISSC or State agencies from adopting additional recordkeeping or tagging requirements. The recordkeeping and tagging requirements in these regulations are the minimum necessary to ensure that shellfish can be traced through distribution channels, back to the harvest source. FDA explained why each of the specific requirements is necessary in the preamble to the proposed regulations, and the comments did not take issue with the agency's explanation with respect to any of the particulars. Therefore, FDA disagrees with the comments that the recordkeeping or tagging requirements are more restrictive than they need to be, or that they would interfere with the NSSP tagging program.

Moreover, as stated previously, the agency has drafted the regulations broadly enough so as not to conflict with any improvements that the ISSC may wish to make in the form that a tag may take or in how information on tags is to be stored. The definition of the word ''tag'' at § 123.3(t) (added at § 1240.3(u) for consistency) reads, in part, ''a record of harvesting information attached to a container of shellstock * * *.'' This definition is sufficiently broad to include such systems as bar codes, embossed plastic, or other nontraditional methods of identification that may be used by the industry in the future. The agency is supportive of efforts to improve the existing methods of recording harvesting information.

Nonetheless, it is important for the regulations to identify the minimum specific information that must appear on a tag. During past illness outbreaks, FDA, State regulatory agencies, and industry have had difficulty tracing the implicated shellfish to their sources, especially after they have been in the possession of several different processors (Refs. 99; 100; 102–106; 109; 218; and 219, pp. 37–39). These difficulties in tracing the shellfish have occurred because the shellfish were not in compliance with the tagging and recordkeeping provisions of the NSSP. The requirements at § 123.28 will enable FDA to help the States to enforce minimum tagging and recordkeeping requirements for imported and domestic products. Moreover, the agency believes that placing the tagging and recordkeeping requirements in Federal regulations will emphasize the nationwide importance of this information in protecting the public health, as described earlier.

148. One comment noted that the NSSP does not specify that the name of the harvester must be on a molluscan shellfish tag, but that the proposed regulations would require this information.

The NSSP specifies that the number assigned to the harvester by the shellfish control authority must be listed on the tag. The agency recognizes that there may be a variety of effective ways to identify the harvester of the molluscan shellfish, depending on the method of harvest, State requirements, and local tradition. For this reason, the agency has modified § 1240.60(b) to read that the tag shall disclose:

> * * * by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel).

For consistency, FDA has made a similar change in § 123.28(c)(5).

149. A significant number of comments recommended that FDA modify § 1240.60(b) to allow bills of lading or other shipping documents to accompany bulk shipments of shellstock in lieu of tags, as long as they provide the same information. A few comments suggested that bills of lading or other shipping documents be used in lieu of tags on individual containers of shellstock when a shipment consists of a large volume of shellstock in sacks or boxes. Several comments asked for clarification of the impact of the proposed requirements on current repacking operations that commingle shellstock from various harvesters into one container.

FDA recognizes that an inconsistency existed between proposed § 123.28 and proposed § 1240.60 because the former would have allowed shipping documents to provide the required information for bulk shipment, and the latter would not. FDA agrees with the comments that recommended providing for the use of shipping documents and has modified § 1240.60(b) to provide the needed consistency. Under existing industry practice the truck, cage, or vessel hold serve the same purpose as a container for the shellstock, making tagging impractical. In that case, the shipping document serves the same function as the tag.

However, the agency does not agree with the suggestion that containers of shellstock in large shipments be allowed to be covered by shipping documents in lieu of tags. FDA cannot justify treating shellstock in large shipments differently than shellstock in smaller shipments, nor could the terms ''large'' or ''small'' be readily defined. Large shipments can be subdivided, perhaps many times, or commingled with other lots of molluscan shellfish. The source information would, therefore, be necessary on each container to ensure proper identification. Without tags, the identity of individual containers could be lost. FDA is requiring that all shellstock, even after repacking, bear a tag that identifies the prescribed information, including the identification of the harvesters to ensure that all shellstock is readily traceable (§ 1240.60).

7. Other Considerations

150. Comments from a few trade associations and from seafood processors stated that FDA should require a production code on each container of shucked molluscan shellfish. The comments suggested that the code consist of an identifying mark that allows the processor to determine where the remainder of the lot was shipped, and where and when the relevant shellstock was harvested.

FDA agrees that production codes can be useful on containers of shucked molluscan shellfish to facilitate trace back of questionable product. The agency encourages the use of codes by molluscan shellfish processors. However, such a requirement is not within the scope of the proposed regulations. The agency will consider whether such a requirement should be pursued in a separate rulemaking.

151. Comments from several consumer groups stated that if a warning label is not mandated by FDA on raw molluscan shellfish to alert at-risk consumers of the danger to health posed by the product, FDA should require that Gulf Coast oyster processors adequately cook the product to

eliminate risks from *Vibrio vulnificus* during periods when shellfish cannot be harvested free from this bacterium. They further stated that cooking should not be required when the shellfish are free from this bacterium.

FDA agrees that effective controls are needed to protect consumers from the hazard posed by *V. vulnificus* in Gulf Coast oysters during certain times of the year. The agency is evaluating the potential effectiveness of a variety of control mechanisms. Mandating specific mechanisms, however, would be outside the scope of this rulemaking. FDA is therefore taking these comments under advisement.

152. A few comments urged that the word ''processor'' be changed to ''certified dealer and licensed harvester'' throughout § 123.28 to make the terminology consistent with the NSSP and to clarify that these requirements apply to everyone who buys and sells shellfish before the shellfish reach the retail marketplace. The comments also recommended changing the word ''shipper'' to ''processor or packer'' in the provision that is codified at § 123.28(d)(3) in these final regulations to include the shucker, repacker, shipper, reshipper, or depurator.

As mentioned in the ''Definitions'' section of this preamble, the agency has concluded that the definition for ''processor'' covers all NSSP classifications of shellfish dealers, without specifically naming each one. For consistency throughout the regulations, use of the term will remain unchanged.

FDA agrees, however, that the word ''shipper,'' as the agency used it in the proposed regulations, could cause confusion because that term has a different meaning in the NSSP Manual of Operations. Therefore, FDA has changed the language of the final regulations to read ''packer or repacker.'' The certification number of the packer or repacker is readily available to the processor since it is required, under the NSSP standards, on each label of shucked product. For consistency, FDA has modified § 1240.60(c) to also read ''packer or repacker'' where it had previously read ''processor.''

153. A few comments stated that proposed § 123.28(b), which referred to molluscan shellfish that ''originate from growing areas that are approved for harvesting,'' appears to prohibit processors from using products from harvest waters classified under the NSSP as ''conditionally restricted.'' Under the NSSP, shellstock taken from such waters cannot be directly marketed for human consumption but can be ''relayed'' to an open growing area for harvest at a later date. In addition, the comments pointed out that the word ''approved'' is a formal classification designation used in the NSSP. These comments said that harvesting is permitted from areas with other than ''approved'' classifications but would appear to be prohibited under the provisions of proposed § 123.28(b). The comments suggested use of the term ''open'' growing waters, which would apply to several different NSSP harvest area classifications.

FDA agrees that the word ''originate'', as used in proposed § 123.28(b), is too restrictive and has revised this section to say ''harvested from.'' With regard to the word ''approved,'' FDA concludes that no change is warranted. The proposal neither adopted nor referenced the NSSP growing water classification system. The phrase ''approved for harvesting'' should not be construed to be limited to those waters classified by a State under the NSSP as ''approved'' areas. The phrase ''approved for harvesting'' is used in the final regulations for its common sense meaning (i.e., those areas from which harvesting is allowed), which FDA believes is appropriate.

154. For clarification purposes, definitions for the terms ''certification number'', ''shellfish control authority'', and ''tag'' have been added at § 1240.3(s), (t), and (u), respectively. These definitions are taken directly from § 123.3.

155. One comment urged that the regulations be modified to specifically state that a HACCP plan for raw molluscan shellfish that contains the controls specified in subpart C of part 123 is deemed to meet the requirements of § 123.6.

The agency disagrees with this comment. The requirements of subpart C of part 123 are designed to control the environmental hazards associated with the harvest waters from which molluscan shellfish are taken, particularly those relating to sewage-related pathogens, chemical contaminants, and natural toxins. For this reason, they must be included in the HACCP plans of all raw molluscan shellfish processors. However, they are not intended to control process-related hazards resulting from, for example, time-temperature abuse of the product, improper use of food additives, or metal fragments. To control these hazards, the processor needs to follow the general approach set out in subpart A of part 123. The agency has developed the two subparts to be complementary and has strived to eliminate any redundancy in their provisions. Thus, it is theoretically possible that a HACCP plan that contains the controls specified in subpart C alone of part 123 still might not meet all the requirements of § 123.6.

FDA has made two modifications in § 1240.60(b) for clarity only. Where the proposed regulations required that the tag identify the ''* * * place where harvested * * *,'' FDA has added, ''(by State and site).'' This change makes § 1240.60(b) consistent with § 123.28(c)(2). Additionally, where the proposed regulations stated that improperly tagged or labeled product would be ''subject to seizure and destruction,'' FDA has amended the language to read, ''subject to seizure or refusal of entry, and destruction.'' This change is to make clear that, for imported products, the appropriate regulatory procedure is refusal of entry, rather than seizure.

O. Compliance and Effective Date

1. Effective Date

FDA proposed that these final regulations be effective and enforced 1 year after the date that they are published in the Federal Register. The purpose of this proposed effective date was to provide processors with enough time to develop and implement HACCP plans. The agency invited comment on whether 1 year would be adequate.

156. FDA received more than 60 comments about the proposed effective date. Virtually all comments agreed that the agency should provide some period before the regulations become effective. The comments either agreed with a 1-year implementation period or requested a longer period of 2 years or more. There were also a number of comments that responded to the agency's question about whether implementation dates should be staggered based on such factors as size of firm and level of risk.

A minority of comments stated that 1 year for implementation is adequate. These comments argued that after 1 year, the industry would have had 3-years notice of the requirements. The comments argued that 3 years was sufficient total time to be informed about impending regulations. Another comment stated that one year might be sufficient for the seafood industry, but other food industries could need considerably more time.

Several comments recommended that FDA provide an implementation period of longer than 1 year but did not recommend a specific alternative. These comments were concerned that HACCP training would not be completed in time for a 1-year implementation date; that foreign processors would need more

time to implement HACCP; and that 1 year after Canada required HACCP for its seafood industry, only half of its firms had complied.

The largest number of comments on this topic recommended that FDA make the regulations effective 2 years after publication. The reason most often cited was that it will be more than 1 year before most of the affected firms can complete HACCP training. The next most frequently cited reason was that firms and trade associations needed more time for HACCP plan development. Several comments also discussed the time required to modify equipment and raise capital; to respond to initial, voluntary reviews of HACCP plans by regulatory agencies; and for Federal, State, and local officials to understand HACCP and how to enforce it and to arrange for cooperative enforcement. A few comments stated that FDA needs sufficient time to develop agreements with foreign countries.

Several comments contended that more than 2 years should be allowed to implement the regulation. These comments mentioned the cultural change that HACCP will require and concern about the impact that the regulations will have on small firms as well as on large firms with multiple products and lines. They also mentioned the time needed for training.

Over 20 comments recommended that FDA stagger effective dates. A majority of these comments stated that such a phased-in start-up should be based on product risk. The remainder of the comments split in favor of either considering both the size of a firm and the risk from the products it makes or just the size of a firm.

A smaller number of comments argued against a staggered start. These comments expressed the view that small firms and foreign products should not be treated differently and pointed out that all firms will already have had 3 years of notice. Some of these comments stated that it would be hard to justify staggering implementation based on risk when the illness data are so incomplete. Others expressed the view that administering a staggered start would use up valuable resources and only result in confusion; that staggering would put some firms at a competitive disadvantage; and that it might encourage procrastination.

After fully considering all of these comments, FDA agrees with the comments that suggested that a 2-year effective date is appropriate. Based on FDA's participation with the Alliance that is developing training materials for this program, FDA has come to realize that 2 years must be provided to establish training programs and to give participants enough time to take them. Two years is also the minimum time necessary to train regulatory personnel. The additional time is also necessary so that the States will have a full opportunity to understand and respond to the effects of these regulations. It will also increase the likelihood that more agreements with other countries will exist.

The additional year will also increase the opportunity for processors to engage in ''voluntary'' HACCP inspections in advance of the effective date in order to obtain preliminary, nonregulatory feedback from the agency on their progress.

The agency acknowledges that it has urged the industry to begin preparing for HACCP well before the issuance of these final regulations. However, as this preamble amply demonstrates, a significant number of questions were raised as a result of the proposal that could not be answered until now. Moreover, the entire support structure for HACCP, including the issuance of the first edition of the Guide and the development of training courses, model plans, and other forms of technical assistance that will be useful to the industry, and especially to small businesses, will not be in place in time to permit a 1-year effective date.

On the other hand, more than 2 years does not appear at this time to be warranted. The agency is concerned that additional time would adversely affect the momentum for this program without adding significantly to the likelihood that it will succeed.

On the other hand, FDA is sensitive to the need to ensure that small businesses will not incur an unreasonable threat to their survival by an effective date that is too short. The agency intends to monitor the progress of the industry after the regulations are published and invites feedback on this subject. If FDA determines that the effective date is placing a significant and unreasonable burden on the industry, particularly on small businesses, the agency would be willing to consider an extension for as much as one additional year or some form of additional technical assistance. The agency would consider whether the delay is needed for training, drafting plans, or taking other measures that directly relate to the installation of a HACCP system, or whether the time is needed to comply with existing CGMP's, which are a prerequisite for HACCP. FDA will likely be reluctant to give firms an extended period of time to achieve compliance with existing requirements.

FDA also finds that there is not an adequate basis at this time for staggering the starts based on size or risk. The arguments for and against staggering generally parallel those for and against exempting firms from these regulations altogether on the basis of either size or risk. These arguments are discussed in the section of this preamble entitled ''Should Some Types of Processors Be Exempt?'' In summary, a good case can be made that implementation by small firms should not be delayed because such firms account for much of the products with significant potential for risk, such as cooked, ready-to-eat products. Moreover, most seafood processors are small firms. Risk-based, as opposed to size-based, criteria for staggering firms would inevitably be arbitrary to some degree because data from foodborne illness reporting systems tend to skew the reports toward more easily diagnosable illnesses.

The comments received on the subject of staggering do not provide a ready way to overcome these problems. Moreover, the 2-year effective date (rather than 1 year as proposed), guidance, technical assistance, and training that will be available to all processors should make staggering much less necessary than it otherwise might have been.

As stated above, however, the agency welcomes feedback on the progress that processors are making to implement HACCP that could have a bearing on whether staggering or an extension of the effective date would be appropriate, especially for small businesses.

157. Several comments asked for a form of staggering based on when an inspection occurs before the effective date. These comments stated that processors who voluntarily submit to inspection under the regulations before the effective date and are advised that their HACCP systems are not yet in compliance with the regulations should have at least a 6-month grace period to correct the problems. The example given in these comments was that of a processor who is so advised 1 day before the effective date and thus is inevitably out of compliance on the effective date.

As reflected in the comments, inspections of HACCP systems before the effective date will occur because a firm desires feedback and volunteers for it when an FDA investigator arrives for an inspection. That feedback will constitute informal advice only and will provide training for the investigator as well as for the processor. There may be some advantage to a processor to obtain feedback and training sooner rather than

later, but the results will have no formal status with the agency and would not warrant an extension of the effective date.

The agency has heard considerable concern that it will automatically seek to seize or otherwise remove from commerce all products being produced under a HACCP system that is determined to be deficient in any respect. That concern is unfounded. The consequence of being out of compliance with HACCP requirements, on the first inspection after implementation or otherwise, is addressed throughout this section. In summary, FDA's reaction will depend, as it does today, on the overall public health significance of the deficiency.

2. Public Meetings

158. One comment suggested that FDA conduct public meetings to explain the requirements of these regulations to the seafood processing industry between the publication date and effective date of these regulations. The comment also encouraged a coordination of research, training, and educational efforts between industry and FDA in order to facilitate the implementation of this HACCP program.

FDA fully agrees with the comment. It is the intent of the agency to engage in a dialog with industry, through a combination of public meetings and discussions at trade association meetings, to facilitate a thorough understanding of the regulations. FDA's affiliation with the Alliance reflects the agency's commitment to a cooperative relationship among industry, government (Federal and State), and academia in the areas of research, training, and technical assistance.

