federal register

Wednesday
June 27, 1990

Part II

Department of Health and Human Services

Food and Drug Administration

Department of Commerce

National Oceanic and Atmospheric Administration

21 CFR Part 197
50 CFR Ch. II

Voluntary Seafood and Fish and Fish Products Inspection Program; Invitation to Participate in a Pilot Study; Proposed Rule and Notice

C-31

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 197

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Ch. II

[Docket No. 90N-0080]

Seafood Inspection

AGENCIES: Food and Drug Administration, HHS; and National Marine Fisheries Service, NOAA, Commerce.

ACTION: Advance notice of proposed rulemaking; request for public comment.

SUMMARY: The Food and Drug Administration (FDA) and National Marine Fisheries Service (NMFS) are jointly issuing this advance notice of proposed rulemaking (ANPRM) announcing their intent to establish a voluntary, fee-of-service inspection program for fish and fish products to be operated by both agencies. The proposed new program is intended to enhance existing Federal seafood inspection programs operated by FDA and NMFS. The new program is intended to address both safety and marketing and would provide an opportunity to extend the voluntary use of Hazard Analysis Critical Control Point (HACCP) principles more broadly in the fish and seafood industries.

The agencies request public comment on the outline of the program presented in this document and on various aspects of the program that would require regulations to implement.

DATES: Comments by August 13, 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, and rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Generic model HACCP plans, which have been developed by industry under the congressionally-mandated Model Seafood Surveillance Project (MSSP) and are discussed in section C(2), may be obtained at no charge from the National Seafood Inspection Laboratory, P.O. Drawer 1207, Pascagoula, MS 39567.

FOR FURTHER INFORMATION CONTACT:

Richard Cano, Office of Trade and Industry Services, National Marine Fisheries Service, 1335 East—West Highway, Silver Spring, MD 20910, 301-427-2355

or

George Hoskin, Center for Food Safety and Applied Nutrition (HFF-400), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-245-1231.

SUPPLEMENTARY INFORMATION: Seafood safety is regulated at the Federal level primarily by FDA, which operates a comprehensive, mandatory program under the authorities of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the Public Health Service (PHS) Act. The FD&C Act charges FDA with assuring that foods, including seafood, are safe, wholesome, and not misbranded or deceptively packaged. FDA's authority under the PHS Act relates to the control of the spread of communicable diseases from one state, territory, or possession to another or from outside the United States into this country.

Under these authorities, FDA conducts mandatory inspections of processors, shippers, packers/repackers, labelers/relabelers, warehouses, and importers of fish and fish products. Some of this work is carried out by the states, under contracts with FDA. In addition, although subject to FDA regulation, the many hundreds of thousands of retail outlets and restaurants selling seafood products are inspected by the state and local health departments with technical assistance and training from FDA through its Retail Food Protection Program. FDA's program also includes sample analyses of both domestic and imported products, research into rapid detection methodologies for potential hazards and other matters affecting the regulation of seafood, substantial interaction with states, other Federal agencies, and foreign countries, enforcement activities, and education and information-sharing activities.

NMFS operates a voluntary, fee-for-service seafood inspection program under the authorities of the Agriculture Marketing Act of 1946 and the Fish and Wildlife Act of 1956. A memorandum of understanding (MOU) exists between NMFS and FDA relating to this program. Under that MOU, NMFS ensures that industry participant's operations and products meet the requirements of the FD&C Act, as well as NMFS's own quality and identity requirements. The program includes inspection, grading, and certification services, as well as the use of official marks that indicate that specific products have been Federally inspected. The program encompasses approximately 12 percent of seafood consumed in this country and approximately 9 percent of edible fishery exports. FDA takes the NMFS program into account when it targets inspection under its mandatory program.

The proposed program announced in this notice is included as part of the President's fiscal year 1991 budget as a voluntary, fee-for-service inspection program that is to be operated jointly by FDA and NMFS. As currently viewed by the agencies, the key differences between this new initiative and the current NMFS program, aside from joint operation, are that: (1) It will provide an additional incentive for firms to voluntarily implement HACCP principles across a broad array of fish and seafood products, and (2) it aims to cover imports as well as domestic and exported products. Like the current NMFS program, this new program would include the award of a mark for participants signifying that the participant is meeting the requirements of the program. This new program would be based in part on section 702A of the FD&C Act, which authorizes the display of such a mark under a voluntary inspection program supported by user fees.

The current NMFS program would continue to provide grading and related services. Ultimately, continuation of the other aspects of the current NMFS program would depend upon such factors as the extent to which participants opt to switch to the new HACCP-based program.

A. HACCP

The HACCP concept of identifying and monitoring potential hazards during processing has matured to the point where it can be formally implemented beyond its current application by regulation to the prevention of botulism in low-acid canned foods, a number of which are seafoods. HACCP principles may find useful application at many stages in the chain from harvest to market. The HACCP system is an approach to controlling consumer product hazards relating to safety, but may also be extended to economic fraud and wholesomeness as well. It is a two-step system. First, the range of hazards and concerns must be identified and evaluated, second, it involves: (1) Defining each operational step of a processing operation, (2) identifying the critical control points in the process to control the identified hazards to acceptable levels, (3) defining preventive measures to control the hazards, (4) detailing the procedures—either by observation or measurement—

C-32

that can be used to monitor the critical control points, and (5) defining the minimum records necessary to verify that the hazards are being controlled.

HACCP has proven itself since the early 1970's principally in the low-acid canned food industry and recently has been the subject of considerable analysis and endorsement by the National Academy of Sciences, the National Advisory Committee on Microbiological Criteria for Foods, including its Seafood Working Group, and others. In 1988, Congress directed NMFS to design an improved surveillance and certification system for fishery products base upon the HACCP concept. This study, known as the Model Seafood Surveillance Project (MSSP), will be completed this year with a report to Congress scheduled for December 1990. Preliminary results from that study are being used in the development of this proposed program through the use of generic model HACCP plans that were developed for various types of fishery products. These model plans could be used by firms as guides in developing their own company-specific HACCP-based plans.

B. The Proposed FDA-NMFS Program

FDA and NMFS expect that this joint voluntary HAACP-based, fee-for-service inspection program will lead to more cost-effective regulation of the seafood industry and will increase the industry's awareness of the benefits of the HACCP system. The agencies believe that such a program will enable them to focus more effectively on the prevention of economic hazards, such as additive abuse, short weight, species substitution, and overbreeding. At the same time, it will help reassure consumers about the safety and wholesomeness of fish and seafood products.

It is important to note, however, that the program is not intended to be a self-certification program. Although HACCP involves substantial self-monitoring by the industry, the program is intended to rely ultimately on routine regulatory monitoring inspections by NMFS and periodic verification inspections by FDA. By means of these inspections, FDA and NMFS intend to review the data being produced through industry self-monitoring to determine whether each HACCP-based system that may be established by a participant is in compliance with that participant's HACCP-based plan and to check for overall sanitation, compliance with current good manufacturing practices, labeling, and other requirements.

The agencies contemplate that the regulations for this program would provide for a voluntary, contractual program. They would address such issues as what the parties agree to do, the terms of a contract, and the rights of termination. The agencies' current thinking is that each contract should specify those records relating to a participant's HACCP-based plan that the parties agree will be subject to access by the agencies. The proposed regulations are also likely to address eligibility factors, the application process, and the development and submission of an HACCP-based plan by an applicant, as well as what factors an applicant's HACCP-based plan must adequately address, the significance of the mark and how it will be awarded, and the fee structure.

