New Inspection Program for the Nation's Seafood

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Earlier this year, the U.S. Food and Drug Administration (FDA) announced a groundbreaking initiative to further ensure the safety of the Nation's seafood. Known as Hazard Analysis Critical Control Points (HACCP), the plan requires seafood processors to adopt a program that identifies potential food-safety hazards and adopt controls specifically targeted to those hazards to prevent them from occurring or at least to minimize the likelihood of their occurrence.

HACCP focuses on prevention of product contamination rather than on detection of contaminated products. Verification that HACCP is in place and is working would be an added feature of FDA's current system of periodic mandatory inspections of processing plants to produce a more effective system of ensuring the safety of seafood. FDA expects to finalize the rule in early 1995. The proposed rule, published for public comment on January 28, 1994, proposed an effective date of 1 year from the issuance of the final rule.

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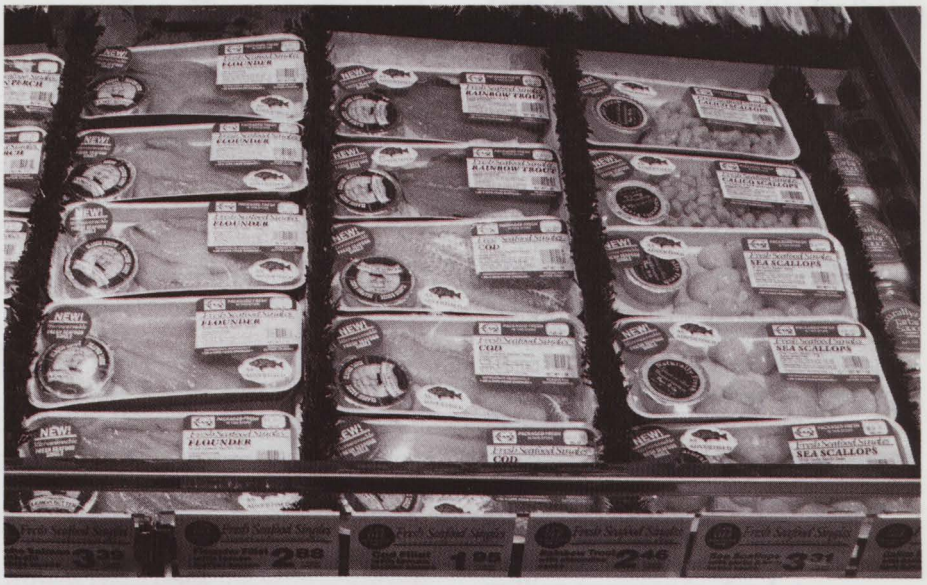
Ensuring a Safer Supply

In 1992, per capita consumption of seafood was 14.7 pounds, down from its peak of 16.1 pounds in 1987. This decrease is due partly to changes in the relative prices of seafood, red meats, and poultry. Some consumer concerns about seafood safety may also be a factor.

There are numerous types of foodborne illnesses caused by seafood, ranging from the very severe bacterium, *Vibrio vulnificus*, which kills one out of every two people it infects, to the very mild illness Neurotoxic Shellfish Poisoning. Seafood contaminants include bacteria, viruses, natural toxins, parasites, and chemical contaminants. Control of some of these hazards (such as ciguatera) relies primarily on harvest management, whereas other hazards (such as scombro-



Nearly 5,000 U.S. seafood manufacturers—those that fillet, bread, and can fish and other seafoods—would be affected by the proposed rule. The rules would also apply to 2,400 packers, re-packers, wholesalers, and U.S. importers, as well as all foreign companies providing seafood to U.S. consumers.

toxin) are either introduced or may be controlled by manufacturers, retailers, or consumers.

Molluscan shellfish, such as clams, oysters, and mussels, which are served raw or partially cooked, present the greatest risk of likelihood of illness to consumers. These shellfish concentrate environmental contaminants and microorganisms in their flesh.

Only about 33,000 of the estimated 6.5 million to 33 million cases of foodborne illnesses that occur each year in this country are estimated to be attributed to seafood, representing less than half of 1 percent of the total. However, if seafood consumption increases, so will exposure to risks from seafood-carried diseases.

Monitoring Commercial Distribution, Step by Step

FDA estimates that Federal, State, and local authorities collectively spend about $100 million each year on the regulation of seafood. Regulatory agencies have relied primarily on testing the final products and inspecting processing plants. However, only a small number of samples can reasonably be tested relative to the number of seafood products and processors. Thus, both Government and businesses have begun to examine new methods and technologies and their potential for reducing foodborne illness in ways that are both workable and economically feasible.