3. Penalties for Noncompliance

159. A significant number of comments, from processors and trade associations, requested that FDA address how noncompliance with the mandatory sanitation control procedures will be handled. Several of these comments also requested that FDA describe the penalties that can be imposed upon a processor and its officers for: Failure of a processor to have and implement a HACCP plan; noncompliance with sanitation control procedures; and failure to meet minor requirements of the regulations, such as the lack of a signature on a document. One comment stated that FDA's legal authorities and enforcement procedures do not provide a means for the agency to respond in a manner that is related to the severity of deficiencies—that is, a less severe response to a less significant deficiency.

FDA has a longstanding practice of tailoring its regulatory response to the facts. A deviation from any of the provisions of these regulations, including those involving the control of sanitation, carries the potential for regulatory action pursuant to section 402(a)(4) of the act. However, FDA intends to enforce these regulations in a manner that focuses on those deviations that have the greatest potential for causing harm. It is not FDA's intent to pursue regulatory action against a product or a processor exclusively for clerical errors or minor errors of omission. To do so would certainly not be an efficient use of agency resources, nor would it be in the best interests of the consuming public.

The penalty provisions for food found to be adulterated are described at ''Prohibited Acts and Penalties,'' in chapter III of the act. The statutory sanctions that FDA may seek include seizure and condemnation of a food and injunction and criminal penalties against a person (i.e., a firm and its responsible management).

FDA may also use existing administrative procedures, such as warning letters and conferences with a processor, to bring instances of noncompliance to the processor's attention as it frequently does under its current inspection programs.

The agency cannot state precisely what type of action it will take when it detects a deficiency because FDA evaluates each deficiency on a case-by-case basis to determine the public health significance of the violation and the appropriate response.

4. Preapproval of HACCP Plans

In the preamble to the proposed regulations, FDA tentatively concluded that HACCP plans would not have to be submitted to the agency or otherwise preapproved before their implementation by processors. The reasons for the agency's tentative conclusion included: (1) HACCP plans should be judged in the context of the processing plant, a process best accomplished during routine FDA inspections of processing facilities; and (2) the agency does not have sufficient resources to review HACCP plans from all domestic and foreign seafood processors in advance of either HACCP implementation by the processor or the conduct of HACCP-based inspections by FDA.

160. Approximately 20 comments addressed this issue. About two-thirds of these comments, from consumer advocacy groups, processors, trade associations, and State government agencies, contended that a processor should be required to file a HACCP plan and obtain approval from FDA before implementing the plan. The remaining comments, from processors, trade associations, and a foreign government, agreed with FDA's tentative conclusion that HACCP plans need not be submitted to the agency or preapproved before they are implemented.

Some of the comments favoring preapproval argued that FDA should have control over the design of each plan before it is implemented to ensure that all of the CCP's are identified, and that appropriate records will be kept. Other comments contended that, in the absence of a preapproved plan, a processor may implement a plan that FDA would later judge to be inadequate, possibly raising concerns about the product already produced under the plan.

Several comments in opposition to preapproval argued that it would be too expensive and difficult for both FDA and the processors (the latter because implementation would be delayed while processors waited for FDA to preapprove the plan and every subsequent change to the plan). One comment expressed concern that, in formally approving a HACCP plan, regulatory authorities would assume some responsibility for the HACCP system of an individual processor.

A few comments stated that HACCP plans will evolve as operations are adjusted, based on the processor's verification activities. These comments argued that a requirement for the preapproval of HACCP plans would encumber a processor's ability to update its HACCP plan.

The resource situation since the proposal was issued in January, 1994, has not changed in any way that would make the preapproval of HACCP plans by FDA practicable. Thus, FDA's analysis of the comments has focused on whether a lack of preapproval raises significant implementation problems that the agency must address. The comments have not convinced the agency that it does. FDA finds that a preapproval system would unduly burden the agency's resources, without providing significant advantages to the public health. The effectiveness of a HACCP plan, including monitoring, recordkeeping, and verification, can best be evaluated under actual operating conditions.

The preapproval of HACCP plans is distinguishable from the situation for low acid canned foods, where FDA reviews submissions of scheduled processes and revisions to these processes without hinging that review on a visual inspection of the facility. For

low-acid canned foods, the submission relates solely to the adequacy of the cooking process to control one hazard (*C. botulinum*). This process lends itself to a paper evaluation.

FDA agrees with the comments that suggested that a requirement for agency approval of a processor's changes to an existing HACCP plan would unnecessarily slow the process of plan improvement. The ability to modify the plan quickly based on feedback from verification activities is an important aspect of HACCP that could be degraded by a preapproval requirement.

With regard to the concern that the lack of plan preapproval will expose a processor to risk of product loss if a HACCP plan, under which it had been operating, is deemed by FDA to be inadequate, the agency advises that there are several issues that should mitigate this concern. First, the agency is committed to providing guidance, in the form of the Guide, to assist processors in the development of HACCP plans that are likely to be acceptable to the agency. The Guide will be further discussed later in this section.

Second, FDA is convinced that the training requirements of these regulations will serve to inform the regulated industry about the expectations of the agency with respect to HACCP plan content. FDA is working closely with the Alliance to ensure that training reflects FDA policy.

Third, FDA recognizes and accepts that, for HACCP plans to be effective and efficient, they must be tailored to the operating conditions of the individual processor. Of necessity, this fact means that there may be multiple ways to control an individual hazard. Consequently, FDA investigators will be trained to objectively evaluate the processor's HACCP plan from the standpoint of whether it accomplishes its intended function (i.e., hazard control), rather than whether it follows any preconceived model.

Finally, as described earlier, for the HACCP program, FDA intends to respond proportionally to deficiencies that it finds during inspections. The nature of the agency's response will depend on the totality of the situation and on the public health implications of the deficiency. When circumstances permit, the processor will be given the opportunity to make appropriate corrections.

5. Filing Plans With FDA

161. A few comments stated that FDA should require processors to file HACCP plans with the agency, not necessarily to obtain preapproval, but to allow FDA to compile HACCP plans from all seafood processors. The comments suggested that FDA selectively audit a sample of processor HACCP plans from the file copies, perhaps based on product risk, the presence or absence of certain CCP's, or other relevant factors. Some of these comments recommended that FDA request voluntary submission of plans prior to the implementation deadline.

A file, or library, of HACCP plans of all seafood processors would likely present various benefits from the standpoint of trend analysis and program evaluation. The agency finds, however, that the burdens would outweigh the benefits, largely for the same reasons that rule out the preapproval of plans by FDA. For example, the library would have to be updated every time that any processor updated its plan. Therefore, FDA is not requiring that processors file their plans with the agency.

6. Third Party-Approval

162. Several comments urged FDA to include a provision requiring third-party approval of processors' HACCP plans, especially if preapproval by FDA is not required. The comments suggested that the lack of a requirement for a processor to use a disciplinary team approach to develop a HACCP plan, as suggested by the NACMCF, coupled with infrequent FDA inspections, could mean that a processor might operate for years without an appropriate plan. The comments noted that competent processing authorities are available to provide third-party plan approvals and audits.

On the other hand, one comment argued that a requirement for third party HACCP plan approval is not necessary. This comment stated that a nonregulatory first inspection would obviate any form of preapproval.

FDA recognizes that some processors may benefit from obtaining third-party assistance in developing their HACCP plans and in evaluating their implementation. An independent audit is often helpful in locating problems in a system and offers the benefit of bringing in expertise not always possessed by many seafood processors. FDA is aware that some processors have engaged in these kinds of arrangements in the past and encourages their use.

However, the agency cannot agree that third party assistance should serve as an ''approval'' for regulatory purposes. First, to maximize consistency and fair treatment, the responsibility for the initial HACCP plan evaluation (outside of the processor's own verification activities) belongs to FDA, through routine inspections of processing plants. Second, establishing, certifying, and auditing a network of third parties whose approvals FDA would automatically accept would impose significant burdens on the agency that FDA could not accommodate.

As discussed above, FDA is engaging in significant efforts to facilitate the development of appropriate HACCP plans. The overall high level of policy guidance and technical assistance that will be available to processors from FDA and a variety of other sources should minimize the incidence of processors developing and implementing plans that do not address those hazards that are reasonably likely to occur. Therefore, FDA is not providing for third-party approval of HACCP plans.

7. The First Inspection

In the preamble to the proposed regulations, FDA tentatively concluded that, after the effective date of these regulations, FDA's review of processors' HACCP plans and procedures would occur at the time of the routine establishment inspection. FDA requested comment on whether the first HACCP review should be nonregulatory, even though the inspection of the processor would otherwise be regulatory.

163. Approximately 30 comments, mostly representing processors and trade associations, addressed this issue. All but one of the comments asked that the first review of a processor's HACCP plan and procedures be nonregulatory. Approximately one-fourth of these comments further asked that the second such evaluation also be nonregulatory.

The comments stated that a nonregulatory visit by FDA would assist the processor in determining deficiencies in its plan without fear of enforcement action and would provide FDA investigators with hands-on experience in a HACCP-based inspection. The comments suggested that this arrangement would foster a cooperative spirit between the agency and the industry and would provide the time necessary for the investigator to discuss with the processor how the plan should be tailored to address the details of the processor's operation.

One comment stated that the initiation of a sweeping, new program will generate many questions and will necessitate innumerable judgments on the part of both processors and investigators. The comment suggested that it would be preferable for these questions and judgments to occur during nonregulatory visits.

On the other hand, one comment suggested that the first review of a processor's HACCP plan should be

regulatory, because once the effective date has been reached, compliance with the regulations should be enforced.

FDA agrees with the comments that suggested that a smooth transition to a mandatory HACCP system of preventive controls is more likely the result of dialogue than regulatory action. For HACCP to succeed, processors must be committed to it because they perceive benefits to themselves from its use other than simply the avoidance of regulatory sanctions.

FDA has concluded that a 2-year effective date, rather than the 1-year date that was proposed, will provide substantial opportunity for dialogue. Moreover, the proportional response to problems that FDA intends to employ, taking into account the newness of the system, should obviate many of the comments' concerns about excessive regulatory sanctions early in the process. Consequently, FDA concludes that an officially designated, nonregulatory first inspection is not necessary.

FDA has concluded that 2 years is sufficient time for a processor to train employees or secure properly trained consultants, perform a hazard analysis, develop a HACCP plan, and implement and evaluate HACCP control procedures that will comply with these regulations. The additional year will enable the agency's field investigative force and the industry to begin sorting out many of the issues that are likely to develop during implementation.

As stated earlier, the agency intends to perform informal HACCP evaluations of willing processors during routine inspections conducted during the 2-year implementation period. These evaluations should serve to aid the development of both the industry's HACCP programs and the agency's HACCP inspectional skills. They will also largely take the place of the proposed type of nonregulatory inspections.

FDA agrees with the comment that pointed out that the initiation of this program will generate many questions and issues that will have to be worked out between processors and the agency. Moreover, FDA accepts that, despite the years of groundwork and the pilot programs that have been the basis for agency policy decisions to date, there will be details that will have to evolve over time as the program is implemented. It is highly likely that this evolution will continue well after the effective date of these regulations. FDA will take this factor into account in its initial interactions with processors after the effective date. The agency may find it appropriate to use its regulatory discretion when it finds a basis for concern about a processor's HACCP plan or procedures that relate to a matter about which policy is still being formulated.

However, the agency is concerned that there could be significant problems if it officially designated its HACCP review during the first inspection as being nonregulatory. First, such a step could create unfair situations. For example, FDA could find itself in the position of pursuing regulatory action against one processor for failure to adequately control a particular hazard while, at the same time, treating a similar deficiency by another processor as ''nonregulatory.'' Second, it could foster actions by firms to avoid application of the regulations, such as name changes or reorganizations to create the argument that the ''new firm'' is entitled to a nonregulatory inspection. Third, it is not clear how long such a policy should last. Arguably, the reasons in support of a nonregulatory first inspection become much weaker in the case of a firm that goes into business for the first time a number of years after the effective date of the program.

For all of the foregoing reasons, FDA has concluded that it can accomplish the things that led it to inquire about the possibility of, and the comments to support, designating the first HACCP inspection as a nonregulatory inspection without making such a designation and creating the problems that such a designation could cause.

8. Role of the FDA Investigator

164. In the preamble to the proposal, FDA stated its tentative conclusion that its investigators would, among other things, evaluate the adequacy of processors' HACCP plans during routine inspections. A few comments objected to this role for the investigators. These comments stated that investigators should be responsible for verifying that the processor has performed a hazard analysis; developed a HACCP plan where warranted; implemented the HACCP plan; and recognized, corrected, and recorded deviations from the HACCP plan. The comments further stated that investigators should not be in a position to challenge the adequacy or design of a HACCP plan.

The comments pointed out that HACCP plans are tailored for each operation, designed by either a company team or a knowledgeable individual thoroughly familiar with the operation. They questioned whether an FDA investigator would have the expertise to determine the acceptability of the plan.

Many FDA investigators already have considerable training in HACCP and food science, and most have an academic background in the sciences. They will also receive training during the implementation period that focuses on compliance with these regulations. The investigators will be exposed to the Guide, among other sources, for information about potential hazards to be considered for particular products and processes. This exposure, coupled with investigators' experience with the industries with which they work, will give them a sound basis for making screening determinations about the adequacy of processors' HACCP plans. There is little doubt that the caliber of investigator screening decisions will improve with experience with these regulations and with exposure to more and varied processor HACCP programs. FDA is confident that its field investigative staff will quickly adjust to the task of fostering compliance with these regulations, as they have to past initiatives.

Where investigators are unsure about the adequacy of a processor's HACCP plan, they will have ready access to, and will be encouraged to consult with, district, regional, and headquarters experts. Investigators will also be instructed to discuss with plant management the reasons and scientific support for hazard analysis and HACCP plan decisions that are in question. Where, because of the complexity of a particular situation, the investigator cannot reach a decision about the adequacy of a particular aspect of a processor's HACCP plan, the investigator will be instructed to collect as much information, including supporting data, as is necessary in order to facilitate further agency review.

Therefore, FDA concludes that the existing system adequately addresses the concerns of the comments.

9. Disagreements and Appeals

165. A significant number of comments, primarily from processors and trade associations, stated that FDA should have a mechanism to resolve differences between an FDA investigator and a processor regarding the adequacy of the processor's HACCP plan, especially given the subjective nature of the determination as to what the hazards are that are reasonably likely to occur and that therefore must be controlled through HACCP. The comments contended that a cooperative discussion between FDA and the processor's HACCP experts would be preferable to an enforcement confrontation, and that this discussion would allow a processor to explain its decisions and procedures. Other comments urged FDA to formalize an

appeal process in the regulations that would establish a processor's rights to contest any HACCP compliance action by FDA. Moreover, these comments stated that FDA should not take enforcement action based on a disagreement in the field between an investigator and the developers of the plan.

As previously mentioned, agency investigators will be instructed to discuss their concerns about potential inadequacies in processor HACCP plans with the management of the firm in an effort to learn the basis of the firm's decisions. If the investigator retains concern that a plan is inadequate in some regard even after discussing it with the firm, the investigator will list findings on the report that is provided to the management of the firm at the conclusion of the inspection (Inspectional Observations, FDA483). The FDA483 only represents the opinion of the investigator and is not necessarily the final opinion of the agency. The investigator will document the processor's response to, or explanation of, the findings listed on the FDA483 report.

It has been longstanding FDA policy to conduct an internal review of investigators' inspectional findings before initiating regulatory action. There is an opportunity at each stage for discussion between the firm and the agency. These FDA review practices will not change under a HACCP-based system.

Based on the foregoing, the agency concludes that the concern expressed in the comments about possible precipitous compliance action as a result of the findings of FDA investigators is unwarranted. It is worth repeating that the agency intends to engage in conflict resolution through dialogue wherever possible and appropriate. Given these facts, FDA has concluded that a provision for a special appeals process for matters concerning these regulations is not necessary.

10. Status of the ''Guide''

In the preamble to the proposed regulations, FDA discussed the ''five preliminary steps'' to HACCP recommended by the NACMCF. These steps lead a processor through a logical process for identifying hazards that are likely to occur in a product and for developing a HACCP plan. In an effort to facilitate this process, especially for the many small businesses involved in seafood processing, FDA is developing the Guide, a draft of which was made available shortly after publication of the proposed regulations. The draft Guide provides information on hazards and appropriate controls by species and by product type. The preamble said that the information contained in the draft Guide is the kind of information that would likely result in a HACCP plan that is acceptable to the agency. FDA received considerable comment on the contents of the draft Guide and intends to publish a redrafted first edition shortly after the publication of these regulations.