C. Request for Comments

In the development of this program, FDA and NMFS intend to take full advantage of the generic HACCP models that have been developed primarily by the industry under the MSSP. To further aid in the development of this program, the agencies are soliciting comments and advice from the public on several specific areas, as set out below. Comments and advice are encouraged on any other aspect of the program as well.

The agencies intend to take these comments into account in drafting a notice of proposed rulemaking.

1. Eligibility

What factors should be taken into account in establishing criteria for eligibility under this program?

It is worth noting in this regard that the agencies are considering making the low-acid canned food industry eligible to participate in this program with regard to fish and fish products even though that industry is already operating under an HACCP-based system. That system was established to control the occurrence of botulism. HACCP could be applied to other types of control points in that sector of the industry as well, making it eligible for the new inspection mark.

Should eligibility encompass fish and fish products intended for food for animals as well as for humans?

2. MSSP Generic Model HACCP Plans

Among the work products of the MSSP mentioned above are generic model HACCP plans for specific commodities or operations. The generic model plans address, among other things, the critical control points normally associated with a commodity or operation, the hazards associated with the critical control points, activities that could be undertaken to assure that the identified hazards do not occur, and the types of records that must be maintained in order to record the effective monitoring of critical control points. Generic model plans have already been drafted or are under development for: breaded shrimp, cooked shrimp, raw shrimp, breaded fish and specialty items (includes breaded molluscan shellfish, stuffed products, entree items, and surimi analog products), blue crab, raw fish, import products, scallops, smoked fish, west coast crab, molluscan shellfish, crawfish, vessels, lobsters, and aquaculture products. Those generic model plans already drafted may be obtained from the National Seafood Inspection Laboratory (address above). Interested parties may also submit comments on these generic model plans.

Because the generic model plans were developed by the industry under the MSSP for other purposes, i.e., as part of a congressionally-mandated project to design a mandatory inspection system using the HACCP concept, they constitute unofficial guidance for the development of plant-specific HACCP-based plans, and they may not be directly applicable to the voluntary program described here. FDA and NMFS intend to evaluate them for applicability to this program and modify them as necessary.

The agencies currently believe, however, that program applicants may find the generic models useful for developing their own HACCP-based plans. (For this reason, the agencies are encouraging firms with products for which generic model plans already exist to volunteer for a pilot test for this program targeted for later this year, although the pilot is not intended to be limited solely to such firms. A notice inviting volunteers for the pilot is being published separately.) However, applicants may develop their own HACCP-based plans independent of these generic models. Review and approval of an applicant's plan by the agencies is likely to be one condition for acceptance into the program. The generic models should provide guidance on critical control points, actions that could be undertaken to control hazards, and necessary records.

(a) Because the MSSP generic model plans were developed for different purposes as described above, to what extent should FDA and NMFS modify the generic plans to accommodate this alternative application? What other guidance should NMFS and FDA provide applicants for the development of their plant-specific HACCP-based plans?

C-33

(b) Should the above list of generic model plans serve to define, in whole or in part, eligibility into the program?

(c) If eligibility should be broader and include commodities or operations not listed above, what additional commodities/operations should be included? How should generic model HACCP plans for these additional commodities/operations be developed? Should eligibility be delayed until such generic model HACCP plans are prepared?

(d) Should eligibility be phased in on a commodity/operation basis? If so, which commodities or operations should be eligible first?

3. HACCP-Based Plans

The agencies intend to require each participant in this program to have an approved HACCP-based plan. The agencies further intend to provide that all products produced in the facility to which the plan applies must be covered by the plan. (For example, an HACCP-based plan could not cover just one production line out of four in a facility but would have to cover all four lines.)

In order to be approved, it is likely that HACCP-based plans would have to adequately address a number of factors. Those factors currently under consideration include current good manufacturing practices, training of personnel, the safety and suitability of ingredients, necessary structures, equipment and procedures, production and process controls, control of containers, maintenance of records, sanitation, and product testing by the firm. Comments on how any or all of these factors should be specifically addressed in an HACCP-based plan are encouraged. Should any other factors, such as recall procedures, be included? Do small businesses face problems that would require special consideration as they develop specific HACCP-based plans? Should the agencies provide technical assistance to small businesses in developing these plans?

4. The Mark

The agencies intend to allow those who meet the requirements of this program to display a mark on the labeling of their products. It is expected that the mark will signify that the facility is a member in good standing in this program, has a Federally approved HACCP-based plan, and is appropriately monitoring critical control points as evidenced by the results of Federal regulatory monitoring and verification inspections.

Competent application of HACCP principles may enhance the safety of fish and seafood products, which are already much safer than other foods that provide similar nutritional value. Nevertheless, HACCP is not intended to guarantee and cannot provide a risk-free product. It must be understood that the Government intends to reserve the right to act against a product bearing a mark if that product is later found to violate applicable Federal laws. Compliance with this program can, however, attest to the overall marketability of the product, including general freedom from species substitution, overbreading, and other forms of economic deceptions, as well as provide an additional assurance of the product's underlying safety and quality. With these principles in mind:

(a) How can the mark be designed to communicate the message that products bearing it have satisfied program requirements, without inadvertently creating misperceptions, in particular misperceptions about relative risk, relating to products sold without the mark?

(b) What should be the statement and configuration of the mark? For bulk fresh product, for example, how should the mark be displayed?

(c) Should the mark signify compliance with minimum sanitary and product wholesomeness criteria or some higher level acceptability? For example, should the mark be permitted on products containing a minimum unavoidable amount of decomposition, as currently reflected by FDA's defect action level for decomposition, when current good manufacturing practices are followed, or should the mark be allowed only on products that exceed minimum quality, *e.g.*, that contain no decomposed material as determined by a specified analytical and sampling plan? Higher minimum quality levels above current good manufacturing practices are achievable but could possibly require greater effort and cost.

i. If the mark were to signify that the product was free of decomposition, what percentage of a lot should be sampled to assure that the lot is free of decomposed products?

ii. Should the mark be permitted when source material has to be reworked in order to bring it or the final product into compliance with a no decomposition requirement?

(c) How should this mark relate to established U.S. marks (*e.g.*, Packed Under Federal Inspection, Grade A)?

(d) Should the agencies require that this mark be displayed on products originating from participating facilities, or should display be at the option of the firm?

(e) If retailers are eligible for this program, should they be held to the same standard as processors with regard to source material? For processors, the agencies contemplate that the door to the plant is, figuratively, a critical control point for source materials. The agencies intend that materials should either come from a source that is in the FDA/NMFS HACCP-based program or that is adequately controlled (*e.g.*, sampled) if the source is other than in this program. Also, for retailers, could the mark be in the form of a sign posted in the store? (See also question 9(c) on imports.)

5. Fees

Fees under the current NMFS voluntary program are based on an hourly rate and are set at a level intended to recover costs to NMFS. FDA and NMFS intend to establish a fee schedule for this program that is economically sound, avoids unfair cross-subsidization across participant firms and industries, and provides efficient incentives for participants to comply with program requirements. What factors should be used in deciding upon the fee structure for this new program? Should fees be limited to recovering costs to FDA and NMFS of inspection and sample analyses only, or should they include costs incurred by those agencies associated with informing consumers about the meaning of the mark? What alternative fee structures are available that would accomplish the goals outlined above?