HACCP is a preventive system of hazard control designed to minimize contamination of the product at all points in the production chain, including under-refrigeration and insufficient cooking times.

Initially developed by the Pillsbury Company in the early 1960's to provide safe food for U.S. astronauts in space, HACCP's step-by-step process of contamination prevention has been refined and adapted to commercial processing. It is not a "zero-risk" system, but it is designed to reduce the risk of food-safety hazards to a minimum.

In the 1970's, FDA mandated HACCP-type principles for canned fruit and vegetables that are not highly acidic. Several large U.S. food firms use HACCP-type systems in their plants. Canada has adopted HACCP for its seafood industry, and the European Union has stated its intention to adopt HACCP for seafood.

HACCP consists of seven steps. Under FDA's proposal, seafood processors must:

- Identify the likely health hazards to consumers in a given product
- Identify the critical control points (CCP's) in the production process where a failure of control is likely to introduce or intensify the risk of contamination
- Establish safety measures to prevent a hazard from occurring
- Monitor the system to ensure that the safety measures are working
- Establish the appropriate remedy if monitoring shows a problem
- Establish detailed recordkeeping to document the monitoring, the steps taken to prevent the hazards, and the remedies taken
- Verify that the control system is working (both the company and the Government would be involved at this step)

FDA's seafood HACCP proposal is based on these seven principles.

Imports Also Subject to HACCP

As the world's second largest seafood importer, the United States purchases 55 percent of its supply of edible seafood from some 135 countries, amounting to nearly $6 billion. Many of these imports come from developing countries that may not have the same level of seafood inspection as the United States.

HACCP would better ensure the safety of imported products. FDA now physically inspects a small percentage of imported seafood. Under FDA's new proposal, domestic importers of seafood will be required to have a HACCP plan of their own and to obtain HACCP plans from their foreign suppliers. Importers will also have to take affirmative steps to ensure that their suppliers are in compliance with HACCP. The proposal offers several ways to meet this requirement, including inspecting overseas plants, obtaining certification of foreign inspections, or testing the end product. This requirement would be deemed to be met if the importer's foreign supplier is located in a country that has entered into a mutual recognition agreement (MRA) for seafood with the United States. An MRA would establish that the foreign country has in place a mandatory, HACCP-based safety system equivalent to the U.S. system.

Initial Implementation the Largest Cost

FDA estimates that nearly 5,000 domestic seafood manufacturing plants would be affected by the proposed rule. Seafood manufacturers include companies that fillet, bread, and can fish and other seafoods. The rules would also apply to 2,400 packers, re-packers, wholesalers, and U.S. importers, as well as all foreign companies providing seafood to U.S. consumers.

The proposal does not specifically include aquaculturalists, fishing vessels, transporters, retail stores, or restaurants. However, many of these businesses would also be affected through buyer-seller relationships, that is, through restrictions that manufacturers will place on businesses in order to control hazards, such as by specifying to suppliers and distributors that the fish be properly refrigerated.

HACCP is primarily a fixed-cost system (the costs of the control program do not vary significantly with the amount of product produced). But costs do vary from plant to plant, based in part on risk and complexity. The more complex the processing system, the more CCP's that may have to be monitored.

Ideally, firms will adjust the frequency of monitoring to the likely frequency of failure of a CCP. Thus, the HACCP system should create incentives for firms to invest in more reliable equipment.

The fixed nature of HACCP costs will cause a relatively larger burden for small plants. Thus, firms with smaller sales over which to spread the cost of HACCP will likely shift away from production systems that have numerous CCP's. For example, a small seafood manufacturer may remove ready-to-eat shrimp cocktail from its product line. Whether this shift occurs may well depend on the condition of the plant. Plants that already have controls in place will find HACCP to be less of a burden than firms that do not.

Firms face costs in both developing a system and maintaining it. For purposes of estimating industry implementation costs, FDA acquired, through trade associations, some limited data from firms that have implemented HACCP. FDA economists also adapted a cost study performed for the National Oceanic and Atmospheric Administration (NOAA), which had previously conceived of a similar plan for seafood manufacturers. For the latter study, 130 manufacturing plants were examined for information on sanitation practices, processing controls, and recordkeeping.

The data based on actual implementation range from $2,000 to $20,000 per year. (A comparison of compliance costs to small firm profits may help put this in perspective. The average small seafood processor has annual sales revenues of about $250,000. At an estimated 3-percent return on sales, the average small processor has a profit of $7,500.)

The costs based on the NOAA modeling tended to be higher. More data are needed to reconcile these differences. Until such data become available, FDA's estimates must be considered tentative.