166. A number of comments expressed concern about how the Guide would be used by FDA investigators when evaluating a processor's HACCP plan. The commenters were troubled by the prospect that FDA investigators would not be trained to evaluate HACCP plans that differ from the Guide, and that, therefore, they would take exception to a HACCP plan that deviates from the Guide. The comments stated that industry experience with HACCP demonstrates the need to provide flexibility so that HACCP plans can be tailored to the specific operating conditions of a processor.

Other comments stated that the Guide did not provide express guidance on the meaning of the key phrase ''reasonably likely to occur.'' The comments stated that the Guide should clarify whether it is FDA's intention that the hazards identified in the Guide are the ''reasonably likely'' hazards under all conditions for the specific species and processing operations that are listed.

Several comments cautioned that the Guide should not be characterized as a ''safe harbor,'' i.e., that FDA should not promote strict adherence to the Guide regardless of the circumstances. Such a characterization, they argued, could cause processors to omit the critical hazard analysis step in HACCP plan development and risk developing plans that do not fit the conditions of their processes.

The Guide is, in the agency's opinion, a compilation of the best available information on the subject of hazards and controls in seafood processing. It contains FDA's recommendations as to the hazards that it believes are ''reasonably likely'' to occur in specific species and finished product forms under ordinary circumstances, but it also provides information on rarer hazards as well. FDA recognizes that the first edition of the Guide must clearly distinguish between the two.

The term ''reasonably likely'' is now effectively defined in § 123.6(a). It is worth noting that, under § 123.6(a), whether a hazard is ''reasonably likely'' will depend, at least in part, on the circumstances that exist at the time that the hazard analysis is conducted. For example, a certain toxin might be rare, but if it starts presenting itself in fish and becomes known, it may warrant a new hazard analysis that may identify it as ''reasonably likely'' for a period of time.

FDA also recognizes that circumstances may occur in which hazards will exist that are not identified in the Guide. These hazards may be the result of a previously unidentified phenomenon (e.g., the identification of a natural toxin in a species previously not associated with that toxin) or of unique conditions in the way that the product is handled by a particular processor (e.g., unusual equipment or processing methods). Thus, a definitive determination of ''reasonably likely to occur'' can come only as a result of a carefully conducted hazard analysis performed for a specific product under specific processing conditions.

FDA recognizes that a HACCP approach requires flexibility and will endeavor to make the Guide consistent with such flexibility. FDA will provide training to its investigators so that they will be prepared to evaluate a HACCP plan that is not consistent with the Guide and to evaluate the effectiveness of controls that differ from those suggested in the Guide. The agency agrees that the Guide is not a ''safe harbor'' for all situations. Processors who utilize the Guide should compare it to their own circumstances and make whatever adjustments in the approach suggested in the Guide that are necessary.

11. Trade With the EU

167. One comment suggested that, because of directives issued by the EU, many processors may need early recognition of their HACCP programs by FDA. The comment further suggested that early recognition could be used by the agency as a means of training FDA inspectional personnel.

FDA is aware of the directives of the EU. The agency intends to consider how it can best help processors respond to those directives, among other factors, as it formulates its plans for implementation of these regulations.

12. Measuring Program Success

In the preamble to the proposed regulations, FDA asked for comment on what tests should be used to measure the success of the HACCP program as a whole, and how often those tests should be conducted.

168. A significant number of comments stated that indicators of the success of the seafood HACCP program could include: A reduction in the number of seafood-borne illnesses; improved consumer confidence in

seafood consumption; and a reduction in the number of violative products that enter the marketplace. Several comments stated that periodic inspections of, and sampling at, processors and importers by FDA, State, and foreign officials, coupled with illness reporting from a strengthened CDC program, would provide adequate verification of the effectiveness of the program. However, two other comments stated that the success of the seafood HACCP program cannot be measured solely by a decrease in illnesses, because many food-borne illnesses are the result of problems in the retail sector, which is neither covered by these regulations nor adequately regulated by the States.

The agency agrees with those comments that suggested that the ultimate goal of these regulations should be the improved safety of fish and fishery products—a reduction in the actual number of seafood-related illnesses. FDA will continue to closely monitor the CDC system, as well as reports of illness and death attributable to the consumption of seafood that it receives from other sources, for trends that may indicate an emerging problem or the intensification or modification of an existing problem. However, the agency also agrees with those comments that suggested that, because many of the seafood-related illnesses are attributable to recreational or subsistence fishing or to problems in the retail and food-service sectors (Ref. 7, pp. 2; 15; 27; and 28), improvements in process controls that result from the implementation of HACCP may not be fully reflected by a reduction in the number of illnesses. Additionally, as has been previously discussed, the CDC system encompasses only reported illnesses and is an imperfect means of judging reductions in actual numbers of illnesses. FDA is supportive of a strengthening of the CDC reporting system.

Based in part on the comments received, the agency will be looking at ways to assess a relationship between success of the HACCP program and levels of consumer confidence, levels of violative product in the marketplace, improvements in the quality and quantity of preventive controls throughout the industry; and the results of FDA and cooperating State and foreign inspections. As indicated in the summary of the Regulatory Impact Analysis elsewhere in this preamble, FDA is planning to evaluate key features of this program within the first several years of implementation. This evaluation will include an assessment of its effectiveness.

169. One comment suggested that end-product testing should be used by FDA for program surveillance purposes, particularly for imports. This comment encouraged FDA to conduct statistically reliable baseline and monitoring surveys, modeled after those used in the MSSP, conducted by NMFS, to: (1) Determine how often consumer hazards occur; (2) set specific goals, objectives, and operational strategies for the HACCP program; and (3) provide a means by which the program's success can be measured.

FDA has historically collected and analyzed surveillance samples during and outside the course of its routine inspections. The purposes for these sample collections, in many ways, align with those suggested by the comment. The agency is committed to continued surveillance sampling and intends to use such sampling in an assessment of the HACCP program.

170. Another comment suggested that HACCP will only be successful in improving confidence in seafood if the program is accompanied by a consumer education effort that explains the benefits of HACCP. The comment encouraged FDA to perform a baseline study that assesses the level of consumer anxiety with respect to seafood consumption and compare it to the results of a study that it performs sometime in the future.

FDA agrees that another major goal of these regulations is to increase consumer confidence in the safety of seafood. The agency recognizes that publication and enforcement of regulations aimed at improving seafood safety alone will not achieve that goal. Consumers must be informed of the benefits of producing products under HACCP preventive controls. Within its budgetary constraints, the agency intends to engage in a program of consumer education for that purpose. The prospect of baseline and followup studies of consumer confidence (or anxiety) will also be considered.

P. Other Issues

FDA received a number of additional comments that did not address any specific provision of the proposal, although some of them were in response to invitations in the preamble to comment on various subjects.

1. Relationship to Other Programs

In the preamble to the proposed regulations, FDA invited comment on how FDA's HACCP program for seafood processors should mesh with existing State HACCP programs for seafood, in order to avoid imposing inconsistent Federal and State HACCP requirements. In the preamble, FDA acknowledged that many States are under considerable pressure to cut back on programs where there is an overlapping Federal program. Nonetheless, the agency urged States to maintain, if not strengthen, their seafood programs and to work with FDA to develop an integrated Federal/State, HACCP-based seafood control program.

171. Approximately 12 comments, representing processors, trade associations, and State government agencies, recommended that FDA coordinate its HACCP program with existing State and Federal seafood control programs. Several comments emphasized that a coordinated effort would ensure uniform application and interpretation of HACCP principles, while preventing duplication of effort that wastes limited enforcement resources. One comment stated that such a coordinated effort would be facilitated if only a single HACCP plan were required for each processing facility, rather than one that was designed to meet FDA requirements and another that would meet State requirements. Another comment noted that a multitude of differing HACCP regulations would only serve to confuse processors and dilute the effectiveness of the Federal program. The comment further recommended that FDA work with AFDO to promote State laws and regulations that are compatible with FDA's HACCP program.

One comment suggested the formation of a task force representing the food industry, FDA, USDA, and DOC to work towards the goal of reducing regulatory duplication.

The agency agrees that there is a need for Federal/State partnership to facilitate the efficient implementation of HACCP programs. FDA believes that coordination with the States would permit both the agency and the States to leverage their inspectional resources. FDA, as well as the States, would benefit by dividing the workload and sharing data and other information. Such coordination would also benefit industry through consistent inspections and regulatory requirements.

The agency has already begun to coordinate its efforts with the States on seafood. The formation of the Alliance, to which AFDO is a member, is one such endeavor. The Alliance is described in detail in the ''Training'' section of this preamble.

With FDA's support, AFDO passed a resolution supporting the development of FDA/State partnership agreements at its 1994 meeting in Portland, ME (Ref. 220). The resolution specifically recommended that HACCP be the basis of such partnerships and noted the

shared roles of FDA and State regulators in seafood safety, the limited resources of both levels of government, and the existence and the potential impact of the Alliance.

Meanwhile, FDA is increasing its use of partnership agreements with State enforcement agencies. For instance, the Northeast Region of FDA has entered into a threeway partnership agreement with the Northeast Food and Drug Officials Association and individual States to provide industry with HACCP training at the retail level. FDA also expects to enter into partnership agreements with States to implement HACCP pilot programs for foods other than seafood. FDA's Northeast Region has already signed such an agreement with the Commonwealth of Massachusetts, and more are anticipated.

These initiatives demonstrate the agency's desire to coordinate its efforts with the States. The agency's cooperative efforts in the area of HACCP reflect a trend. The agency has used cooperative efforts in other areas, such as pesticide sampling and workplan sharing. FDA will continue to explore ways to coordinate the Federal and State role in the regulation of seafood.

172. A number of comments recommended that States act as the primary enforcement agencies for these HACCP regulations, while FDA's responsibility would be to evaluate the States' compliance with HACCP inspection protocols. Some of these comments suggested that such a program could be patterned after the NSSP.

FDA is adopting these HACCP regulations to implement and enforce the act. While FDA plans to work cooperatively with the States in all ways possible, the agency cannot delegate its authority under the act. It is possible that in some aspects of seafood processing, the States will serve as the primary enforcement agencies, with FDA serving primarily an auditing function. However, responsibility for enforcing the act and these regulations must remain with FDA.

173. A number of comments, from processors, trade associations, and one consumer advocacy group, maintained that FDA's HACCP regulations should preempt any existing State HACCP programs. The comments contended that Federal preemption would ultimately reduce confusion caused by conflicting State programs, reduce costs, and promote uniformity. Examples of the specific areas of conflict were not provided by the comments.

As was previously stated, FDA intends to work through AFDO and through Federal/State partnerships to seek consistency in State regulatory approaches to HACCP for seafood inspection and through the NSSP process and the ISSC to attain this goal specifically for molluscan shellfish. Moreover, processors in each State must comply with Federal HACCP requirements if their product moves in interstate commerce. For these reasons, the agency has concluded that there is no need for Federal preemption of State regulatory requirements.

174. Several comments encouraged FDA to work closely with NMFS to coordinate FDA's program with the existing NMFS' HACCP program. The comments noted that cooperation with NMFS would help the two agencies avoid wasteful duplication of effort and would reduce the burden on those firms already operating under the NMFS program.

FDA agrees with these comments and notes that FDA and NMFS are coordinating their HACCP programs to ensure compatibility. Nonetheless, FDA advises that the NMFS program is a voluntary, fee-for-service program and is likely to continue to include features that go beyond the requirements of these regulations, especially in the area of preventive controls for economic fraud and plant and food hygiene.

A 1974 MOU between FDA and NMFS recognizes the respective roles of the two agencies and commits the two agencies to consistency and cooperation. FDA will continue to work with NMFS to maintain a coordinated Federal effort.

2. ''Whistleblower'' Protection

175. A few comments urged that these regulations include ''whistleblower'' protection for employees of seafood processors. Whistleblower protection is designed to protect workers from being fired or otherwise discriminated against for revealing wrongdoing by their employers. The wrongdoing in this case, presumably, would likely involve the falsification of HACCP records. The comments argued that: ''Whistleblowers are iispensable as the eyes and ears for overextended FDA personnel making limited spot checks. The public's line of defense will be no stronger than the shield protecting industry worker's rights to obey and help enforce this law.''

One concern that FDA has heard about the credibility of a HACCP system is that important records can be falsified. It is alleged that, without whistleblower protection, it is much less likely that the agency will know about falsifications.

While the agency is confident, based in part on its experience reviewing records in the low-acid canned food program, that it can detect falsification, FDA also expects from experience that it will be alerted to possible wrongdoing from time to time by employees of processors even in the absence of whistleblower protection. FDA has received, and acted upon, confidential information from employees of regulated firms for decades. This assistance has proven invaluable on many occasions. The only protection to these employees available from FDA has been confidentiality.

The question raised by the comments is whether, in addition to the actions against the product or the processor that would be available to FDA as a result of violations of the requirements of the act and these regulations, there must be specific protection for employees in order for the program to succeed. The agency has concluded that, like other FDA programs, this program can be successful in the absence of specific whistleblower protection, and that congressional action would be necessary to provide protection other than confidentiality.

FDA cannot provide whistleblower protection in these regulations. FDA believes—and case law bears out—that there must be a nexus between the conduct being required by regulations and the focus of the underlying statute, in this case primarily section 402(a)(4) of the act. An analysis of the application of section 402(a)(4) of the act to these regulations can be found in the ''Legal Basis'' section of this preamble.

While FDA has determined that an assessment of processing risks and a plan that ensures that these risks are minimized has the requisite nexus to section 402(a)(4) of the act, and that this nexus justifies adopting these regulations, the agency does not see a sufficient nexus between whistleblower protection and the prevention of adulteration of food. If a firm retaliates against an employee who brings complaints or other information about the firm to FDA, the implication of such an action is that there is a condition at the firm that may need investigation, not that the products produced by the firm are necessarily adulterated. It may be the case that the products are adulterated, but such a conclusion does not flow as directly from section 402(a)(4) of the act as does the conclusion that seafood products not produced under a HACCP plan have been produced under insanitary conditions whereby they may have been rendered injurious to health. For this reason, FDA concludes that it lacks

clearcut authority to provide whistleblower protection in these regulations.

3. Separation of Quality Control (QC) and Production

176. A few comments requested that the regulations mandate structural independence within a processing firm between ''HACCP QC [quality control] personnel'' and ''production'' personnel. Otherwise, according to the comments, ''HACCP QC personnel could still be hired and fired by a production supervisor.''

FDA does not believe that a change in the regulations would be beneficial in this regard. It is important to recognize that, under HACCP, production personnel are the observer/operators who perform the initial monitoring of CCP's as well as the recordkeeping that documents the results of this monitoring. The operation of the HACCP system must involve the whole organization, not just QC personnel.

However, it is reasonable to expect that, where practical, verification activities should be performed by individuals other than those who made the records in the first place. For verification, the agency encourages the kind of organizational separation that is being urged in the comments.

The agency recognizes, however, that many seafood companies will not be large enough to have distinct, independent organizational units that can verify each other's work. The seafood industry is characterized by small businesses. FDA has concluded that such a requirement is not practical for this industry.

It is worth noting that the regulations at parts 113 and 114 for low-acid canned foods and acidified foods contain recordkeeping requirements and some verification requirements that are similar to the provisions of these regulations. In certain respects, parts 113 and 114 served as models for the seafood HACCP program. Those regulations have succeeded even though they do not require a separation between QC personnel and production personnel. Given this history, the agency is reluctant to mandate the internal structure of seafood processors.

4. Education

177. FDA received a number of comments on the subject of seafood safety education. These comments were in response to an invitation in the preamble to the proposed regulations for comments on risk reduction activities that could be regarded as complementary to HACCP, primarily directed toward postprocessing handling. In addition, FDA asked for comment on appropriate education and information that should be directed toward consumers and recreational fishermen, even though education aimed at these groups is actually outside the scope of this rulemaking. FDA made this request based on a recognition that HACCP cannot reasonably be expected to solve every problem. The agency recognizes that HACCP must be integrated into a comprehensive program for seafood safety. Education is another important component of that program. As one comment noted:

> * * * the responsibility for seafood safety should be met at every level of seafood distribution, from harvesters to processors to retailers, restaurants and, finally, the consumers themselves. Regulations are not a substitute for informed and responsible behavior and it is impractical to extend the scope of the proposed regulations to everyone involved in handling and consuming seafood.