6. Inspection Intervals

The seafood industry is far from uniform and is characterized by a great variety of processing and other operations. To what extent should inspection rates vary based on the complexity of the operation, the numbers and types of critical control points, and the success that the firm is having in operating under an HACCP-based plan?

7. Sampling and Analysis

The agencies invite comment on the extent to which participants in the program should be expected to have their own source materials, in-process materials, and end products analyzed for defects. The laboratories used, whether in-house or contract, would be expected to use methodologies that are consistent with, or at least as sensitive as, those used by the agencies, in order to facilitate the interpretation of the data, among other things. Should Federal inspection of contract laboratories be a part of the verification procedures of the joint FDA–NMFS program?

C-34

8. Delisting

If a firm is consistently unsuccessful in meeting the conditions of the program, it becomes questionable whether the firm should be permitted to continue to participate. What should be the criteria for delisting and reinstatment?

9. Training

An HACCP-based program must involve the training of key people involved in food processing, as well as the training of regulatory personnel.

(a) For industry personnel, what specifically should be included in the curriculum? Should there be different levels of training?

(b) Should the program require that each participating firm have at least one person who is certified in HACCP by virtue of appropriate training?

(c) Should training for industry personnel be undertaken wholly or in part by the private sector?

(d) Should the Federal program develop specific training and testing criteria, certify that training, or require private instructors to receive some Federal training?

10. Imports

The United States is currently the second largest importer of fish and fishery products in the world.

Therefore, FDA and NMFS believe that this program should be structured to the extent possible to include imported fish and fish products. It is not currently contemplated that a mark could be awarded under this program solely on the basis of end product testing of imports because verified sanitary control up to the end product stage, based on the requirements of this program, would be lacking. Consequently, inspection of foreign suppliers would be necessary. The agencies' current view is that foreign suppliers that participate in the program would be subject to the same HACCP-based planning and self-monitoring requirements as domestic participants.

(a) Should the program negotiate MOU's with foreign countries that have sufficient regulatory mechanisms in place to conduct these inspections on the program's behalf? Under such a MOU, should the foreign country conduct both the monitoring and verification inspections?

(b) Should the frequency rate of inspection for foreign suppliers be the same as the rate for domestic processors?

(c) Should the mark be the same?

(d) From whom should the program collect fees?

i. The importer?

ii. The foreign firm?

iii. The foreign country (assuming the existence of an MOU)?

(e) Should imports from program participants be limited to certain U.S. ports to facilitate entry?

11. Exports

The United States is currently the largest exporter of fishery products in the world. Therefore, the structure of this program should adequately address the needs of U.S. exporters to assure foreign governments and consumers that U.S. fishery products are safe, wholesome, and in compliance with recognized, established criteria for their respective countries.

The use of scientifically-based regulations and inspection procedures continue to be important topics of discussion in international bodies such as the General Agreement on Tariffs and Trade (a forum that addresses international trade disputes) and CODEX Alimentarius (a joint commission of the Food and Agriculture Organization for the purpose of establishing international standards for trade.) The value of a HACCP-based inspection program has already been established for low-acid canned foods and an extension of that type of program to other forms of seafood should help maintain the U.S. position in international trade.

This premise has been recognized in the meetings of the Technical Working Group on Fish and Fishery Product Inspection under the Canada-U.S. Free Trade Agreement. The Canadian delegation has proposed the formal recognition of the FDA–NMFS HACCP-based inspection program by the Canadian inspection service upon its implementation. Also, the FDA–NMFS program is one of several topics for discussion at the June 1990 bilateral consultations between the United States and the European Community in Brussels, Belgium.

The agencies are operating under the premise that exports from a plant participating in this program ought to be subject to the same requirements as products for the domestic market. Is this a valid premise? What effects, positive or negative, could it have on trade? What features directed toward exports should the program include?

Interested persons may, on or before August 13, 1990, submit to the Dockets Management Branch (address above) written comments regarding this ANPRM. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This ANPRM will be followed by a notice of proposed rulemaking that will propose, among other things, to remove the existing FDA regulations at 21 CFR part 197 relating to the inspection of canned oysters and processed shrimp under section 702A of the FD&C Act. As noted above, section 702A of the FD&C Act authorizes the Secretary of Health and Human Services to establish a voluntary, fee-for-service seafood inspection program involving the display of a mark for compliance with the statute and applicable regulations.

The original version of section 702A of the FD&C Act was enacted in 1934 (as section 10A of the Food and Drugs Act of 1906) to establish an inspection service that would alleviate problems with decomposition of shrimp then being experienced in the Gulf of Mexico area. Regulations under then-section 10A were issued in 1939 for the inspection of canned shrimp. The program was extended by regulation in 1944 to canned oysters. In their present form, the successors to these regulations require the assignment of inspectors to participating establishments for specified periods of time on a continuous basis and contain a number of other detailed requirements. These regulations have been unused since 1957, however, when the voluntary inspection service under section 702A was discontinued. The current FDA mandatory inspection program for seafood operates under other provisions of law, and a successor fee-for-service program operated by NMFS continues to function successfully, based in part on an MOU with FDA.

Now that FDA and NMFS intend to rely in part on section 702A of the FD&C Act as a basis for the new fee-for-service program that is the subject of this ANPRM, FDA intends to repeal the existing but unused regulations for shrimp and oysters, and the agencies intend to replace them with regulations that will implement a voluntary HACCP-based program based on current theory and experience, as described previously in this notice.

C-35

Authority: This ANPRM is issued under secs. 402, 403, 404, 701, 702A, 704, and 891 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 343, 344, 371, 372a, 374, and 381), title II of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), sec. 6(a) of the Fish and Wildlife Act of 1956 (16 U.S.C. 742e), and Reorganization Plan No. 4 of 1970 (84 Stat. 2000).

Dated: June 18, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

William W. Fox, Jr.,

Assistant Administrator for Fisheries.

[FR Doc. 90–14800 Filed 6–21–90; 4:12 pm]

BILLING CODE 4160–01–M

C-36

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 90N-0080]

Voluntary Fish and Fish Products Inspection Program; Invitation To Participate in a Pilot Study

AGENCIES: Food and Drug Administration, HHS.

ACTION: Notice: invitation to industry to participate in a pilot study of the voluntary fishery products inspection program.

SUMMARY: The Food and Drug Administration (FDA) and the National Marine Fisheries Service (NMFS) intend to conduct a joint, fee-for-service inspection program that will enhance the existing programs for seafood now being operated by the two agencies. These programs relate to the safety, wholesomeness, and proper labeling of fish and fish products. The planned joint program will be based on Hazard Analysis and Critical Control Point (HACCP) principles, and participation will be voluntary. The two agencies are soliciting participants for a 2-month pilot study presently scheduled to begin October 1, 1990.

DATES: Letters of inquiry from volunteers must be submitted by July 27, 1990.

ADDRESSES: Letters of inquiry to the Division of Microbiology (HFF-232), Food and Drug Administration, Rm. 3824, 200 C St. SW., Washington, DC 20204. The generic model plans already drafted, as discussed below, may be obtained from the National Seafood Inspection Laboratory, P.O. Drawer 1207, Pascagoula, MS 39567.

FOR FURTHER INFORMATION CONTACT: John E. Kvenberg, Center for Food Safety and Applied Nutrition (HFF-232), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-245-1221.