FDA estimates that total first-year costs for monitoring and testing equipment, training, operational changes, and other adjustments needed to implement a HACCP program would average $24,000 for small plants and $23,400 for large plants. Costs are larger for the average small plant because unlike many larger seafood manufacturing plants, many smaller plants do not currently have HACCP-type controls in place. Costs of this proposed Federal program include only new, mandatory expenditures.

Recurring charges for operating a HACCP program in subsequent years would cost small plants $14,700 a year, large plants $15,700 a year. Both initial and recurring costs of the HACCP program will vary for individual plants, based on the level of HACCP controls already in place.

In FDA's analysis, small plants are defined as those with annual sales of less than $1 million and large plants are those with annual sales of $1 million or more. Three-quarters of U.S. seafood manufacturing plants fall into that "small" definition (table 1). These manufacturers account for 7 percent of total industry sales.

Table 1
Three-Quarters of U.S. Seafood Manufacturing Plants Have Annual Sales Below $1 Million

Plant sales	Number of plants	Share of plants	Volume of industry sales
Million dollars	*Number*	*Percent*	*Percent*
Under 1	3,586	74	7
1-9.9	984	20	25
10-49.9	237	5	35
50-99.9	24	**	13
100 or more	15	**	20
Total	4,846	100	100

Note: **Under 1 percent.

Under a HACCP-type program explored by NOAA, 334 small firms could have gone out of business if the program had become mandatory, according to the work performed for NOAA. When Canada instituted its HACCP program in 1993, 2 percent of seafood processors closed. Small plants may be forced to close because they cannot spread the costs of compliance over their output as easily as large plants could. However, FDA asked for comment in its proposed rule on ways to mitigate the impact of the final rule on small businesses, such as allowing a longer time for them to comply.

According to FDA's preliminary estimate, total costs of the HACCP system for domestic seafood manufacturers would be $116 million in the first year and $65 million annually thereafter. Costs to foreign processors were estimated to be $96 million in the first year and $44 million in succeeding years. The costs will be passed on to consumers in the form of higher prices.

Benefits of HACCP

The primary benefits of the proposed rule are from reductions in foodborne illnesses (see table 2). For hazards which usually occur from mishandling seafood during harvesting or processing—such as scombroid poisoning (a generally mild disease that requires no medical care)—HACCP will greatly reduce health risks. FDA estimates that between 6,500 and 19,000 cases of seafood-caused illnesses, or in some cases deaths, could be averted under the HACCP program each year at a value of between $15 million and $75 million per year.

Some risks from seafood are not addressed by HACCP. For example, the program will not reduce any cases of Neurotoxic Shellfish Poisoning because the disease is primarily associated with products caught in recreational fishing—not commercial harvesting.

Consumers and the seafood industry should also benefit from increased confidence in the safety of seafood. Increased consumer confidence could boost demand for seafood. However, higher prices as a result of HACCP will mitigate this effect, so the change in consumption remains uncertain.

The higher demand for seafood could provide health benefits as people substitute seafood for protein sources with higher fat contents. For example, FDA estimates that if Americans increased consumption of fish by 1 and 5 pounds per person per year, the incidence of death would be reduced by 673 and 2,782, respectively, from coronary heart disease and cancer over a 10-year period. This results in benefits valued at $3 billion and $14 billion, respectively, over a 10-year period.

The Vice President's plan for reinventing Government has included consideration of HACCP for the entire food supply. With seafood as the first step, both FDA and USDA are currently examining the feasibility and desirability of HACCP for all other foods.

For More Information...

This article is adapted from FDA's preliminary regulatory impact analysis of the HACCP seafood proposal. The report details FDA's preliminary estimates of the costs of the proposed HACCP program for different types of seafood manufacturing plants and the methodology used in calculating the public-health benefits. Copies of the full analysis are available upon request to the authors. ■

Table 2
Hazards Associated With Seafood Consumption

Hazard	Annual cases prior to HACCP	Cases to be averted under HACCP
	Number	
Bacteria:		
Campylobacter jejuni	200	100-150
Clostridium botulinum	4	0-1
Clostridium perfringens	70	53-70
Salmonella, nontyphi	200	100-150
Shigella	70	18-35
Vibrio vulnificus	48	0-24
Other *Vibrios*	10,000	1,000-5,000
Natural toxins:		
Ciguatera	800	50-200
Neurotoxic shellfish poisoning	48	0
Paralytic shellfish poisoning	13	0
Scombrotoxin	7,960	3,980-5,970
Parasites:		
Anisakis	100	10-75
Diphyllobothrium latum	1,000	250-750
Giardia	30	0-8
Viruses:		
Hepatitis A	92	15-46
Norwalk	12,400	1,000-6,200
Total	33,035	6,576-18,679