The comments overwhelmingly endorsed the value of education. They strongly supported education for: (1) Consumers on the handling and purchasing of seafood, especially through brochures at the point of purchase and information available at pharmacies, and on the significance of HACCP, especially with regard to the government's verification role; (2) recreational fishermen, provided by the State during licensure (with guidance from the Federal government) and through articles in popular fishing and outdoors magazines; (3) subsistence fishermen; (4) retailers, including food service and restaurants.

FDA greatly appreciates these comments. The agency agrees that education is an essential complementary activity to HACCP as well as to other aspects of FDA's overall seafood program. The comments will be taken into account as the agency develops its educational program.

178. FDA also invited comment on whether the agency should consider proposing to require handling instructions for consumers on the labeling of seafood. Any action that FDA were to take along these lines would be as part of a separate rulemaking.

The agency received about 20 comments on this issue. Approximately half of those comments supported the notion of mandatory safe handling instructions. One business noted that safe handling instructions would help to ensure the safety of a product through the distribution chain, while another business said that such instructions had a real potential to decrease seafood-related illness. One individual commented that safe handling instructions would increase consumer confidence in these products. One industry comment noted that a task force composed of industry, Federal and State agencies, and consumers should agree on the appropriate statement. Some comments indicated that safe handling instructions might be appropriate for high-risk products.

The remainder of the comments on this issue disagreed that safe handling instructions for seafood should be required by FDA. Many of these comments noted that most seafood products include such instructions voluntarily. One trade association commented that such a requirement would limit retailers' flexibility and creativity and impose significant new costs on retailers and consumers. Most of those comments noted that requiring new information would detract from other labeling requirements.

FDA appreciates these comments and the different points of view that they represent. The agency will use the comments in its deliberations on this issue.

179. Finally, FDA described some of its educational efforts aimed at medically compromised individuals about avoiding raw molluscan shellfish and invited comment on types of education and information activities that might be useful in this regard. The agency received about a dozen comments on this subject.

Most of these comments addressed whether there should be mandatory warning labeling for raw molluscan shellfish. A majority of the comments stated that the agency should require warning labeling. Three comments from consumer groups stressed the need to protect high-risk individuals. One State government commented that warnings for raw molluscan shellfish should be tied to specific locations and times of year. One professional association requested that the warning state that the shellfish should only be eaten if it is certified and tagged.

Three comments stated that warning labels would be inappropriate. One comment noted that shellfish are not consumed in enough quantity to be a problem. Another comment stated that warning labels would unduly alarm those not at risk and that better channels exist for educating those at risk.

A few comments did not specifically address warning labels but recommended that FDA target advice directly to compromised individuals. Those comments suggested that FDA direct information to the medical community involved in the treatment of those individuals.

Again, FDA thanks the comments for providing views on a matter that is outside the scope of this rulemaking. FDA is working to provide information to at-risk populations and its strategy on how best to do so is evolving. The agency will take the comments into account as it develops policy in this area.

In summary, the agency agrees that education is an essential complementary activity to HACCP as well as to other aspects of FDA's overall seafood program. The comments relating to education will be useful to the agency as it develops its education programs.

5. Traceback Mechanisms

180. One comment recommended that FDA develop and incorporate methods to trace back fish and mandate such traceback in these regulations. The comment described the use of bar codes and computer-based tracking numbers by a meat products company that enable it to trace a specific cut of meat from a store or restaurant to its source.

The agency acknowledges that traceback to the water would be useful for certain species of fish associated with certain hazards, e.g., ciguatoxin. On the other hand, traceback to the water for scombrotoxin would not be particularly useful, although traceback through the distribution chain to find out the source of mishandling would be useful. The agency urges the industry to consider this comment. FDA advises that it is willing to explore this idea further, although not as part of this rulemaking.

6. Tribal Governments

181. FDA received a few comments on the effect of these regulations on tribal governments. The preamble to the proposed regulations noted that Executive Order 12875 of October 26, 1993, requires, among other things, consultation with tribal governments before the formal promulgation of regulations containing unfunded Federal mandates. While FDA does not believe that these regulations impose an unfunded Federal mandate, the agency wishes to foster consultation on matters that might significantly affect tribal communities. Consequently, FDA requested comment on the economic effect of the regulations on tribal governments.

FDA received no comments from tribal governments. One comment, from a tribal business, stated that the impact of the regulations on tribal governments will be beneficial because they will result in safe products, positive consumer perceptions, and positive market impacts. The other comment that mentioned this subject was from an academic, who expressed the view that the regulations will have a major impact on tribal groups involved in fisheries and contains unfunded Federal mandates. The comment did not elaborate. Neither of these comments justifies any change in these regulations.

The agency remains interested in fostering consultation with tribal communities as they see fit and encourages correspondence from tribal governments.

7. HACCP System Improvements

182. A comment urged that there be a process to continually amend or update these regulations.

FDA points out that such a mechanism exists in its regulations. Under § 10.30 (21 CFR 10.30), interested persons are provided with a process by which they can petition the agency to amend and update these regulations.

From a less mechanistic viewpoint, the agency recognizes that these regulations represent a pioneering program that has not been attempted before. While the agency believes that sufficient groundwork has been laid to adopt these regulations and to begin to implement them, FDA also acknowledges that full scale implementation will reveal modifications that may be necessary, both in the short and long terms. Consequently, the agency will be highly receptive to feedback from all parties who are affected by these regulations and will remain open to changes that are necessary in the regulations. The ''Verification'' section of this preamble reflects the agency's interest in evaluating this program.

183. A number of comments asked for improvements in the foodborne-illness reporting system operated by CDC. Some comments urged collaboration between FDA and CDC. One comment advocated the creation of an active reporting system.

These comments are essentially outside the scope of this rulemaking. Nonetheless, the agency recognizes that the strength of the foodborne-illness reporting system bears directly on the ability of the agency to measure the public health impact of HACCP. Both FDA and CDC agree that underreporting is an undesirable feature of the current system. FDA and CDC have been collaborating on an active-type reporting system. The limiting factor, however, will always be resources. Significant improvements in the current system will involve considerable expense.

184. One comment provided views on factors that would limit the effectiveness of HACCP. The comment cited:

> [P]oor commitment by company management and lack of allocation of necessary resources; improper training; lack of understanding and planning in all stages of implementation of a plan[,] and failure to recognize the need to understand the corporate culture change which must accompany an effective HACCP program.

FDA agrees with this comment but hopes that company management will embrace HACCP and recognize the benefits that it offers to the firm.

III. Paperwork Reduction Act of 1995

This final rule contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collections are shown below along with an estimate of the annual recordkeeping and periodic reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Reporting and recordkeeping requirements for processors and importers of fish and fishery products under the provisions of 21 CFR parts 123 and 1240. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products.

Description: This regulation implements the use of Hazard Analysis and Critical Control Point (HACCP) methodology to ensure that processed and imported fish and fishery products are safe within the meaning of sections 402(a)(1) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) and 342(a)(4)).

Description of Respondents: Businesses or other for profit organizations.

Although the January 28, 1994, proposed rule provided a 60 day comment period (extended to 90 days in the April 7, 1994, Federal Register, 59 FR 16578) under the Paperwork Reduction Act of 1980, and this final rule incorporates the comments received, as required by 44 U.S.C. section 3507(d), FDA is providing additional opportunities for public comment under the Paperwork Reduction Act of 1995, which applies to this final rule and was enacted after the expiration of the comment period.

Therefore, the agency solicits public comment on the information collection requirements in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper

performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Individuals and organizations may submit comments on the information collection requirements by February 16, 1996, and should direct comments to FDA's Dockets Management Branch (address above).

Prior to the effective date of this final rule, FDA will publish a notice in the Federal Register when the information collection requirements in this rule are submitted for OMB approval, and again when OMB makes a decision to approve, modify or disapprove the information collection requirements.

Sections of this final rule require that certain businesses collect information and keep records. Under Public Law 104–13 Federal agencies are required to estimate the hours and costs attributable to collections of information, as defined in 44 U.S.C. 3502(3), that are required by Federal regulation. Table 1 sets forth an estimate of the hours that are required annually for compliance with each section in part 123 that requires regulated entities to collect or record information.

TABLE 1.—ESTIMATED AVERAGE ANNUAL INFORMATION COLLECTION AND RECORDKEEPING BURDEN

21 CFR	No. of respondents	No. of responses per respondent [1]	Hours per response [2]	Total hours
123.6(a),(b),(d)	4,850	1	16	77,600 [3]
123.6(c)(5)	4,850	4	0.3	5,280
123.8(a)(1),(c)	4,850	1	4	19,400
123.12(a)(2)(ii)	1,000	80	0.2	16,000
123.6(c)(7)	4,850	280	0.3	470,400
123.7(d)	1,940	4	0.1	1,940
123.8(d)	4,850	47	0.1	22,795
123.11(c)	4,850	280	0.1	135,800
123.12(c)	1,000	80	0.1	8,000
123.12(a)(2)	20	1	20	4,000 [3]
123.10	24	1	24	116,400 [3]
First year total burden hours	.....	.....	.....	877,615
Annual recurring total hours	.....	.....	.....	679,615

[1] Based on an estimated average of 280 working days per year.
[2] Estimated average time per 8 hour work day unless one time response.
[3] Nonrecurring burdens.
The above estimates include the information collection requirements in the following sections:
123.16 Smoked Fish—process controls (see 123.6(b))
123.28(a) Source Controls—Molluscan Shellfish (see 123.6(b))
123.28(c),(d) Records—molluscan shellfish (see 123.6(c)(7))
123.9 Records control general (see recording and records)

The time and costs of these activities will vary considerably among processors and importers of fish and fishery products, depending on the type and number of products involved, and the nature of the equipment or instruments required to monitor critical control points. The burdens have been estimated using the typical small seafood processing firm as a model because these firms represent a significant proportion of the industry.

The burden estimate in Table 1 includes only those collections of information under this rule that are not already required under current statutes and regulations and are being added by this rule. For example, the current good manufacturing practices provisions in 21 CFR part 110 already require that all food processors ensure good sanitary practices and conditions, monitor the quality of incoming materials, monitor and control food temperatures to prevent bacterial growth, and perform certain corrective actions and verification procedures.

In addition, the estimate does not include collections of information that are a usual and customary part of businesses' normal activities. For example, the tagging and labelling of molluscan shellfish (§ 1240.60) is a customary and usual practice among seafood processors. Consequently, the estimates in Table 1 accounts only for new information collection and recording requirements attributable to part 123.

There are no additional capital costs associated with this regulation that are not also attributable to the preexisting requirements of part 110.

FDA estimated in the proposal that the total burden to all respondents would be 2,826,850 hours. That estimate, however, significantly overestimated the burden because it included activities performed by domestic processors that are not related to information collection and recordkeeping, and, more significantly, did not account for existing regulatory requirements and usual and customary business practices, as described above.

The agency has recalculated the recordkeeping burden in a manner that is more consistent with the intent of Public Law 104–13. Therefore, the burdens presented in Table 1 are those actually associated with collecting and recording the pertinent HACCP information. The burdens for HACCP plan development, plan reassessment, and record review are also included in the recalculated burden. In estimating the time for the preparation of a HACCP plan, the agency believes that a significant portion of the training hours can also be characterized as time spent on preparation of the plan.

Additionally, the agency recognizes that the regulations will place a burden on seafood importers. For this reason, FDA has included in the burden

estimate the time necessary for importers to develop a written verification plan, verify compliance of imports, and keep records of their verification activities.

Few comments provided information on the number of hours that a processor would expend on information collection and recordkeeping, as described in the preamble to the proposed regulation. One comment estimated that the annual burden would vary from 200 to over 700 hours, depending on the type of product, and another comment suggested that one hour per day, or 365 hours per year, would be required. One comment stated that the agency's estimate of 650 hours per year was reasonable. Another comment estimated four to five hours per day, or 1,820 hours per year as the likely burden. None of these comments provided information to support how the commenters arrived at their estimates.

It seems likely that the estimates suggested by the comments were calculated based on the same errors that the agency made in the proposal, that is, by combining the burdens associated with HACCP data collection and recordkeeping with other HACCP activities unrelated to information collection and recordkeeping, with usual and customary information collection and recordkeeping practices, and with collections of information required by the provisions of the Federal Food, Drug, and Cosmetic Act and implementing regulations. This conclusion is supported by the fact that some of the comments expressed agreement with the agency's calculations. For these reasons, FDA concludes that no changes in its corrected calculations are necessary to respond to the comments.

IV. Economic Impact

A. Introduction

In accordance with Executive Order 12866 and the Regulatory Flexibility Act, FDA has examined the impacts of the final rule. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act (Pub. L. 96–354) requires analyzing options for regulatory relief for small businesses.

The Unfunded Mandates Reform Act (Pub. L. 104–4) requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation). The Unfunded Mandates Reform Act also requires (in section 205) that the agency identify and consider a reasonable number of regulatory alternatives and, from these alternatives, select the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule. Even though FDA finds that the costs of this final rule may be below $100 million a year, estimating these costs is a difficult task involving uncertainties. This analysis, together with the preamble published in the Federal Register and supporting analysis and materials, constitutes a final RIA. Therefore, FDA has treated the final rule as an economically significant regulatory action under Executive Order 12866. Consequently, the agency has completed this full RIA which demonstrates that this rule is consistent with the principles set forth in the Executive Order and in these two statutes. In addition, this document has been reviewed by the Office of Management and Budget as an economically significant regulatory action under Executive Order 12866. FDA has concluded that the net benefits of this rule (benefits minus costs) are largest for the regulatory option selected as specified by Executive Order 12866. FDA has also concluded that, pursuant to the Unfunded Mandates Act, the regulatory option selected is the least burdensome option to accomplish the goal of controlling all physical, chemical, and microbiological hazards reasonably likely to be present in seafood.

As a part of the preamble to the proposed regulation, FDA published a summary of the Preliminary Regulatory Impact Analysis (PRIA) and placed on file with FDA's Docket Managements Branch the complete PRIA. In addition, FDA has placed the full final Regulatory Impact analysis on file at Dockets Management Branch (address above).

FDA has fully reviewed the information on which the PRIA was based, the comments on the PRIA, and other available information on the costs and benefits of HACCP for the seafood industry. Based on this review, FDA has arrived at two estimates of the costs in this final rule as well as upper and lower estimates of benefits. As can be seen in the agency's summary of costs and benefits are summarized in Table 2, FDA believes that the costs of the final rule will range from $677 million to $1.488 while the benefits will range from $1.435 to $2.561 billion. In its final analysis, the agency maintains that the total benefits of this mandatory seafood HACCP rule will exceed the total costs.

Regulatory Options

The agency raised and received comment on a number of regulatory options in the PRIA. The most significant two options raised were regulating only high risk products or the most serious hazards and providing regulatory relief for small businesses. The first option is inconsistent with the objective of this regulation, to control all physical, chemical or microbiological hazards reasonably likely to be found in seafood products. Although FDA has not granted relief only for small business, the agency has extended the compliance date for all firms from 1 year to 2 years.

TABLE 2.—SUMMARY OF TOTAL COSTS AND BENEFITS

Year	Costs from FDA models (millions)	Costs adjusted from NMFS model (millions)	Benefits lower (millions)	Benefits upper (millions)
1	$69	$162	$73	$108
2	42	9173	108	
3	41	83	85	156
4	38	80	87	158
Total[1]	677	1,482	1,435	2,561

[1]The total defines the total discounted costs and benefits beyond the 4th year and discounted at 6 percent.

B. Costs

In the PRIA, FDA was reluctant to rely only on results of the limited experience with HACCP in the seafood industry. FDA balanced the reports of some seafood firms, which showed that the costs of HACCP were low, with a study of the costs of HACCP that had been done under contract with NMFS by A. T. Kearney, Inc. (Contract No. NA88AA–H–SK006). This study showed significantly higher costs (as reflected in the range of cost estimates summarized above) but had several flaws that engender skepticism about its results as well. For example, none of the plants that were the subjects of the study had actually implemented HACCP, and the system whose costs were studied was significantly more demanding than the system embodied in the 21 CFR part 123. Despite these facts, the cost estimates in the PRIA were based on the results of the NMFS study because FDA considered it to represent the best evidence available at that time.

As explained more fully below, FDA used modeling technique and the experience reported about seafood firms to produce estimates that are in general agreement and that are approximately one-fourth of those estimated in the NMFS study reported in the PRIA.