SUPPLEMENTARY INFORMATION: Elsewhere in this issue of the Federal Register an advance notice of proposed rulemaking (ANPRM) is being published jointly by FDA and NMFS announcing their intent to establish a voluntary, fee-for-service inspection program for fish and fishery products to be operated by both agencies. Prior to starting the joint inspection program, the two agencies will conduct a pilot study. The pilot study is intended to measure the ability of industry to implement operation of an HACCP-based system in the production and distribution of seafood under an approved plan. The pilot study will enable FDA/NMFS to develop systems to monitor and verify that the HACCP-based plans are operating effectively.

Individual HACCP-based plans will be developed by the industry participants and may be either independently drafted or patterned from existing seafood commodity models developed under the Model Seafood Surveillance Project (MSSP). The MSSP models were developed by industry participants in cooperation with NMFS. (See the ANPRM for a detailed discussion of these model plans and their applicability to this program.) Critical controls for safety, hygiene, and economic fraud must be addressed in the HACCP-based plans developed for this pilot study.

Volunteers for participation in the pilot study are sought from individual firms involved in various aspects of the harvest, production, distribution, and retail sale of seafood in the continental United States. Also, because of the significance of imported seafood in the United States marketplace, participation by foreign firms and firms involved with imported seafood products is also sought to the extent that such participation is practicable.

Selection of firms for the pilot study will be made by the Commissioner of Food and Drugs and the Administrator of the National Oceanic and Atmospheric Administration. Factors to be used in selection will include: (1) Geographical location, national representation is desirable; (2) size of firm, both large and small volume operations are sought; and (3) type of commodity, those covered by completed MSSP models are desirable.

Ideally, the pilot study should include cooked, raw, and breaded products as well as products that represent a substantial volume of sales in the United States. Currently, MSSP model plans have been completed for cooked shrimp, raw shrimp, breaded shrimp, breaded fish, specialty items (i.e., fish entrees), blue crab, and raw fish. With the exception of blue crab, these MSSP model plans reflect the criteria for commodity types stated above.

Previous experience in HACCP-based operations or participation in the MSSP model development program are not necessary for participation in the pilot study. In fact, it is desirable to include firms with varying degrees of prior HACCP experience.

Selected firms must each agree to designate one or two individuals to be responsible for the development and implementation of an HACCP-based plan designed specifically for the selected firm. These individuals will be expected to participate in a 2-day training course prior to their independent development and implementation of the HACCP-based plan for that firm. The industry training course will be held on or about August 7 and 8, 1990 in Chicago, IL. Transportation and other expenses for industry trainees must be paid by the individuals attending or by their sponsor firms.

Selected firms must agree to allow inspection and record review of critical control point data identified in the HACCP-based plans that are developed by the participants and accepted by the agencies. Specific records that will be maintained and made available for review will be agreed to by the parties in advance as part of the application process.

In order for this test of an HACCP-based system to be manageable yet sufficiently comprehensive, the agencies reserve the option of conducting more than one pilot, possibly sequentially, each one focusing on different types of products or processes. The agencies will decide whether and how to exercise this option based in part on the response to this notice.

For further details refer to the ANPRM published elsewhere in this issue of the Federal Register.

Interested persons are invited to submit a letter of inquiry to the Division of Microbiology (address above). Letters must be submitted by July 27, 1990.

Dated: June 21, 1990.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 90-14801 Filed 6-21-90; 4:14 pm]

BILLING CODE 4160-01-M

C-37

COMPARISON OF HOUSE SEAFOOD INSPECTION BILLS

	Energy & Commerce (H.R. 3155)	Agriculture (H.R. 3508)	Merchant Marine & Fisheries (H.R. 2511)
TITLE	Fish and Fish Products Safety Act (Sec. 1)	Fish Safety Act of 1990 (Sec. 1)	Consumer Seafood Safety Act of 1990 (Sec. 1)
LEGISLATION AMENDED	Federal Food, Drug & Cosmetic Act (Sec. 1)	New program; also, Act of May 8, 1914 (Sec. 31)	New Program; Magnuson Fishery Conservation & Management Act (Sec. 107)
LEAD AGENCY	Health & Human Services (HHS) (Secs. 2 & 4)	Agriculture (USDA) (Secs. 2, 3 & 5)	Commerce; Food and Drug Administration (FDA) for shellfish safety program (Secs. 3, 102 & 202)
PRODUCTS AFFECTED_	Applies to all fish (freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians and other forms of aquatic animal life) and fish products (which include any edible human food product derived in whole or part from fish) (Sec. 8)	Applies to fish (any aquatic animal, including amphibians, whether from wild or cultured sources capable of use as human food) and fish products (Secs. 3 & 5)	Fish defined as all freshwater or marine finfish, crustaceans, and other forms of aquatic animal life, whether wild or cultured, other than shellfish, birds or mammals; applies to fish/products intended for human consumption (Secs. 3 & 201). Shellfish covered under separate, new shellfish safety program

C-39

	Energy & Commerce	Agriculture	Merchant Marine & Fisheries
TYPE OF INSPECTION PROGRAM	Requires HHS to "enter and conduct frequent and random, unannounced inspections of facilities" where fish/products are processed, including: intensive sampling for contaminants, parasites & toxins; "conducted with such frequency and in such manner" as determined by Secretary, taking into account appropriate factors including: (A) degree of probability fish/products may affect public health; (B) history of compliance; (C) production volume and complexity of operations; (D) incidents of employee injuries and illness. Inspection of any processing facility shall "extend to all things therein" affecting compliance with Act and may include photography (Sec. 4)	"Comprehensive and efficient health-based" inspection to: (1) be specifically designed to take into consideration the special characteristics of fish/fish products; (2) be based on a comprehensive assessment of fish/fish products and their processing/handling that identifies and assesses severity of hazards/risks and that prescribes health-based sanitary standards for processing establishments; (3) be based on consideration of processing/distribution procedures including assessment of potential fish-related health risks; determination of sources and points of potential contamination; potential for persistence/growth of contaminants; (4) be based on need to require and monitor procedures to prevent, eliminate or control potential fish contaminants; (5) be designed to take into consideration distinctive characteristics, hazards, control points, processing procedures for different fish species; (6) assure, through "frequent, and unannounced or announced" inspections, that processing complies with standards (considering nature and frequency of operations; adequacy of monitoring; history of compliance; recommendations of the Model	Requires implementation of 2-stage seafood safety program. <u>First stage</u> requires: (1) Within 12 months, development by FDA of a National Shellfish Safety Program (Sec. 101) (see shellfish, below); (2) Establishment by Commerce, if needed to protect public health, of standards for handling, storage and transportation of fish/products on fishing and fish tender vessels, with six specific criteria for standards; (Sec. 102) (3) Establishment of a system to monitor growing and harvesting areas (Sec. 103) (see growing/ harvesting areas, below) <u>Second stage</u> calls for a "comprehensive and efficient" fish safety program that incorporates the first stage program and includes essentially the same additional requirements as in H.R. 3508 (at left) (Sec. 202)