In estimating the costs in this PRIA, there are three checks that have helped ensure the accuracy of the costs that would be imposed by adoption of this regulation. The first is the cost comments, but these, the agency's analysis revealed, were in most cases rather general, not well supported, and of only marginal assistance. The second is modeling by FDA experts based on their experience with the use of HACCP in the seafood industry; working with aquatic species and the public health problems that they present; inspecting and studying both seafood plants and low acid canned food plants (which have operated under HACCP principles for almost two decades); and participating in the FDA–NMFS seafood pilot. The results of this modeling are detailed below. The third source is information that FDA received from firms that have actually implemented HACCP. Even though FDA finds that the costs of this final rule may be below $100 million, estimating these costs is a difficult task involving some uncertainties. The agency recognizes that the rule may affect in a material way a sector of the economy. Therefore, FDA has treated the final rule as a significant regulatory action under Executive Order 12866. Consequently, the agency has completed a full Regulatory Impact Analysis.

The agency received approximately 230 comments on issues involving the PRIA. These comments are fully summarized and addressed in the full RIA which is included in the record as Reference 229. However, because of the problems with these comments noted above, FDA did not generally use them in the revised estimates reported here and in the full RIA. The reasons for this are more fully explained in the full RIA.

These adjusted NMFS model cost estimates result in per plant costs for domestic manufacturers of $23,000 in the first year and $13,000 in subsequent years. Total costs for compliance with these regulations using the adjusted NMFS data are shown in Table 3. FDA has also concluded that the PRIA represents a reasonable upper estimate of the costs of HACCP. Table 3 also summarizes the specific cost estimates that FDA arrived at using data from the NMFS model with cost refinements received from commenters and FDA seafood industry experts.

TABLE 3.—DISAGGREGATED COSTS FROM ADJUSTED NMFS MODEL

	Million
1st Year:	
Domestic manufacturers and Importers	$112
Major plant repair and renovation	13
Sea Grant expertise	1
Repackers and warehouses	14
Harvesters for rejected raw product	1
Shellfish vessels	3
Foreign processors	18
Total	162
2d Year:	
Domestic manufacturers	65
Sea Grant expertise	1
Repackers and warehouses	14
Shellfish vessels	1
Foreign processors	10
Total	91
3d Year:	
Domestic manufacturers	65
Sea Grant expertise	1
Repackers and warehouses	14
IQF Shellfish plants	3
Total	83
4th Year:	
Domestic manufacturers	65
Sea Grant expertise	1
Repackers and warehouses	14

TABLE 3.—DISAGGREGATED COSTS FROM ADJUSTED NMFS MODEL—Continued

	Million
Total	80

Total discounted costs beyond the 4th year and discounted at 6 percent, the costs are $1,482 million.

1. Alternative Model for Estimating the Costs

In addition to the cost estimate based on the NMFS modeling, FDA is presenting a second cost estimate for these regulations. The uncertainties associated with the choices made by seafood processors to control hazards justify providing a range of potential costs based on more than one model.

In examples created by seafood experts within FDA, the cost of compliance with these regulations was estimated for two small hypothetical seafood processors that the agency believes to be representative of a significant portion of the seafood industry. One of the plants is assumed to be in substantial compliance with existing CGMP requirements. Therefore, the costs experienced by that plant are attributable exclusively to the establishment and maintenance of a HACCP system. The other plant has some CGMP deficiencies that the agency believes are typical of those displayed by seafood processors. This plant is identical to the first plant except for the CGMP deviations. The costs calculated for this second plant represent the cost associated with the establishment and maintenance of HACCP as well as costs associated with the correction and monitoring of sanitation conditions.

The models concern two plants that cut and package tuna which is received frozen and that also distribute orange roughy fillets. The complexity of the processing operations, and the nature and number of hazards, are assumed to be roughly equivalent to that of the other types of operations. FDA recognizes the difficulty in validating these assumptions. Nonetheless, the results demonstrate that processors may have costs that are significantly below the averages estimated by means of the NMFS report. As discussed later, data received from firms that have implemented HACCP are generally supportive of the results of this modeling.

a. *Small plant cost example 1.* This is the example of a firm that is a processor of frozen tuna steaks and distributor of imported orange roughy fillets who receives all fish frozen. This plant is

located in a major seafood processing region, so there is no need for plant personnel to travel to other cities to receive training as it would be available locally. This processor operates 280 days per year. The plant manager is paid $15 per hour and production workers are paid $8.50 per hour. No food safety hazards are reasonably likely to occur in orange roughy, so a written hazard analysis shows hazards for tuna only. This processor has no need to make CGMP improvements so the plant costs are limited to the following:

(1) Training—($760). This is calculated as follows: $400 tuition plus the opportunity cost of training time ($24 hours x $15 per hour). The processor is expected to do most of the hazard analysis during the class.

(2) HACCP Plan Refinement—($240). This is calculated by taking 16 hours billed at $15 per hour using the FDA Fish and Fishery Products Hazards and Controls Guide.

(3) Plant Sanitation Audit—($0). This is done 3 times daily for 20 minutes each time. However, because the firm is modeled as being in compliance with existing CGMP's, it is assumed that these audits are already being done. It is assumed that there is a negligible cost for recordkeeping.

i. *Critical Control Points (CCP).* (4) Receiving CCP (histamine)—($3,200). This processor gets a freezing log from the tuna harvester and makes a visual check of the fish to see that they are frozen. The processor keeps a copy of the freezing log and makes a note of the visual check. The fish are then transferred to a plant freezer. The monitoring takes 15 minutes per lot for 4 lots per day. Similar monitoring is already occurring and the marginal cost for the recordkeeping is negligible.

The processor drills a representative sample of each lot and performs an organoleptic examination for decomposition of the tuna. It is assumed that this monitoring is not being done previous to this regulation and takes 20 minutes per lot for 4 lots per day. Monitoring is billed at $8.50 per hour. Also, there is a cost for a new drill ($50) and it is assumed that recordkeeping costs are negligible.

(5) Cutting CCP (metal fragments)—($0). A worker checks the saw blade at every break to look for broken saw teeth and keeps a log of checking on the teeth. Monitoring takes a few minutes per break. It is assumed that there is a negligible marginal cost for the monitoring and recordkeeping. Fish is weighed, packed, labeled and returned to the freezer.

ii. Corrective actions. (6) Problems with incoming product—($0). It is expected that product rejects in the first year would be higher but they would return to current levels in the second year as harvesters became aware of the processor's new requirements. The total cost for the industry is $1 million for the first year and zero in the following years. Because harvesters and not processors bear the cost of rejected raw product, this cost is included in Table 4 as a separate line item and not in Table 3 which includes only costs borne by processors.

(7) A saw tooth breaks every two years—($20). A worker needs to examine potentially affected product every 2 years. This is expected to take 4 hours billed at $8.50 to check two hours worth of cutting.

iii. *Verification.* (8) Record review—($400). This involves a review of five sanitation records, five receiving records, and a log book for the cutting operation. These are expected to be very simple (e.g., check mark records). Consequently, this review is expected to take 30 minutes per week billed at $15 per hour.

(9) Review hazard analysis & HACCP plan—($60). This is expected to take 4 hours per year at $15 per hour.

(10) Administrative changes—20 percent of all of the other costs in the first year and 10 percent in the second year.

b. *Small plant cost example 2.* The categories of costs that are different from Example 1 are explained below.

(1) Plant Sanitation Audit—($2,800). This will need to be done 3 times daily taking approximately 20 minutes for each audit. It is assumed that some minimal sanitation assessment is already being done once per day, but an additional 40 minutes would be required to perform three adequate audits. Again, it is assumed that there is a negligible cost for recordkeeping.

(2) Extra Equipment Cleaning and Sanitizing—($2,480). This is assumed to take 1 hour per day billed at $8.50 per hour. Also, additional water, and cleaning and sanitizing materials are assumed to cost $100.

(3) Eliminate Fly Infestation—($330). Torn screens need to be repaired taking 2 hours billed at $8.50 per hour. Also, screening materials assumed to cost $15 are needed. An exterminator to apply pesticides costs $300.

Table 4 represents the models described above in tabular form.

TABLE 4.—FDA MODELS OF SMALL PLANTS

Category	Small plant 1 (no GMP costs)		Small plant 2 (GMP costs)	
	Year 1	Year 2—	Year 1	Year 2—
Training	760	0	760	0
HACCP plan refinement	240	0	240	0
Sanitation audit	0	0	2,800	2,800
Receiving CCP	3,200	3,200	3,200	3,200
Cutting CCP	0	0	0	0
Sawtooth monitoring	20	20	20	20
Record review	400	400	400	400
HACCP plan review	60	60	60	60
Equipment cleaning	0	0	2,500	2,500
Eliminate pests	0	0	330	0
Administration	940	370	2,100	900
Per plant costs	$5,600	$4,000	$12,400	$9,900

In order to estimate an average plant cost from these FDA model plants, FDA assumed that, based on the results of the agency's 1990/1991 survey of the seafood industry, 20 percent of small firms are similar to the model plant that requires some GMP improvements (Small Plant 2) and that 80 percent of the small firms are similar to the model plant that is in compliance with current CGMP's (Small Plant 1). The agency has also assumed that the cost of

compliance for large firms is the same as that of small firms. There are offsetting considerations that have led the agency to make this assumption in this model. For example, agency experience suggests that it is likely that small firms will, on average, have larger sanitation costs and thus incur greater expenses to rectify existing CGMP deviations. Large firms, on the other hand, are more likely to have a greater number of products and processing lines, resulting in greater costs of plan development and monitoring. However, the agency believes that large firms are more likely to already have preventive controls, formalized sanitation programs, and record keeping systems in place than small firms. Additionally, large firms are more likely to take on new monitoring regimes with their existing quality control and production staffs than are small firms. The agency believes that these considerations would counteract each other and should result in fairly equal costs for large and small firms.

To complete the FDA model, FDA assumed that exporters (one- half of the 1,000 large firms) would only need to spend $1,000 in order to comply with this rule. Combining the two plant total costs as reported in Table 4 and weighting the proportion of the industry they are assumed to represent, average plant costs are estimated to be $6,400 in the first year and $4,800 in subsequent years.

The foreign processor costs associated with this rule and passed on to U.S. consumers are estimated to be 13 percent of the average domestic plant costs. The total cost of this regulation using this method of cost modeling is $71 million in the first year and $38 million in the fourth year and beyond.

Total costs for compliance with these regulations using the FDA model are shown in Table 5.

TABLE 5.—DISAGGREAGATED COSTS FROM FDA MODEL

1st Year Costs:	
Domestic manufacturers and importers	$32 million.
Major plant repair and renovation	13 million.
Sea Grant expertise	1 million.
Repackers and warehouses	14 million.
Harvesters for rejected raw product	1 million.
Shellfish vessels	3 million.
Foreign processors	5 million.
Total	69 million.
2d Year Costs	
Domestic manufacturers	$ 23 million.
Sea Grant expertise	1 million.
Repackers and warehouses	14 million.
Shellfish vessels	1 million.
Foreign processors	3 million.
Total	42 million.
3d Year Costs:	
Domestic manufacturers	23 million.
Sea a grant expertise	1 million.
Repackers and warehouses	14 million.
IQF Shellfish plants	3 million.
Total	41 million.
4th Year (and subsequent years) Costs	
Domestic manufactures	23 million.
Sea Grant expertise	1 million.
Repackers and warehouses	14 million.
Total	38 million.
Total Discounted Costs:	
Beyond the 4th year and discounted at 6 percent, the costs are $677 million.	

There are a number of explanations that would account for the uncertainty between the FDA and NMFS models. Virtually all of the difference can be explained by the two different estimates of what it would take to come into compliance with 21 CFR part 110 (FDA's CGMP regulations). In the case of the NMFS study, the contractors estimated the cost of coming into full compliance with all CGMPs. Using this methodology, they found that approximately 80 percent of the plants were out of compliance. On the other hand, the FDA model uses the results of FDA's own survey of the industry, which only listed plants as being out of compliance if the CGMP violations were related to potential contamination of the seafood product. In this case, FDA found that only about 20 percent of the firms were out of compliance. In addition, the FDA cost model assumes the simplest, least expensive corrective action to solve the CGMP violation. The NMFS model did not use the same approach in all cases.

2. Other Cost Reports

Reports received by FDA on the cost of implementing HACCP discussed below appear generally to support the results of FDA modeling across the seafood industry. While the modeling was limited to certain types of small operations, the firms for which FDA has information on reported costs represent a cross section of processing operation types, including canned, fresh, frozen, smoked/salted, molluscan shellfish, and cooked, ready-to-eat products as well as warehouses and repacking operations. It should be noted that these costs are reported only as an additional source of information. They were not used to generate FDA's model plants.

The cost information obtained from industry includes responses to a 1991 evaluation questionnaire from four firms that participated in the FDA/NOAA seafood HACCP pilot in 1990–1991. It also includes information provided to FDA from seven firms through the assistance of the National Food Processors Association. (These 7 firms operate a total of 44 processing plants.) It further includes information from two seafood trade associations, the National Fisheries Institute and the New England Fisheries Development Association

(NEFDA), which provided FDA with summary information about member firms that had implemented HACCP systems. The 2 seafood trade associations provided information on 16 firms. NEFDA operated a HACCP pilot with member firms through a Federal grant. All of this information was received by FDA before the publication of the proposed regulations and was reported in the PRIA. After the publication of the proposal, FDA received information from a large processor-exporter on its HACCP start-up costs. This processor reported start up costs of $1,000 per plant. In total, FDA has information on 86 plants (Refs. 129 and 223).

Many of these firms have implemented HACCP as participants in either pilot programs, the NOAA fee-for-service program, or the State of Alaska program, and therefore their HACCP systems have been subject to some form of third party verification. Virtually all of these plants have developed HACCP plans, many of which included critical control points for quality or economic fraud or both in addition to safety. In this respect, many firms implemented a more extensive form of HACCP than is being mandated by FDA.

More complete information on start-up costs received from 22 firms who have implemented HACCP is summarized in Table 6. Some of these costs are for multi-plant firms and some for firms operating only one plant.

TABLE 6.—START-UP COSTS

No. of firms	Start-up costs ($)
4	<1,000
15	1,000–5,000
1	5,000–10,000
1	10,000–15,000
1	>20,000

FDA notes that there are several uncertainties with these data. The agency does not have sufficient information to extrapolate the costs observed by these firms to the entire industry. FDA also does not know the extent of previous HACCP-type activities in these firms so that they may have different incremental costs than the industry average. Additionally, for subsequent year costs, some of the firms reported costs that exceeded the start-up costs shown in the table although some were below, and it is not clear if costs that might be incurred in order to comply with CGMP's are represented.

Nevertheless, the range of reported costs, are consistent with the FDA model for a processing operation that does not incur such costs. Notably, the estimates developed for NMFS of the costs of operating HACCP systems for small businesses are consistent with the FDA model and with the reports to FDA by trade associations discussed above.[1] Thus, three independent sources of information suggest that annual HACCP costs, at least for small businesses, are within a range of $3,000 to $6,000 per plant if sanitation costs are not included. Although the HACCP cost estimates made for NMFS did not include certain aspects of a HACCP system such as HACCP plan development, plan verification, and taking corrective actions, the estimates did include the costs of operating HACCP systems for quality and economic adulteration in addition to safety. These costs were not included in the NMFS cost estimates reported here. The FDA HACCP system involves safety only and is therefore less expensive.

It is also worth noting that three independent sources (FDA's own inspection experience, NMFS inspection experience with plants purchasing its voluntary inspection services, and the contractor's report for NMFS) confirm the existence of sanitation deficiencies in some seafood plants. Because FDA holds that these conditions must be corrected under existing requirements, the costs associated with these corrections will be borne by processors regardless of whether sanitation provisions are included in the seafood HACCP regulations or somewhere else. Sanitation controls for processors may address a number of enteric pathogens discussed elsewhere in this analysis including Salmonella, *Shigella*, hepatitis A, *L. monocytogenes*, *campylobacter*, and *C. botulinum*. Contamination may come from either the raw product or from poor hygiene practices such as insufficient control of vermin (flies and rodents) or insanitary water. In addition, poor sanitation may cause contamination of the product with pesticides, lubricants, cleaning compounds, or other toxic substances because of improper labeling, storage or use. The system in the seafood HACCP regulations is based on the monitoring of sanitation conditions by processors. FDA is not aware of any method for processors to take control of the sanitation conditions within their plants other than by a method that involves routine monitoring. Recording the results of these observations, as required by the regulations, need involve only minimal additional cost.

[11] The costs referred to here are those estimated for NMFS for the type of HACCP system it was studying. For the purposes of the PRIA and RIA, FDA made adjustments to the costs estimated for NMFS so as to be consistent with FDA's own regulation. These adjusted costs from the NMFS models are the estimates presented earlier in this document.

3. Seafood Prices

A number of comments referred to the effect that the regulation will have on the price of seafood that consumers experience at the retail level. In the PRIA, it was presumed that most of the cost of compliance of the proposed regulations would be passed on to consumers. In the PRIA, it was calculated that if the domestic industry passed on to consumers all of the costs estimated in the PRIA, prices for domestically produced seafood would increase by less than 1 percent in the first year and less than one-half of 1 percent in succeeding years. It was noted in the PRIA that price changes of such magnitude are unlikely to have a significant impact on general seafood purchases.

Some commenters claimed that all of the cost of the regulation would be born by processors, and that none of the increase in cost would be passed on to consumers. These commenters explained that seafood is currently at a disadvantage compared to other flesh foods for consumers' food dollars because seafood has a higher price per pound. If the relative price of seafood were to increase further, consumers would eat less seafood. The commenter also explained that domestic seafood processors are at a competitive disadvantage compared with seafood that can be imported at low cost (i.e., lower wages). If domestic processors were to raise their prices, seafood imports would take an even larger part of the seafood market away from domestically produced seafood.

Other comments said that processors will pass on all of the cost of the regulation, and that the regulation will cause the consumer price of seafood to rise. Some said that the price increase would be large enough to cause a decrease in seafood consumption.

Both theories have some merit, although neither is completely correct. The agency agrees that, all other things remaining the same, an increase in the price of seafood will decrease seafood consumption and increase the consumption of other fresh foods. However, the decision of a consumer to purchase a product depends on a number of factors.

Seafood includes many invertebrate and vertebrate species which vary in price per pound, often by over 100 percent, for a particular species (depending, in part, on seasonal supply). Such diversity, compared with

meat and poultry, makes it clear that there is not perfect substitution among the flesh foods. Nevertheless, data bases on food consumption are equally clear at showing that as people have increased their consumption of various seafood products, they have reduced their consumption of meat and poultry.

There are other nonprice factors in the consumption decision. A consumer survey found that taste, quality, and freshness were rated above price (''moderately important'') in decisions to order seafood in a restaurant or to purchase for preparation at home. In a survey of retailers' experiences, consumers ranked quality ahead of price in making seafood selections and rated the need for information on cooking as a concern equal to price (Refs. 244 and 225).

Another relevant consideration is the fact that a disproportionate percentage of seafood is consumed in restaurants as a luxury item where the cost of the raw material is not as important a factor in the purchasing decisions made by these consumers.

All of this information is consistent with other data in this analysis that suggests that a 1 percent change in price results in less than one-half of one percent change in seafood consumption.

Another major factor that lessens any competitive cost advantage meat and poultry products might experience from an increase in seafood cost is that USDA is proposing similar HACCP regulations for meat and poultry. USDA's proposal, if finalized for meat and poultry products, suggests that all segments of the flesh food market may face cost increases in the near future. It is entirely possible that the price of seafood relative to meat and poultry will not change. The agency agrees that some seafood imports have a cost advantage over domestically produced seafood, primarily due to lower labor and capital costs of production. However, because the regulation applies to imports as well as domestic products and because importers from EU member nations will soon be under HACCP requirements and experiencing increased costs, it is reasonable to assume that the price of imported seafood relative to domestic seafood will not change.

In the short run, the ability of producers to pass on cost increases is largely determined by the elasticity of demand (the degree to which consumers reduce their consumption of a good in response to a given increase in price) and the elasticity of supply (the degree to which producers increase their production of a good in response to a given increase in price). The elasticity of demand is determined in turn by, among other things, the presence or absence of close substitutes. Thus, for example, if there are close substitutes and the price of a good goes up, consumers will not continue to consume the higher priced good but switch to one of the substitutes.

If manufacturers know that consumers will not switch to a substitute when there is a price increase, then they are free to pass along all of the increased costs (from complying with the regulation) in the form of price increases. However, where there are close substitutes for seafood, such as other flesh foods, consumers respond to price increases by reducing their consumption of the high priced good. Rather than attempting to pass on all of the costs of the regulation in the form of higher prices, producers must accept reduced profits and bear some, if not all, of the burden of the cost increase.

In very competitive markets, such as the market for flesh food, where meat, fish, and poultry are considered substitutes, producers bear the entire burden of any increases in fixed costs. Fixed costs are costs that do not change, despite the size of the firm and changes in the level of output. Examples of fixed costs are costs of plant, equipment, and management; much of these costs are expected to be borne by processors. Because large firms spread fixed costs over larger output, they may be able to pass on these costs when smaller firms cannot.

In addition, also in the short run, producers may bear some portion of the variable costs that cannot be profitably passed on to consumers. Variable costs are costs that vary with changes in the amount of output. Examples of variable costs are costs of raw materials and hourly labor. However, it is likely that much of the variable costs will be passed on to consumers.

When firms in a competitive market cannot pass on all of a cost increase in the short run, profits decline. Beyond some point profits become either so low or negative that the firm is forced to close (discussed more fully in the Regulatory Flexibility Analysis below). In the long run, the exit of these marginal firms reduces the industry supply (of seafood) and permits the remaining firms to raise prices to cover the full costs of production, both variable and fixed costs. Thus, in the long run, seafood prices will rise by the full cost of the regulation.

A few comments requested a better analysis of price changes. These commenters criticized the approach used to estimate price increases in the Executive Summary of the PRIA. Rather than dividing the estimated domestic cost of the regulation by the total domestic production, the commenters suggested estimating price changes for each market segment. The advantages of this approach are that different types of seafood are treated separately (the change in the price of raw tuna might be very different from the change in the price of ready-to-eat shrimp cocktail) and that different sized firms are treated separately (small firms may be forced to raise prices more than large firms).

FDA agrees that this method of determining price changes is more legitimate than the method employed in the PRIA. However, FDA did not receive any information from commenters that would enable the agency to calculate prices in this manner. It is worth noting, however, that the contractor that performed the study upon which many of the estimated costs in this RIA are based did take product type into account when estimating cost increases. That contractor estimated a range of cost increases from negligible to 1.3 percent, depending on the product. Again, it is important to note that that study included costs for the control of types of hazards not covered by this final regulation.

Finally, while the methodology used in the PRIA might not produce accurate price changes, it suggests that overall price increases due to this regulation could well have a negligible effect on demand.

C. Benefits

In the PRIA, FDA estimated that the proposed option, which is being adopted in this final rule, would: (1) Reduce the amount of foodborne illness that results from consumption of seafood and; (2) generate significant nutrition benefits as a result of the increased consumption of seafood (brought about by a decrease in consumer anxiety) with a concomitant decrease in the consumption of meat and poultry; (3) reduce the amount of rent seeking (rent seeking is a term economists have applied to activities which do not contribute to societal welfare but only seek to transfer resources from one party to another); and (4) generate export benefits by allowing U.S. exporters to continue to export to countries requiring HACCP.

The last benefit, the export benefit, is characterized as the benefit to firms exporting to countries that require federal oversight and certification of HACCP programs. In addition to the benefits cited in the PRIA, the agency is addressing benefits derived from reduced enforcement costs, and is discussing other unquantified benefits of adopting the seafood HACCP

regulations. The agency has fully considered all of the comments on benefits. These estimates are more fully explained in the full RIA. What follows is FDA's conclusion as to how these benefits should be valued.

1. Safety Benefits

In the tables below, FDA presents revised estimates of the benefits of mandatory HACCP for seafood processors. Several changes from the preamble to the proposal are noteworthy. First, based on the comment that said that FDA had underestimated the number of cases, FDA has reestimated the baseline numbers of cases for certain illnesses (Ref. 226). Next, some changes were made to the valuations of particular cases, as better information was obtained concerning the probabilities of death per type of illness. Finally, as mentioned above, some changes have been made to the estimates of the percentages of the illnesses reduced.

Although Canada, for example, has mandatory HACCP for its seafood processors, no data exist on the efficacy of HACCP. Therefore, for the percentages of the illnesses reduced, FDA used three different types of its experts (seafood experts, epidemiologists familiar with microbial hazards, and microbiologists) to address the efficacy of seafood HACCP. Each of these experts reviewed the literature on each type of hazard as well as the requirements of HACCP. The ranges reflect likely upper and lower bounds on how effective HACCP will be at controlling production deficiencies by processors, including indirect controls exerted by processors on the owners of harvesting vessels. In addition, the tables reflect the fact that some of the cases of illness are not addressable by this rule as they are caused by either consumer or restaurant mishandling or poor fishing practices by recreational fishermen.

In order to calculate the number of cases (annual cases resulting from exposure to hazards associated with seafood consumption) that would be reduced by HACCP, each of the four experts followed a series of methodical steps. The first was to determine the types of seafood associated with each hazard. The second step consisted of reviewing the various aspects of the rule to determine the areas of seafood harvesting and processing that the rule could affect. The third step was to eliminate those cases that could not be affected by the rule.

These would be cases that seafood processors could neither eliminate through processing nor prevent from being introduced, either by their own staff or by control over raw materials. Cases caused or controlled by factors outside of the HACCP system include recreational harvest (approximately 20 percent of all seafood harvested) that does not pass through processing plants and problems caused by restaurant, supermarket or consumer improper cooking or mishandling. In addition, there will be some types of hazards that will not, for the foreseeable future, be controllable by means other than avoiding contaminated waters, which will not be 100 percent effective (ciguatera, for example). Until rapid, inexpensive tests are developed, HACCP cannot be 100% effective at controlling these hazards.

Once each expert had accounted for those cases that could not potentially be reached by this rule, the experts then assessed the likely effectiveness of control steps associated with broad sanitation improvements and mandatory controls on specific hazards and specific species.

Ciguatera: Both the lower and upper bound reductions in illness are relatively small in the near term because there does not yet exist a rapid, inexpensive test for this toxin. Processors and commercial fishermen must rely on information about whether geographic areas are ciguatoxic. Moreover, many illnesses are attributable to recreational harvest.

Hepatitis A virus: This illness derives mostly from molluscan shellfish. For molluscan shellfish, the controls are harvesting from approved waters and good sanitation in the plant. These regulations specifically involve both types of controls. The upper bound number is 50 percent of the total estimated number of illnesses largely because of the problems that states have in patrolling and controlling illegally harvested molluscan shellfish.

Norwalk virus: This illness derives from raw molluscan shellfish that are contaminated from human pollution in harvesting areas. Control involves harvesting from approve waters. These regulations include this kind of control. The upper bound number is 50 percent of the total estimated number of illnesses largely because of the problems that states have in patrolling and controlling illegally harvested molluscan shellfish and because of the uncertainty of the control of sewage from harvesting and recreational vessels.

Vibrio vulnificus: This illness essentially derives from eating raw molluscan shellfish from the Gulf of Mexico. Vibrio vulnificus is a naturally occurring, ubiquitous, marine organism. The lower and upper bound numbers reflect the fact that controls are newly emerging for this organism and still have uncertainties associated with them.

Table 6a sets out the new estimates of baseline cases of foodborne disease related to HACCP and the range of cases averted by HACCP.

TABLE 6a.—ESTIMATE OF ANNUAL CASES AVERTED

Hazard	Estimated number of cases [1]	Number of cases averted (lower) [2]	Number of cases averted (upper) [1]
Anasakis	100	25	60
Campylobacter jejuni	200	100	150
Ciguatera	1,600	96	200
Clostridium botulinum	10	3	5
Clostridium perfringens	200	100	150
Diphyllobothrum latum	1,000	250	600
Giardia	30	15	23
Hepatitis A Virus	1,000	150	500
Other Marine Toxins	20	.....	1
Norwalk Virus	100,000	15,000	50,000
Other Vibrio's	1,000	200	500
Paralytic Shellfish Poisoning	10	.....	1
Salmonella non typhi	200	100	150
Scombrotoxin	8,000	4,000	6,000

TABLE 6a.—ESTIMATE OF ANNUAL CASES AVERTED—Continued

Hazard	Estimated number of cases [1]	Number of cases averted (lower) [2]	Number of cases averted (upper) [1]
Shigella	200	100	150
Vibrio vulnificus (3d year)	60	12	30
Total	113,630	20,151	58,520

[1] These numbers were determined in consultation with representatives from the Centers for Disease Control and Prevention.
[2] The upper and lower bounds were determined by a panel of scientists at CFSAN (Dr. George P. Hoskin, Dr. Karl C. Klontz, Dr. Kaye I Wachsmuth and Dr. Thomas C. Wilcox.

Table 7 reflects revised estimates of the total cost of seafood illness.

TABLE 7.—ANNUAL COST OF SEAFOOD ILLNESS

Hazard	Value per case	Total cost of seafood illness
Anasakis	$1,703	$170,332
Campylobacter jejuni	9,390	1,877,924
Ciguatera	15,247	24,395,438
Clostridium botuli num	223,252	2,232,524
Clostridium perfrin gens	6,551	1,310,164
Diphyllobothrum latum	2,753	2,752,617
Giardia	6,104	183,112
Hepatitis A Virus	22,669	22,668,870
Other Marine Toxins	269	5,380
Norwalk Virus	575	57,500,000
Other Vibrio's	2,955	2,954,842
Paralytic shellfish poisoning	92,356	1,200,628
Salmonella non-typhi	8,199	1,639,756
Scombrotoxin	339	2,708,755
Shigella	16,750	3,349,961
Vibrio vulnificus	2,008,917	120,535,039
Total	.....	245,485,342

Table 8 shows the estimates of the efficacy of mandatory seafood HACCP at reducing foodborne disease in the third year following the date of implementation (undiscounted).

TABLE 8.—ESTIMATE OF THE EFFICACY OF MANDATORY HACCP AT REDUCING FOODBORNE DISEASE IN THE THIRD YEAR

Hazards	Lower bound estimate (3d year)	Upper bound estimate (3d year)
Anasakis	$42,583	$102,199
Campylobacter jejuni	938,962	1,408,443
Ciguatera	1,463,726	3,049,430
Clostridium botulinum	558,131	1,116,262
Clostridium perfringens	655,082	982,623
Diphyllobothrum latum	688,154	1,651,570
Giardia	91,556	137,334
Hepatitis A Virus	3,400,331	11,334,435
Other Marine Toxins	.....	269
Norwalk Virus	8,625,000	28,750,000
Other Vibrio's	590,968	1,477,421
Paralytic Shellfish Poisoning	.....	46,178
Salmonella non-typhi	819,878	1,229,817
Scombrotoxin	1,354,377	2,031,566
Shigella	1,674,981	2,512,471
Vibrio vulnificus (3d year)	24,107,004	60,267,519
Total	45,010,733	116,097,537

Finally, in response to the comments, FDA has attempted in Table 9 to associate particular hazards with categories of seafood (to the extent the data allow).

TABLE 9.—ASSOCIATION OF PARTICULAR HAZARDS WITH CATEGORIES OF SEAFOOD

Hazards	Estimated number of cases	Affected species
Anasakis	100	Raw Finfish.
Campylobacter jejuni	200	Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish.
Ciguatera	1600	Tropical, reef associated species of finfish.
Clostridium botulinum	10	Vacuum Packaged Fish, Smoked and Salted Fish.
Clostridium perfringens	200	Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish.
Diphyllobothrum latum	1000	Raw Finfish.
Giardia	30	Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish.
Hepatitis A Virus	1000	Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish.
Other Marine Toxins	20	Molluscan Shellfish.
Norwalk Virus	100,000	Molluscan Shellfish.
Other Vibrio's	1,000	Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish.
Salmonella non-typhi	200	Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish.
Scombrotoxin	8,000	Scombroid Species of Finfish.
Paralytic Shellfish Poisoning	10	Molluscan Shellfish.
Shigella	200	Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish.
Vibrio vulnificus	60	Molluscan Shellfish.
Total	113,630	

2. Summary of Safety Benefits

The safety benefits are shown by year in Table 10 (undiscounted).

TABLE 10.—SAFETY BENEFITS

Year	Lower bound benefits	Upper bound benefits
1	32,957,233	67,897,751
2	32,957,233	67,897,751
3	45,010,733	116,097,537
4 and beyond	45,010,733	116,097,537

3. Nutrition Benefits From Mandatory Seafood HACCP and Increased Consumer Confidence

In the PRIA, FDA estimated what the potential nutrition benefits might be if reduced consumer anxiety over seafood safety led to increased sales. FDA hypothesized that this might lead to consumers eating lower fat meals (on average) as they replaced higher fat meat and poultry with lower fat seafood.