	Energy & Commerce	Agriculture	Merchant Marine & Fisheries
		Seafood Surveillance Program (MSSP); potential of the operations and fish species to affect human health; and other factors; (7) not require freezing/cooking of products intended for raw consumption unless needed to control adulteration; (8) provide for identification/classification of fish growing/harvesting areas in conjunction with appropriate Federal/State agencies; (9) provide for delegation of certain inspection/sampling authorities to States (with up to 50% funding); (10) provide for sampling and inspection of products; (11) establish procedures to assist in tracking sources of contamination; (12) provide for naming/labeling regulations (Sec. 5)	
INSPECTOR POWERS	Same authority as for other food facility inspections under Sec. 704 of FFDCA--to enter and inspect establishments at reasonable times; sampling of products; review records, etc. (Sec. 4)	To conduct inspections, enforce compliance, and take other actions including inspection of all locations within establishments; sampling/ testing of products; detention/condemnation of adulterated/misbranded products; inspection/ sampling of imports. Provisions for dealing with condemned products (also, condemned but wholesome products may be distributed free to public and nonprofit feeding organizations) (Sec. 7)	Identical to H.R. 3508 (Sec. 204)

04-2

	Energy & Commerce	Agriculture	Merchant Marine & Fisheries
REGISTRATION /CERTIFICATION REQUIREMENTS	Requires annual HHS registration of all processing facilities (and importers); registration may be revoked for failure to comply with standards (Sec. 3); vessels excluded (Sec. 8)	Requires USDA procedures for certification (or decertification for good cause) of establishments (and importers), which may not process or handle any fish without such certification. Establishments defined (Sec. 1901) as any fish processing vessel subject to U.S. jurisdiction, or any building, premises, structure, or other facility in any State or Territory used to handle or process fish (see below for exemptions). Includes specified procedures/conditions for decertification and reinstatement (Sec. 9).	Similar to H.R. 3508, except that Commerce is responsible for certification, and procedures for decertification/reinstatement differ somewhat (Sec. 206)
VESSELS	Excluded (Sec. 8)	Processing vessels only (Sec. 1901); USDA-Commerce study and recommendation on whether to include fish tender and harvesting vessels required in 2 years (Sec. 23)	Requires Commerce, if there is no practicable alternative to protect public health, to establish standards on handling, storage, transportation of fish on fishing and fish tender vessels; includes list of criteria to consider in setting standards (Sec. 102) Processing vessels included with other establishments subject to certification and other inspection requirements (Sec. 3)
SANITARY/ PROCESSING STANDARDS	Requires HHS to prescribe health-based and other appropriate safety and sanitation standards for processing (Sec. 2)	Requires USDA to issue standards of sanitation and other good processing, etc. procedures (Secs. 5, 8 & 22)	Similar to H.R. 3508, except that Commerce must issue standards (Secs. 202, 205)

	Energy & Commerce	Agriculture	Merchant Marine & Fisheries
CONTAMINANT STANDARDS	Requires HHS to establish (after contracting with NAS to study and report on priorities) standards for chemical/microbiological contaminants, etc., which may include indicators, with fish/products containing contaminants in excess of such standards (or where no standard exists, the contaminant may render product unsafe) considered adulterated. (Sec. 2)	Requires FDA (in consultation with NAS and 5 other specified agencies) to establish tolerances (except those set by EPA) for poisonous/ deleterious substances that may adulterate fish products (see Sec. 3 for lengthy definition of adulteration). Also separately requires FDA to establish tolerances (except those set by EPA) for harmful chemicals, toxins, parasites, pathogenic microorganisms, viruses, bacteria, and other harmful agents. May include indicator organisms. (Sec. 5)	Similar to H.R. 3508, but lacks separate language requiring FDA to establish tolerances (except those set by EPA) for harmful chemicals, toxins, parasites, etc. (Sec. 202)
LABELING	Permits HHS to establish fish/product labeling regulations, including an official mark signifying a product's compliance with inspection standards (Sec. 2)	Requires USDA to prescribe standards for marking fish/products or their containers with official stamp (Secs. 5 & 22); requires establishments to use stamp and appropriate identification on each package (Sec. 10)	Requires Commerce to prescribe standards for marking fish/products or their containers with official stamp (Secs. 202 & 207); requires Commerce to set rules for identifying/naming fish (Sec. 202)
RECORDKEEPING	Requires registering establishments to keep records and make reports as required by HHS regulations and provide HHS access to them; such regulations shall include requirements for records of sampling (Sec. 3)	Requires USDA to set rules for establishments to maintain specified records and to provide them upon request at reasonable times (Secs. 11 & 22)	Essentially the same (but for Commerce) as in H.R. 3508 (Sec. 208)
R E C A L L PROVISIONS	Permits HHS to require processing facilities (and importers) to recall fish/products in violation of Act if such products might cause adverse health consequences or death (Sec. 6)	Permits USDA to require establishments to recall adulterated or misbranded products that may pose health risks (Sec. 14)	Identical (but for Commerce) to H.R. 3508 (Sec. 211)

	Energy & Commerce	Agriculture	Merchant Marine & Fisheries
SHELLFISH	(See growing/harvesting areas, below)	Requires Commerce in consultation with EPA to establish a 5-year shellfish indicator research program (Sec. 23) (see also growing/harvesting areas, below)	Requires Commerce to establish within 12 months of enactment (in consultation with other appropriate Federal agencies) a National Shellfish Safety Program, including standards (consistent if practicable with ISSC guidelines) for: growing, harvesting, handling, processing and shipping shellfish; for water quality; and for bacterial, viral and chemical contaminants of shellfish. Also requires procedures for closing unsafe waters (see below), and requires shellfish States to submit and receive approval of annual safety plans, with Federal funding of States to carry out the program (shellfish from States without approved plans deemed adulterated) (Secs. 101 & 104). Also requires Commerce in cooperation with FDA to establish a 5-year shellfish indicator research program (Sec. 220)
GROWING/ HARVESTING AREAS	Requires HHS to determine (through periodic monitoring of fish/products) if fish harvested from a particular harvest area may be unsafe, and if so designate such as a "fish adulteration area" for that species. For shellfish, such an area will be considered unsafe if State lacks an approved harvesting program for, or has prohibited harvesting from, that area (Sec. 4)	Requires Commerce to establish system for identifying and classifying growing and harvesting areas for fish in coastal areas and Great Lakes; USDA to sample and test products and to notify appropriate agencies to act if products pose significant health threat; provides Commerce with authority to prohibit or restrict sale or harvesting in emergencies or upon receiving USDA notice (Sec. 6)	Requires Commerce to establish system for monitoring/classifying fish and shellfish growing/harvesting areas; provides authority to close or restrict harvesting of particular species violating standards or posing a public health threat (Sec. 103)

	Energy & Commerce	Agriculture	Merchant Marine & Fisheries
S T A T E PROGRAMS	Permits HHS to authorize States (and other Federal agencies) to conduct inspections authorized by Act and to pay up to 50% of their costs (Sec. 4)	Permits USDA to cooperate in 2 types of mandatory State programs: (1) covering intrastate commerce, if State program is at least equal to Federal program; (2) those covering interstate commerce on behalf of the Federal Government, with ongoing USDA monitoring to assure it meets USDA requirements, and with up to 50% Federal funding of program costs for States with approved plans. Under either program, USDA must take over (after proper notice and consultation) if State falls below Federal standards. Permits USDA to approve State requirements that are at least equivalent to Federal requirements; permits a State to exercise concurrent jurisdiction over seafood/products that are outside registered establishments or vessels; State voluntary programs may exceed Federal requirements (Sec. 5)	Requires Commerce to encourage States to continue or establish programs at least equal to Federal; States with U.S.-approved plans can operate such a program in lieu of Federal program, with ongoing Commerce monitoring to assure it meets standards, and with up to 50% Federal funding of program costs. Commerce must reinstate Federal program if (after proper notice and consultation) State falls below Federal standards (Sec. 203)