The agency has considered this issue in greater detail in the full RIA. FDA acknowledged in the PRIA that the entire estimate of nutrition benefits resulting from increased sales of seafood at the expense of meat and poultry sales is speculative. Although the agency believes that increased consumer confidence would result from having a state-of-the-art HACCP system in place for the seafood industry, no data were received to confidently predict the ultimate increase in the quantity of seafood sold as a result of this regulation. Sales data of this type were also not available before or after the agency initiated its low acid canned food regulations. Finally, the agency was unable to determine if any increase in consumer confidence would offset a price increase resulting from HACCP costs.

The agency was equally concerned about possible nutrition benefits as to whether there would be an exact exchange in the nutrient profile between fish as prepared and meat and poultry. The agency finds that some fish dishes as consumed are eaten fried or served with heavy sauces, and that different species of fish have different fat profiles. Thus, for some consumers who make substitutions of fish meals for meat and poultry, it is not totally clear if there will be a favorable decrease in fat intake. Because there are too many unknown variables surrounding these substitutes and the lack of sales data, the agency is unable to quantify this benefit.

4. Rent Seeking

Rent seeking activities were characterized in the proposal as ''public and private resources (which) have been expended in attempts to alter the level of regulatory effort toward seafood safety, as well as alter which Federal agency should oversee the industry.'' ''Rent seeking'' is a term economists have applied to activities that do not contribute to societal welfare but only seek to transfer resources from one party to another. An example often given is lobbying to change the ownership of a government granted special privilege so that profits change hands. In many cases, however, it is difficult to distinguish between activities that ultimately indirectly benefit society from those that only transfer profits. The proposal hypothesized that one benefit of the regulation was to reduce the social costs of rent seeking.

One commenter noted that the reason large firms support HACCP is because they must have HACCP to export to Europe. The commenter noted that mandated HACCP would ''ensure that all domestic processing firms face the same costs, thereby reducing any competitive disadvantage.''

FDA does not agree that this is a justification for HACCP. The reason for implementing HACCP is to reduce the incidence of foodborne disease. However, FDA agrees that this ''rent-seeking'' argument may explain some support for HACCP by larger exporting firms. It is important to note, however, that there are small firms who export to Europe as well.

5. Export Benefits

In the PRIA, FDA asserted that one benefit (unquantified) of the rule was to allow firms now exporting to the EU to continue to do so because of the EU requirement for a federally overseen voluntary HACCP program. Several commenters noted that some countries that import seafood from the United States are beginning to require HACCP. One commenter noted that more than 30 percent of seafood produced in the United States is exported. The same commenter noted the disruption in trade when French authorities did not coordinate their seafood safety requirements with ''other officials.'' Several commenters noted the need for more Memoranda of Understandings (MOU's) between the United States and other countries for seafood. One suggested that such MOU's be based upon HACCP as defined by various international bodies. Finally, one commenter noted that FDA ''should take into account how the international

community is implementing HACCP before the agency imposes regulations that may create unnecessary trade barriers.''

As discussed in the PRIA, this program will benefit those seafood processors who are exporting to nations requiring HACCP. However, as also noted in the PRIA, there is in place a federally overseen HACCP program, specifically, the program being offered to processors by the National Marine Fisheries Service (NMFS).

FDA has made an estimate of the cost savings to exporting firms of being in FDA's mandatory program in lieu of the NMFS program. The alternative to NMFS review (if FDA were not to adopt this regulation) would be inspection of product that is offered for entry into the EU on an entry-by-entry basis and the payment of a significant fee for these inspection services. With approximately 2 billion pounds being exported each year, this savings of resources amounts to, at a minimum, $20 million per year.

In addition, although the EU has announced the requirement that HACCP be in place by January 1, 1996, adoption of a U.S. plan reduces some of the uncertainty for U.S. firms and firms exporting to the United States concerning the ultimate form of an internationally agreed upon HACCP requirement.

6. Reduced Enforcement Costs

Comments qualitatively mentioned other benefits including fewer product recalls and other enforcement actions. FDA agrees that there will be fewer product recalls, seizures, injunctions and detentions of seafood and seafood products. As examples of what benefits could have accrued in 1994, the agency has calculated the value of each of these actions and addressed them below.

a. *Seizures.* A seizure is a civil action designed to remove violative goods from consumer channels. Table 11 shows the actions and their associated costs that follow a determination that a violation exists and that goods should be seized.

TABLE 11.—SEIZURE STEPS

Action	Hours/Other	Cost
Federal personnel collect and analyze samples, write up recommendations (program and general counsel), review the case and make recommendations to the U.S. attorney.	120	$12,840
U.S. attorney files complaint and Court orders goods arrested	16	1,712
U.S. Marshal and other federal official seizes goods at location	8	856
	Travel	200
Firm hires attorney to contest/accept action	16	1,712
Food is reconditioned by firm	16 firm	1,712
	16 Federal lower valued food [2]	1,712
Food is denatured (converted to a non-food use) or;	16 firm	1,712
	8 Federal lower valued food [2]	856
Food is destroyed	8 firm	856
	8 Federal lost food [1]	856

[1] The rate of $107 per hour represents the cost of a loaded (including equipment and benefits) employee plus headquarters support of approximately 70 percent.
[2] Total seizure costs are calculated in Table 12.

Table 12 shows the seizures in 1994. Assuming that half of all seizures are prevented each year, the benefits are expected to be approximately $290,000 each year.

TABLE 12.—SEIZURES IN 1994

Problem	No.	Administrative costs [1]	Action [2]	Total
Decomposition (Destroy)	5	$17,320	$46,565	$320,925
Filth (Denature)	3	17,320	8,709	78,087
Chemicals (Destroy)	2	17,320	10,108	54,856
Other (Destroyed)	4	17,320	14,212	126,128
Total	14			[3] 579,996

[1] Costs of items (1) through (4) in the preceding Table totaled are $17,320.
[2] The actions that are typically taken for each type of hazard are listed in the PROBLEM column. Costs include the value of destroyed food multiplied by the number of actions or, in the case of denaturing, it is assumed that 10 percent of the value of the product is retained. No food was reconditioned.
[3] This number may well underestimate the benefit. FDA recently completed a seizure proceeding (not filed in 1994) in which $5 million of product was condemned. Thus, preventing seizure can have a significantly higher value than that reflected in this table.

b. *Detentions.* A detention is a procedure for preventing violative products from entering the United States. Table 13 shows the actions and their associated costs that follow a determination that a sample is violative, the following actions take place.

TABLE 13.—DETENTION STEPS

Action	Hours/other	Cost [2]
Federal personnel send a detention notice to the importer with an opportunity to introduce testimony	2	$214
Importer hires attorney and introduces evidence. Submits response application	16	1,712
Determination of action to take	24	2,568
Reshipment allowed, or	10	1,070
	Travel, Cost to Reship	200

TABLE 13.—DETENTION STEPS—Continued

Action	Hours/other	Cost [2]
Product is denatured, or	8, Loss of value,[2] Cost of denaturing,[2], Reselling costs [2].	856
Goods are destroyed under Federal supervision	16, Loss of product [1].	

[1] These costs are calculated in table 14 which gives estimates of the numbers and estimated costs for detentions in 1994.
[2] Seizure can have a significantly higher value than that reflected in this table.

TABLE 14.—DETENTIONS IN 1994

Reason	Number of detentions	Quantity [1]	Dollars [1]	Detention disposition [2]	Detention admin [3]
Borates	25	21,484	1,827,173	183,017	112,350
C. botulinum	1	113,790	363,434	363,434	4,494
E.coli/coliforms	14	254,774	742,786	149,413	62,916
Histamines	2	98,023,014	1,361,714	273,199	8,988
Lead	2	102,188	87,440	9,044	8,988
Listeria/Other Pathogens	51	2,792,808	21,369,692	4,274,794	229,194
Mercury	11	7,338,900	12,720,272	1,272,327	49,434
Poisonous/Deleterious sub-nec	7	180,000	446,025	446,025	31,458
Salmonella/arizona	129	221,543,300	76,137,973	15,228,451	579,726
Staphylocci	6	55,810	199,550	40,766	26,964
Sulfites	23	713,653	8,100,620	810,362	103,362
Unsafe food additives—NEC	5	67,160	540,201	540,201	22,470
Total	276			23,591,033	1,240,344

[1] Quantity and dollars include the total amount of both detentions and automatic detentions and are shown to illustrate how detentions were calculated.
[2] Disposition included reshipping which was estimated to be 10 percent times the number of shipments (quantity) times the value per shipment (dollars/quantity); reconditioning which was estimated to be 20 percent of the value of the shipment (dollars) or destruction which was estimated to be 100 percent of the value of the shipment.
[3] Administrative costs are estimated to be $4,494 per detention, the sum of the first three rows of the previous table.

Assuming just half of these detentions are prevented by HACCP, benefits to the federal government and industry would be approximately $12 million per year.

c. *Automatic detentions.* Automatic detentions place each lot of imported products on detention upon arrival at the border until the importer has demonstrated that the products do not violate the Federal Food, Drug, and Cosmetic Act. This is normally done by the importer hiring independent labs to sample each lot. Table 15 shows the number and types of relevant automatic detentions that took place in 1994.

TABLE 15.—AUTOMATIC DETENTIONS IN 1994

Reason	Number of automatic detentions	Sample cost[1]	Storage cost[2]
Borates	53	$132,500	$182,717
C. botulinum	104	260,000	36,343
E.coli/coliforms	8	20,000	74,279
Histamines	63	157,500	136,171
Lead	1	2,500	8,744
Listeria/Other Pathogens	236	590,000	2,136,969
Mercury	397	992,500	1,272,027
Pesticide chlorothalanil	1	2,500	50
Poisonous and Deleterious sub-nec	4	10,000	44,603
Salmonella/arizona	759	1,897,500	7,613,797
Staphylocci	0	0	19,955
Sulfites	12	30,000	810,062
Underprocessed	3	7,500	15,454
Unsafe food additives—NEC	3	7,500	54,020
Total	1,644	4,110,000	12,405,191

[1] 1 Calculation of costs assumes that, for each product placed on automatic detention, 10 lots per year will be analyzed with 1 sample each at a cost of $250 per sample.
[2] Assumes storage costs equals 10 percent of the stated value of the goods.

Again assuming that half of the above automatic detentions are eliminated each year, then the benefits will be approximately $6 million per year.

d. *Recalls.* The costs of recalls to a firm vary from inexpensive notification

of consignees to several million dollars, depending on the nature of the hazard, the type of seafood, the cost and amount of product involved, and the distribution chain of the product. The costs of a recall include searching for the recalled products, removing them from retail and wholesale outlets, replacing the adulterated product, effectiveness checks, and disposal or reconditioning. In some cases recalls cause marketing disruptions, loss of shelf space, and subsequent losses in sales via publicity.

FDA costs include investigative and analytical time and expenses, administrative costs, cost of samples, and auditing time.

FDA assumes that the costs of recalls borne by firms are directly related to the distribution costs associated with the products and to the size of the contaminated lots. Distribution costs account for about one-third of the final value of seafood. FDA assumes that the firm must bear the full amount of the distribution costs of the recall. In addition, the other costs listed above raise the total cost of recalls borne by firms to one-half the value of the product. FDA uses one-half the value of the product as the base for the estimate of total recall costs. The total recall cost of seafood processing firms in 1994 is estimated to be $2,461,906, as shown in table 16. FDA audit checks for seafood took 474 hours in 1994. FDA assumes that total FDA costs per recall were proportional to audit hours. The cost per hour of an audit check is $107, giving an FDA audit cost of $50,718 (474 x 107). FDA collected 72 samples at $250 per sample, giving sample costs of $18,000 (72 x 250). FDA thus estimates additional costs due to recalls to be $68,718 ($50,718 + $18,000). The total recall cost is estimated to be $2,530,624 ($2,461,906 + $68,718). Again, the estimate for the purpose of this benefits analysis assumes that half of all recalls will be prevented or about $1,250,000.

TABLE 16.—RECALLS IN 1994

Fish	Hazards	Amount	Total
Canned tuna	Filth, decomposed, punctured cans, short weight.	6,599 cases	$150,687
Crab	L. monocytogenes	16,156 lbs	64,624
Escolar fish	Decomposed, sc ombroid, illness	1,719 lbs	1,614
Herring, salted Schmaltz	L. monocytogenes	1,200 lbs	1,740
Hilsha fish	Salmonella	2,000 lbs	2,100
Lobster	L. monocytogenes, salmonella	25,920 lbs	243,648
Mahi mahi, fresh	Decomposed	575 lbs	834
Nova chips	L. monocytogenes	54 lbs	157
Oysters, shellstock	V. vulnificus	9,219,430 lbs	1,843,886
Oysters, shucked	V. vulnificus	21,944 lbs	87,776
Sardines, flat fillets	Rusty, leaky, decomposed	33,600, 13 oz cans	50,400
Smoked catfish, salmon, sturgeon, tuna	L. monocytogenes	1,060 lbs	2,963
Tuna steaks	Decomposed	7,110 lbs	11,477
Total			2,461,906.00

e. *Injunctions.* Injunctions are the most severe form of domestic penalties whereby a firm is enjoined from producing/distributing a product until a violation is remedied. There are approximately 5 injunctions by FDA against seafood products each year costing the firm an average of about $70,000 and FDA an average of about $30,000 each or about $500,000 per year. These costs include court costs, analytical testing costs, inspections costs, and lost production costs. Again, if this rule reduced injunctions by half, societal savings would be $250,000.

Total enforcement benefits are the sum of all of the reduced enforcement costs estimated to be approximately $20 million per year.

7. Other Benefits

Commenters also mentioned benefits including better process control (resulting in lower production costs) and improved employee morale.

FDA believes that there may be ''re-engineering'' types of benefits associated with these regulations. For both seafood and other foods for which HACCP has been implemented, FDA has received information that firms have found cost-saving innovations in other areas as they implement HACCP. These innovations are considered trade secrets by firms and thus, their description (actual process innovations) and quantification is impossible as firms have not released this data into the public domain. This phenomenon involves unexpected savings and efficiencies as a result of establishing a new system in a processing operation. The majority of firms that have previously instituted HACCP reported that they believed that the advantages they derived from HACCP were worth the costs to them in terms of better control over their operations, better sanitation, and greater efficiencies, such as reduced waste. Virtually all foresaw long-term benefits from operating under HACCP.

Improved employee morale depends on how HACCP is implemented. If, for example, employees are (1) participating in day-to-day monitoring of critical control points, (2) allowed through corrective action plans to participate in corrective actions including shutting down a line when a critical limit has been exceeded, and (3) are rewarded for this decision rather than penalized or forced to rigorously defend their actions, then employee morale may increase. Such an increase in morale, if valid, may lead to greater productivity. However, it is in the direct financial interest of every company to maintain employee morale such that any additional benefit from this regulation is likely to be small.

A final benefit will be realized for finfish where processing plants and vessels, in an effort to control for histamine formation, keep fish cooled from harvest to retail. This will simultaneously decrease the decomposition rate that causes seafood to be thrown out because of organoleptic problems. The same situation exists relative to cooked, ready-to-eat products and smoked fish. One retailer cited losses of 4 percent to 8 percent of all seafood because of decomposition. If some of this decomposition begins prior to arrival at the retail level and is reduced in any degree by this

regulation, benefits could potentially be large.

However, FDA recognizes that there is also a short term cost (e.g., as molluscan shellfish harvesters attempt to supply processors with untagged shellfish or from vessels without sanitary facilities aboard and find the harvest rejected). The same will also be true for finfish which have not been properly temperature controlled from harvest to processor. These harvests will be discarded although this behavior is not expected to occur often, or more than once in any instance.

D. Costs and Benefits of Sanitation

A portion of the costs and benefits of this rule derive from the improvements in the facilities and CGMP's in seafood plants. Although all food manufacturing plants are required to produce food under sanitary conditions now, FDA's experience, and that of others, indicate that many seafood processors are not producing seafood under those conditions. The sanitation, monitoring, and recordkeeping provisions of this rule are expected to drive processors to improve their sanitation conditions and thus reduce the need for FDA to enforce CGMP's through regulatory actions. These provisions will produce net increases in societal welfare with accompanying costs and benefits.