	Energy & Commerce	Agriculture	Merchant Marine & Fisheries
ILLNESS/HEALTH MONITORING	Requires HHS, through Centers for Disease Control (CDC), to establish an active seafood illness surveillance program (Sec. 15)	Requires HHS-CDC to establish an active surveillance system to estimate the frequency of human disease associated with food, comparing major food categories (Sec. 15)	Identical to H.R. 3508 (Sec. 212)
RESEARCH	Permits research, including on improved processing sanitation and quality control; improved contaminant testing; determining contamination sources; improved inspection techniques; seafood consumption (Sec. 14)	Requires USDA in consultation with other Federal agencies and States to determine research priorities, with "appropriate" Federal agencies to conduct it; establishes research advisory panel; specifically requires shellfish indicator research program (see shellfish, above); also specifically requires research into improved sanitation, contaminant testing, fish inspection techniques; requires USDA-Commerce study of need to include harvesting/fish tender vessels in inspection program (Sec. 23)	Requires shellfish indicator research program (see shellfish, above) (Sec. 220)
EDUCATION	Requires HHS to establish comprehensive public awareness program on proper fish handling (Sec. 13)	Requires USDA to provide $2 million annually to States in conjunction with Extension for food safety information demonstration projects (Sec. 23)	Requires FDA and Commerce to design and implement a national education program that provides information to consumers and processors on the law's standards and good practice requirements; advice to recreational and subsistence fisheries on safety; and other information (Sec. 219)

	Energy & Commerce	Agriculture	Merchant Marine & Fisheries
IMPLEMENTATION TIMETABLE	Final rules for inspection, processor registration, training, and standards on processing safety/sanitation within 1 year of enactment; HHS contract with NAS within 6 months of enactment; NAS report within 6 months of contract; final rules on contaminant standards within 1 year of NAS report; foreign labeling rules within 1 year of enactment (Secs. 2, 3, 4 & 11)	FDA contract (to identify contaminants/other harmful substances likely in fish) within 30 days of enactment; NAS report within 6 months of contract; FDA final rules on contaminants within 1 year of NAS report; USDA implementation of inspection program within 18 months of FDA final rules (up to 37 months total); other Commerce and FDA responsibilities generally must be implemented within 2 years of enactment (Secs. 32, 33 & 34). USDA-Commerce study of vessels due within 2 years of enactment (Sec. 23)	National Shellfish Safety Program required within 12 months of enactment, with first annual State shellfish safety plans due 6 months after that and full implementation of program 20 months after enactment (Sec. 101); no specific timetable for other provisions
RELATION TO OTHER LAWS	Ties new fish inspection authorities to FFDCA	Specifically exempts fish/products from inspection, sampling, regulation, etc., requirements of the FFDCA after implementation of inspection program (Sec. 27); existing HHS, Commerce, USDA laws and regulations affecting fish/products remain in effect until then (Sec. 32)	No comparable language
FUNDING	Authorizes $75 million in FY1991 and such sums as may be necessary in succeeding years (Sec. 16)	Specifically requires Federal funding for inspection costs, except for overtime, which shall be borne by establishment at USDA-set rates (Sec. 28). Authorizes such sums as are necessary to carry out Act (no years specified); plus up to $5 million each in FY1991, FY1992 and FY1993 for research (Sec. 29)	For shellfish safety, vessel standards, and monitoring of growing/harvesting areas, authorizes a total of $5 million each in FY1991 and FY1992 for Commerce and $2 million in each of those years for HHS (Sec. 106). For comprehensive inspection program, authorizes such sums as are necessary (no years specified); also authorizes up to $5 million each in FY1991, FY1992 and FY1993 for shellfish indicator research program (Sec. 225)

94-2

47-D

COMPARISON OF SENATE SEAFOOD INSPECTION BILLS

	Mitchell (S. 1245, reintroduced as S. 2924)	Hollings (S. 2228, reintroduced as floor amendment No. 2431)
TITLE	Fish Safety Act of 1990 (Sec. 1)	Consumer Seafood Safety and Quality Assurance Act of 1990 (Sec. 1)
LEGISLATION AMENDED	Food Security Act of 1985 (Sec. 3); the Act of May 8, 1914 (Sec. 4)	New program
LEAD AGENCY	Agriculture (Secs. 1901 & 1903)	Health and Human Services (HHS) in cooperation/consultation with Commerce. Generally, HHS designs and oversees program and standards; Commerce establishes procedures for registration of processors and importers, and conducts day-to-day inspection activities (Secs. 3, 4, 5, 7)
PRODUCTS AFFECTED	Freshwater or marine finfish, mollusks, crustaceans, and other forms of wild and cultured aquatic life including amphibians, (but excluding birds and mammals) intended for human consumption; fish products are those containing fish in whole or part, except products containing relatively small portions of fish, historically not considered fish by consumers, or exempted by the Secretary (Secs. 1901 & 1903)	Essentially the same as Mitchell (Secs. 3 & 4)

	Mitchell	Hollings
TYPE OF INSPECTION PROGRAM	"Comprehensive and efficient health-based" inspection to: (1) be specifically designed to take into consideration the special characteristics of fish/fish products; (2) be based on a comprehensive assessment of fish/fish products and their processing/handling that identifies and assesses severity of hazards/risks and that prescribes health-based sanitary standards for processing establishments; (3) be based on consideration of processing/distribution procedures including assessment of potential fish-related health risks; determination of sources and points of potential contamination; potential for persistence/growth of contaminants; (4) be based on need to require and monitor procedures to prevent, eliminate or control potential fish contaminants; (5) be designed to take into consideration distinctive characteristics, hazards, control points, processing procedures for different fish species; (6) assure, through "frequent, and unannounced or announced" inspections, that processing complies with standards (considering nature and frequency of operations; adequacy of monitoring; history of compliance; recommendations of the Model Seafood Surveillance Program (MSSP);	"Comprehensive seafood safety and quality assurance program" that: (1) is specifically designed to take into consideration special characteristics of fish/fish products, including distinctive characteristics, hazards, control points, processing procedures related to different species; (2) prescribes health-based standards for safety/sanitation in harvesting/processing; (3) is based on comprehensive evaluation of processing/distribution of fish/products including: identification/assessment of health risks associated with fish and their handling/processing; determination of potential fish contamination sources; assessment of potential for persistence/growth of contamination; (4) provides for and monitors procedures to prevent/control potential contaminants; (5) implements monitoring of growing/harvesting areas; (6) provides inspection authority (and funding) to States; (7) implements national consumer education program on health hazards of fish consumption; (8) establishes a shellfish indicator research program and other research (Sec. 4) Calls for "comprehensive and efficient system" to protect public from adulterated/misbranded

C-48

	Mitchell	Hollings
	potential of the operations and fish species to affect human health; and other factors; (7) not require freezing/cooking of products intended for raw consumption unless needed to control adulteration; (8) provide for identification/classification of fishing growing/harvesting areas in conjunction with appropriate Federal/State agencies; (9) provide for delegation of certain inspection/sampling authorities to States (with up to 50% funding); (10) provide for sampling and inspection of products; (11) establish procedures to assist in tracking sources of contamination; (12) provide for naming/labeling regulations (Sec 1903)	fish/products, with "frequent and random, unannounced" inspections. System shall include: (1) appointment/training of inspection officers; (2) training/certification of processing personnel; (3) sampling of fish/products for contamination; (4) inspection of fish and processing "at such points, in such manner, and with such frequency" as determined by HHS Secretary taking into account: nature/volume of operations; adequacy of monitoring; history of compliance; potential for fish/products to pose health risks; recommendations of MSSP; and other factors; (5) procedures to assist in tracking contamination sources; (6) other activities determined by HHS in consultation with Commerce Secretary (Sec. 7)
INSPECTOR POWERS	To conduct inspections, enforce compliance, and take other actions including inspection of all locations within establishments; sampling and testing of products; detention and condemnation of adulterated or misbranded products; inspection and sampling of imports. Provisions for dealing with condemned products (Sec. 1905)	To conduct inspections and take other actions including inspection of processing facilities; sampling; detention/condemnation; and upon request and at reasonable times review/copy records (Sec. 7)

	Mitchell	Hollings
REGISTRATION/ CERTIFICATION REQUIREMENTS	Requires USDA procedures for certification (or decertification for good cause) of establishments (and importers), which may not process or handle any fish without such certification. Establishments defined (Sec. 1901) as any fish processing vessel subject to U.S. jurisdiction, or any building, premises, structure, or other facility in any State or Territory used to handle or process fish (see below for exemptions). Includes specified procedures/conditions for decertification and reinstatement (Sec. 1907). Requires USDA-Commerce study within 2 years on the need to register/inspect fish tender and harvesting vessels, and so advise Congress (Sec. 1921)	Requires Commerce (in consultation with HHS) procedures for registration of processing facilities (and importers). Processing facilities defined (Sec. 3) as any fish processing vessel or any building, premises, structure or other facility used to handle or process fish. Language on procedures/conditions for decertification and reinstatement differs from Mitchell bill (Sec. 6). Requires Commerce-HHS study within 18 months of need to register/ inspect exempted vessels and aquaculture operations, and so advise Congress (Sec. 21)
SANITARY / PROCESSING STANDARDS	Requires USDA to issue standards of sanitation and other good processing, etc. procedures (Secs. 1903, 1906 & 1920)	Requires HHS in cooperation with Commerce to prescribe health-based and other appropriate standards of sanitation/quality control for fish processing: (A) based on HACCP-type evaluation required under Sec. 4; (B) not require freezing/cooking of products intended for raw consumption unless needed to control adulteration; (C) include all applicable sanitation and good manufacturing practices set by HHS, vessel harvesting/processing practices set by Commerce, and those in the National Shellfish Sanitation Program (NSSP) (Sec. 5)

	Mitchell	Hollings
CONTAMINANT STANDARDS	Requires FDA (in consultation with NAS and 5 other specified agencies) to establish tolerances (except those set by EPA) for poisonous/ deleterious substances that may adulterate fish products (see Sec. 1901 for lengthy definition of adulteration). Also separately requires FDA to establish tolerances (except those set by EPA) for harmful chemicals, toxins, parasites, pathogenic microorganisms, viruses, bacteria, and other harmful agents. May include indicator organisms. (Sec. 1903)	Requires HHS, after contracting with NAS, to identify and report on likely health-threatening fish contaminants, and in cooperation with Commerce, to establish standards (except those set by EPA) for contaminant levels for fish; may include indicator organisms (Sec. 5)
LABELING	Requires USDA to prescribe standards for marking fish/products or their containers with official stamp (Secs. 1901 & 1920); requires establishments to use stamp and appropriate identification on each package (Sec. 1908); requires USDA to set rules for identifying/ naming fish (Sec. 1903)	Requires HHS in cooperation with Commerce to prescribe standards of identity, composition, minimum quality, labeling, etc. Requires definitions of common/usual fish names (Sec. 5); Requires each package to be marked with unique Commerce-assigned code (under Sec. 6) and official mark (Sec. 7)
RECORDKEEPING	Requires USDA to set rules for establishments to maintain specified records and to provide USDA and Commerce access to them upon request at reasonable times (Secs. 1909 & 1920)	Requires registrants to maintain records and provide such information that HHS may require, upon request and at reasonable times. Commerce would have to obtain such records at HHS request (Secs. 6 & 7)
RECALL PROVISIONS	Permits USDA to require establishments to recall adulterated or misbranded products that may pose health risks (Sec. 1912)	Similar to Mitchell, except that HHS has authority (Sec. 9)

	Mitchell	Hollings
SHELLFISH	Requires Commerce in consultation with EPA to establish a 5-year shellfish indicator research program (Sec. 1921) (see also growing/harvesting areas, below)	Requires Commerce with HHS to establish a 5-year shellfish indicator research program, with more detailed requirements than Mitchell bill (Sec. 17); general seafood safety program must be consistent with National Shellfish Sanitation Program guidelines (Sec. 4) (see also growing/harvesting areas, below)
GROWING AND HARVESTING AREAS	Requires Commerce to establish system for identifying and classifying growing and harvesting areas for fish in coastal areas and the Great Lakes; USDA to sample and test products and to notify appropriate agencies to act if products pose significant health threat; provides Commerce with authority to close waters or restrict harvesting in emergencies or upon receiving USDA notice (Sec. 1904)	Requires Commerce in cooperation with HHS and ISSC to establish system for monitoring/ classifying growing/harvesting areas and designate an area as restricted (for that species) if fish from there is found likely to be unsafe. Specifies conditions for designating restricted waters for shellfish (Sec. 8)

C-52

C-53

	Mitchell	Hollings
STATE PROGRAMS	Permits USDA to cooperate in 2 types of mandatory State programs: (1) covering intrastate commerce, if State program is at least equal to Federal program; (2) those covering interstate commerce on behalf of the Federal Government, with ongoing USDA monitoring to assure it meets USDA requirements, and with up to 50% Federal funding of program costs for States with approved plans. Under either program, USDA must take over (after proper notice and consultation) if State falls below Federal standards. (Sec. 1903)	Requires HHS and Commerce to encourage States to continue or establish programs at least equal to Federal; States with U.S.-approved plans can operate comparable program in lieu of Federal program, with ongoing HHS-Commerce-ISSC monitoring to assure it meets standards, and with up to 60% Federal funding of program costs. HHS must reinstate Federal program if (after proper notice and consultation) State falls below Federal standards. Also specifically permits HHS to enforce Federal program for no more than 6 months if needed in emergency posing serious adverse health consequences or death, or State requests it (Sec. 19)

	Mitchell	Hollings
IMPORTS/FOREIGN PROGRAMS	Imports generally must meet the same certification, recordkeeping and standards required of U.S. products, and also be labeled as to country of origin. USDA must enforce through inspections, sampling and other procedures determined necessary; specifies corrective actions for imports refused entry (Secs. 1907, 1909 & 1910)	Imports generally must meet the same registration, recordkeeping and standards required of U.S. products (no country-of-origin labeling). Facilities in which imported fish /products are processed must be inspected at least at the same rate as other facilities. HHS cooperating with Commerce must enforce through random inspections and sampling of imported fish/products and other procedures determined necessary. Specifies corrective actions for imports refused entry. (Secs. 6, 7 & 10)
	USDA must review a foreign inspection program (including inspection of individual establishments) if requested by that country and certify it if it meets U.S. standards. USDA must inspect <u>all</u> fish product imports from <u>non</u>certified countries. Requires annual reports to Congress (Sec. 1910)	Permits HHS cooperating with Commerce and through Secretary of State to conclude reciprocal agreements with countries desiring to export to the U.S., if their inspection programs are determined to be at least equal to U.S. Products from countries with a valid certificate subject to "random inspections, sampling and such other procedures" as are determined necessary. Products from countries without a valid agreement subject to "intensified inspection, sampling, and such other procedures" as are determined necessary. Specifically applies to imports provisions of Sec. 801 of Federal Food, Drug & Cosmetic Act (FFDCA). Requires annual reports to Congress (Sec. 10)