Current goods manufacturing practices include such things as cleanliness and habits of personnel, the conditions of buildings and facilities, equipment, production and process controls, and conditions of warehousing and distribution of the product. It is difficult to differentiate between costs and benefits that are HACCP-related and those that are sanitation-related. For example, processors are required under HACCP to keep records that show that CGMP's such as ''Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act'' are being followed (see 21 CFR 110.80(a) (2) and (4)). However, the benefits derive from making plant and processing changes, uncovering problems in processing due to recordkeeping and taking corrective action which prevents hazardous seafood from being sold. Thus, HACCP and CGMP's are inextricably intertwined and it is difficult to calculate the marginal benefits and marginal costs of each.

E. Costs and Benefits Attributable to Foreign Governments

FDA has reported the portion of the increased costs that are expected to be passed on to U.S. consumers by foreign processors. The justification for this action is that FDA has not included safety benefits that foreign consumers may enjoy when foreign firms that export to the United States introduce HACCP into their plants. FDA has also included, as a benefit of this regulation, reduced enforcement actions toward products produced by foreign firms and reduced illnesses that U.S. consumers suffer from imported seafood.

In a benefit-cost analysis, costs and benefits are attributable to choices made among competing options. However, in this rule, there are difficulties in assigning the costs and benefits to choices made by FDA to require HACCP of domestic and foreign seafood processors. This difficulty arises because other countries either already require HACCP or have indicated that they will do so in the near future—for both their domestic and imported seafood products. No costs or benefits should be ascribed to choices made by the U.S. Government in this rule that affect firms already complying with foreign regulations, if the regulations are the same and no changes need to be made to be in compliance with the U.S. regulation.

Thus, foreign firms in those countries who export to the United States may be required to comply first with the U.S. plan or first with their own country's plan; the timing is impossible to predict. However, FDA does have evidence from the European Union that the seafood produced by the following countries (at least seafood for export) have met the EU standard for HACCP— Albania, Australia, Austria, Belgium, Brazil, Canada, Chile, Columbia, Denmark, Ecuador, England, Faro Is., Finland, France, Germany, Greece, Holland, Iceland, Indonesia, Ireland, Italy, Japan, Luxembourg, Mexico, Morocco, New Zealand, Norway, Peru, Philippines, Sweden, Taiwan, Thailand, and Turkey.

F. Conclusion

As the above analysis demonstrates, FDA finds that the estimated benefits exceed the estimated costs. The estimated costs are approximately one third of those in the PRIA, ranging from $677 million to $1.488 billion. These estimated costs were based primarily on the reports of some seafood firms and modeling done by FDA experts based on their experience with HACCP but also considered the study done under contract with NMFS. The benefits range from $1.435 billion to $2.561 billion and include benefits from safety, nutrition, increased consumer confidence, rent seeking activities, exports, and reduced enforcement costs.

G. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (Pub. L. 96–354) requires analyzing options for regulatory relief for small businesses. In the PRIA, FDA listed for comment a series of regulatory options on how to grant regulatory relief for small firms. In that document, FDA defined small firms as having less than $1 million in annual gross revenue (for non-shrimp processors) and less than $2 million for shrimp processors. In the PRIA, regulatory options for small business relief included:

(1) Requiring HACCP-type controls for those critical control points in individual plants that have a history of failure.

(2) Exempting very small processors from the requirements in the proposed regulatory option.

(3) Allowing a longer implementation period such that HACCP requirements may be phased in over a longer period of time.

(4) Providing generic HACCP plans (without mandatory control points) for certain types of operations, providing federal verification, or less frequent monitoring of critical control points.

FDA received a large number of comments on these options and on the costs that small businesses would incur as a result of the proposed option.

The agency has fully considered all of the comments received on its regulatory flexibility analysis and has responded to these comments in the full RIA. What follows is a summary of FDA's major conclusions from the analysis.

FDA received comments on whether there should be exemptions for processors based on either the size of the processor or the degree of risk associated with the product or process. For example, one commenter supported the exemption of small firms on the basis that small firms that represent 75 percent of the industry in terms of the number of plants, produce less than 10 percent of the seafood consumed.

FDA has concluded that there should be no exemptions for small firms. Small processors often engage in relatively high risk seafood processing, and an exemption based on size could inappropriately exempt high risk operations. An exemption based on risk might entail knowing which seafood might be responsible for a reported and confirmed illness. The agency finds however that because underreporting and skewed reporting of foodborne

illnesses occurs it is not always directly possible to relate the reported illnesses to risk. This subject is also discussed at length in the preambles to both the proposed and final rule.

One comment recommended that no firms be completely exempt, but that some firms be subject to different HACCP requirements depending on size. The smaller the firm, the less strict the record-keeping, testing, and monitoring requirements. The use of a short form for recordkeeping and informal monitoring was supported in some comments.

Again, this is a topic that is extensively covered in the preamble to the final rule. FDA notes that HACCP depends on the degree of risk and complexity of processing and that HACCP requirements for each plant are calibrated based on these factors. Whether the plant is large or small, if there are few hazards and simple processes, HACCP requirements are inherently minimal. If there are no hazards, no HACCP plan is required. Overall, however the agency believes that many smaller firms are associated with simpler processes and that the HACCP system already accommodates the commenter's concern.

In the long run, as processors adopt HACCP and attempt to pass costs on to consumers, the retail price of seafood will rise by less than 1 percent. In the absence of an increase in consumer demand that may result from this regulation, as the price of seafood rises, consumers will purchase less seafood. As producers fail to sell all of the seafood offered at the higher price, output must fall. Moreover, output must decrease in the highest cost sector of the industry, generally small processors. Although it is possible that small processors will cut back production but stay in business, the small profit margins of some small seafood producers strongly imply that the reduction in output will come about because small processors go out of business. For every one percent increase in the price of seafood, approximately 140 small processors could go out of business. The estimated number comes from the following calculation. FDA has estimated that as costs are passed on, HACCP will raise the price of seafood to consumers. The price elasticity of demand, which is the percentage change in quantity purchased divided by the percentage change in price, is estimated to be −0.37 for seafood (Ref. 227). A one percent increase in the price consumers pay for seafood should therefore reduce the quantity purchased by 0.37 percent (1 percent times −0.37). FDA believes that the entire reduction in output attributable to HACCP will be borne by small processors who go out of business. Although close to 80 percent of seafood processors are classified as small, small processors account for only 10 percent of total industry output (Ref. 228). In the case of a 0.37 percent decline in total processing output represents a decline in the output of small processors of 3.7 percent (0.37 percent divided by 0.10). If the decline in the number of processors were proportional to the decline in the output of small processors, the reduction in the number of processors would be 3.7 percent in the case of a 1 percent price increase. FDA is uncertain as to what price increase will actually occur.

The agency finds that the number of small seafood processors that go out of business will be determined by the cost per unit (or per plant) of implementing HACCP, the effect of HACCP on seafood prices, the ability of small plants to pass costs on to consumers, the current practices of the plants and the implementation time. The analysis has assumed that the regulation will have no positive effect on the demand for seafood. If the regulation in fact increases consumer confidence in seafood sufficiently to increase the demand for seafood, then the effect on small business would be less.

Although the economic impact on small firms is difficult to predict, many small firms should be able to implement HACCP at low cost, as they have already fulfilled many of its basic requirements. The closer a firm's current practices are to HACCP, the lower the cost of HACCP and the more likely is firm survival. Some small firms occupy market niches that allow them to pass on more of their costs than the industry average, increasing their likelihood of survival.

The effect of HACCP on small seafood processors depends on their costs of compliance and on the changes in the relative price of seafood. FDA expects the relative price increase attributable to HACCP to be small. For many small firms, the flexibility built into the regulation strongly implies that HACCP costs will be low. In consideration of small firms, the agency has extended the effective date to 2 years from publication. FDA will also be publishing a Guide that will provide small processors with valuable information for developing and implementing HACCP. Additionally, the agency, in cooperation with Sea Grant Universities and others through the Seafood HACCP Alliance, will be providing to small firms assistance on training and other needs.

FDA recognizes that HACCP is an innovative regulatory system that has not been applied on a large scale to ongoing commercial enterprises in the United States. For this reason all of the agency's estimates of firm behavior, costs and benefits necessarily involve substantial uncertainty. As explained in this Regulatory Impact Analysis, FDA has used modeling techniques and informed judgements rather than firm empirical data to estimate many effects. In order to determine the accuracy of these estimates, and also to assist in possible mid-course corrections, FDA and HHS plan to conduct an evaluation study during the first few years after the effective date of these regulations. This study could focus on each major type of one-time or continuing compliance cost, on different types of firms, on different sizes of firms (with particular attention to the smallest firms), and on both costs required by the regulation and on costs that firms may incur unnecessarily. It could also address the ability of firms to understand and implement HACCP properly, and any other problems that may impede rapid and inexpensive implementation. This study could also include an exploratory analysis of benefits, addressing both improvements in processing as measured by elimination of hazards and, to the extent permitted by existing data systems, early trends in reported incidence of illness caused by seafood.

V. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (59 FR 4142, January 28, 1994). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment, and that an environmental impact statement is not required.

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229. Final Regulatory Impact Analysis.

List of Subjects

21 CFR Part 123

Fish, Fishery products, Imports, Reporting and recordkeeping requirements, Seafood.

21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, title 21 CFR chapter I is amended as follows:

1. New part 123 is added to read as follows:

PART 123—FISH AND FISHERY PRODUCTS

Subpart A—General Provisions

Sec.
123.3 Definitions.
123.5 Current good manufacturing practice.
123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) plan.
123.7 Corrective actions.
123.8 Verification.
123.9 Records.
123.10 Training.
123.11 Sanitation control procedures.
123.12 Special requirements for imported products.

Subpart B—Smoked and Smoke-Flavored Fishery Products

123.15 General.
123.16 Process controls.

Subpart C—Raw Molluscan Shellfish

123.20 General.
123.28 Source controls.

Authority: Secs. 201, 402, 403, 406, 409, 701, 704, 721, 801, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393); secs. 301, 307, 361 of the Public Health Service Act (42 U.S.C. 241, 242l, 264).

Subpart A—General Provisions

§ 123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are applicable to such terms when used in this part, except where they are herein redefined. The following definitions shall also apply:

(a) *Certification number* means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(b) *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.

(c) *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.

(d) *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 and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

(e) *Fishery product* means any human food product in which fish is a characterizing ingredient.

(f) *Food safety hazard* means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(g) *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. For the purposes of this definition, ordinarily the importer is not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(h) *Molluscan shellfish* means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

(i) *Preventive measure* means physical, chemical, or other factors that can be used to control an identified food safety hazard.

(j) *Process-monitoring instrument* means an instrument or device used to indicate conditions during processing at a critical control point.

(k)(1) *Processing* means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.

(2) The regulations in this part do not apply to:

(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.

(ii) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.

(iii) The operation of a retail establishment.

(l) *Processor* means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A processing includes any person engaged in the production of foods that are to be used in market or consumer tests.

(m) *Scombroid toxin-forming species* means tuna, bluefish, mahi mahi, and other species, whether or not in 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.

(n) *Shall* is used to state mandatory requirements.

(o) *Shellfish control authority* means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of

molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(p) *Shellstock* means raw, in-shell molluscan shellfish.

(q) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(r) *Shucked shellfish* means molluscan shellfish that have one or both shells removed.

(s) *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.

(t) *Tag* means a record of harvesting information attached to a container of shellstock by the harvester or processor.

§ 123.5 Current good manufacturing practice.

(a) Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

(b) The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

§ 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) Plan.

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

(b) *The HACCP plan.* Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to:

(1) Each location where fish and fishery products are processed by that processor; and

(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

(c) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;

(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;

(viii) Unapproved use of direct or indirect food or color additives; and

(ix) Physical hazards;

(2) List the critical control points for each of the identified food safety hazards, including as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and

(ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;

(3) List the critical limits that must be met at each of the critical control points;

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with § 123.7(b), to be followed in response to deviations from critical limits at critical control points;

(6) List the verification procedures, and frequency thereof, that the processor will use in accordance with § 123.8(a);

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(d) *Signing and dating the HACCP plan.* (1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) Upon verification of the plan in accordance with § 123.8(a)(1).

(e) *Products subject to other regulations.* 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.

(f) *Sanitation.* Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with § 123.11(b) they need not be included in the HACCP plan, and vice versa.

(g) *Legal basis.* Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

§ 123.7 Corrective actions.

(a) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(1) Following a corrective action plan that is appropriate for the particular deviation, or

(2) Following the procedures in paragraph (c) of this section.

(b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with § 123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(c) When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with § 123.10;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation;

(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with § 123.10, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with § 123.8(a)(3)(ii) and the recordkeeping requirements of § 123.9.

§ 123.8 Verification.

(a) *Overall verification.* Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

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

(2) *Ongoing verification activities.* Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(ii) The calibration of process-monitoring instruments; and,

(iii) At the option of the processor, the performing of periodic end-product or in-process testing.

(3) *Records review.* A review, including signing and dating, by an individual who has been trained in accordance with § 123.10, of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;

(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with § 123.7. This review shall occur within 1 week of the day that the records are made; and

(iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(b) *Corrective actions.* Processors shall immediately follow the procedures in § 123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(c) *Reassessment of the hazard analysis.* Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with § 123.10.

(d) *Recordkeeping.* The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the recordkeeping requirements of § 123.9.

§ 123.9 Records.

(a) *General requirements.* All records required by this part shall include:

(1) The name and location of the processor or importer;

(2) The date and time of the activity that the record reflects;

(3) The signature or initials of the person performing the operation; and

(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

(b) *Record retention.* (1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

(2) Records that relate to the general adequacy of equipment or processes being used by a processor, including the

results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.

(3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

(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.

(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.

(2) However, these records and plans may be subject to disclosure to the extent that they 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.

(e) *Tags.* Tags as defined in § 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of § 123.28(c).

(f) *Records maintained on computers.* The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

§ 123.10 Training.

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of § 123.6(b);

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in § 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in § 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in § 123.8(c); and

(c) Performing the record review required by § 123.8(a)(3); The trained individual need not be an employee of the processor.

§ 123.11 Sanitation control procedures.

(a) Sanitation SOP. Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.

(b) *Sanitation monitoring.* Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(6) Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(8) Exclusion of pests from the food plant.

The processor shall correct in a timely manner, those conditions and practices that are not met.

(c) *Sanitation control records.* Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of § 123.9.

(d) *Relationship to HACCP plan.* Sanitation controls may be included in the HACCP plan, required by § 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section they need not be included in the HACCP plan, and vice versa.

§ 123.12 Special requirements for imported products.

This section sets forth specific requirements for imported fish and fishery products.

(a) *Importer verification.* Every importer of fish or fishery products shall either:

(1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:

(i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,

(ii) Affirmative steps that may include any of the following:

(A) Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;

(B) Obtaining either a continuing or lot-by-lot certificate from an appropriate

foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;

(E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) *Competent third party.* An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) *Records.* The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 123.9.

(d) *Determination of compliance.* There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B—Smoked and Smoke-flavored Fishery Products

§ 123.15 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

§ 123.16 Process controls.

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

Subpart C—Raw Molluscan Shellfish

§ 123.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

§ 123.28 Source controls.

(a) In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.

(b) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. Federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the Federal government.

(c) To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in § 1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in § 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:

(1) The date of harvest;

(2) The location of harvest by State and site;

(3) The quantity and type of shellfish;

(4) The date of receipt by the processor; and

(5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.

(d) To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with § 1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:

(1) The date of receipt;

(2) The quantity and type of shellfish; and

(3) The name and certification number of the packer or repacker of the product.

PART 1240—CONTROL OF COMMUNICABLE DISEASES

2. The authority citation for 21 CFR part 1240 continues to read as follows:

Authority: Secs. 215, 311, 361, 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271).

3. Section 1240.3 is amended by revising paragraph (r), and by adding new paragraphs (s), (t), and (u) to read as follows:

§ 1240.3 General definitions.

* * * * *

(r) *Molluscan shellfish.* Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the product consists entirely of the shucked adductor muscle.

(s) *Certification number* means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(t) *Shellfish control authority* means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(u) *Tag* means a record of harvesting information attached to a container of shellstock by the harvester or processor.

4. Section 1240.60 is amended by revising the section heading, by

redesignating the existing text as paragraph (a) and adding the word ''molluscan'' before the word ''shellfish'' the two times that it appears, and by adding new paragraphs (b), (c), and (d) to read as follows:

§ 1240.60 Molluscan shellfish.

* * * * *

(b) All shellstock shall bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority, where applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information.

(c) All containers of shucked molluscan shellfish shall bear a label that identifies the name, address, and certification number of the packer or repacker of the molluscan shellfish.

(d) Any molluscan shellfish without such a tag, shipping document, or label, or with a tag, shipping document, or label that does not bear all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.

Dated: October 3, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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