C-54

	Mitchell	Hollings
EXCLUSIONS/ EXEMPTIONS	Exempts: personal use; nonprocessing vessels; retail stores and restaurants; contract/common carriers (unless carrier had reasonable knowledge of adulteration/misbranding); nonfood products; aquaculture operations; export products meeting specified requirements. Permits temporary exemptions from inspection if appropriated funds are not adequate and an exemption will aid in transition to the new program (Secs. 1901, 1902, 1906, 1911 & 1917)	Essentially the same as Mitchell (Secs. 3, 11, 12 & 21), except lacks authority for temporary exemption from inspection
PROHIBITED ACTS	Separate section cites 10 specific acts prohibited under the law (Sec. 1914); contains somewhat more detailed definitions of "adulterated" and "misbranded" than Hollings (Sec. 1901)	Cites 11 specific acts (many similar to Mitchell) prohibited under the law (Sec. 12); Definitions of "adulterated" and "misbranded" are somewhat less detailed (Sec. 3)
PENALTIES	Includes civil penalties up to $5,000 for 1st violation (each continuous day is separate offense); also criminal penalties up to $20,000 and/or 3 years' imprisonment (Secs. 1915 & 1916). Separate criminal penalties for bribing/assaulting inspectors (Sec. 1919)	Includes civil penalties up to $5,000 for each violation (each continuous day is separate offense); also criminal penalties up to $20,000 and/or 3 years' imprisonment (Sec. 12). Lacks separate penalties on bribing/assaulting inspectors
H E A R I N G PROVISIONS	Administrative hearing opportunity must be provided for persons adversely affected by Act (except in criminal prosecution). Contains more detailed procedural and judicial review provisions than Hollings (Secs. 1915, 1916 & 1918)	Administrative hearing opportunity must be provided for persons adversely affected by Act; procedural provisions less detailed than Mitchell (Sec. 13)

	Mitchell	Hollings
EMPLOYEE PROTECTION	Lacks employee protection ("whistleblower") provisions	Prohibits discharging/disciplining employees who point out violations of Act or refuse to perform work that would result in a violation or that might reasonably pose a public health risk. Includes detailed procedures for investigating complaints by employees believing they have been discharged/disciplined for such actions (Sec. 14)
TRAINING REQUIREMENTS	Requires USDA regulations on procedures for training inspectors (Sec. 5), and permits USDA to establish guidelines for training employees in sanitation/quality control for establishment employees (Sec. 1906)	Inspection program must provide for training of inspection officers, and of processing establishment personnel (Sec. 7)
ILLNESS/HEALTH MONITORING	Requires HHS-CDC to establish an active surveillance system to estimate the frequency of human disease associated with **food**, comparing major food categories (Sec. 1913)	Requires HHS-CDC (in consultation with Commerce) to establish an active surveillance system to estimate frequency/sources of human disease associated with **fish and fish products**; includes several specific data collection requirements (Sec. 15)

C-57

	Mitchell	Hollings
RESEARCH	Requires USDA in consultation with other Federal agencies and States to determine research priorities, with "appropriate" Federal agencies to conduct it; establishes research advisory panel; specifically requires shellfish indicator research program (see shellfish, above); also specifically requires research into improved sanitation, contaminant testing, fish inspection techniques; requires USDA-Commerce study of need to include harvesting/fish tender vessels in inspection program (Sec. 1921)	Requires HHS and Commerce to jointly develop and publish a strategic plan/priorities for fish safety research, including contaminant testing, inspection procedures, sanitation practices. Specifically requires shellfish indicator research program (see shellfish, above) (Sec. 17). Separate section requires study of need to include exempted vessels and aquaculture operations in program (Sec. 21)
EDUCATION	Requires USDA to provide $2 million annually to States in conjunction with Extension for food safety information demonstration projects (Sec. 1921)	Requires HHS and Commerce to establish a national consumer education program on seafood (Sec. 16)
IMPLEMENTATION TIMETABLE	FDA contract (to identify contaminants/other harmful substances likely in fish) within 30 days of enactment; NAS report within 6 months of contract; FDA final rules on contaminants within 1 year of NAS report; USDA implementation of inspection program within 18 months of FDA final rules (up to 37 months total); other Commerce and FDA responsibilities generally must be implemented within 2 years of enactment (Secs. 5, 6 & 7). USDA-Commerce study of vessels due within 2 years of enactment (Sec. 1921)	Program must be established by HHS and Commerce within 2 years of enactment (Sec. 4); HHS contract (to identify contaminants) with NAS within 30 days of enactment; NAS report within 18 months of enactment (Sec. 5); Commerce-HHS study of vessels and aquaculture operations within 18 months of enactment (Sec. 21)

	Mitchell	Hollings
RELATION TO OTHER LAWS	Specifically exempts fish/products from inspection, sampling, regulation, etc., requirements of the FFDCA after implementation of inspection program (Sec. 1925); existing HHS, Commerce, USDA laws and regulations affecting fish/products remain in effect until then (Sec. 5)	Except as directly inconsistent with this Act, nothing in it affects or limits authority of HHS (under FFDCA) or Commerce (under Agricultural Marketing Act of 1946, Title II) (Sec. 22)
FUNDING	Specifically requires Federal funding for inspection costs, except for overtime, which shall be borne by establishment at USDA-set rates (Sec. 1926). Authorizes up to $14 million in FY1991, $40 million in FY1992, $80 million in FY1993, and $100 million each in FY1994 & FY1995--of which FDA would receive 80% in FY1991, 60% in FY1992, 40% in FY1993 and 20% in FY1994 & FY1995, and of which Commerce would receive 10% annually. Also earmarks from total up to $5 million each in FY1991, FY1992 & FY1993 for research (Sec. 1927). Also authorizes $750,000 annually for food safety information activities (Sec. 4)	Authorizes up to $35 million in FY1991, $60 million in FY1992 and $90 million in FY1993 for inspection, plus up to $15 million each in FY1991, FY1992 & FY1993 for research (Sec. 23); provides for fees for specified voluntary grading services (Sec. 20)

C-58

RICHARD E. GUTTING, JR.

Dick Gutting is the Vice President for Government Relations of the National Fisheries Institute. NFI was founded in 1945 and is the largest trade association serving the United States commercial seafood industry. It's members include over 1,200 companies engaged in harvesting, processing or marketing fish and seafood.

Mr. Gutting has been actively involved in fishery issues for over fifteen years. He has held several positions in government including serving as Director of the Office of Policy and Planning for the National Marine Fisheries Service, the NOAA Assistant General Counsel for Fisheries, the Counsel for the House Subcommittee on Fisheries and Wildlife Conservation and the Environment and as a senior legal advisor to the President's Council on Environmental Quality. Prior to his government service he practiced law as a specialist in oceans, environmental and natural resources law. He received his law degree from Stanford Law School.

C-59