

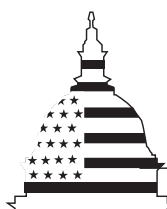
GAO

Report to the Committee on Agriculture,
Nutrition, and Forestry, U.S. Senate

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FOOD SAFETY

Federal Oversight of Seafood Does Not Sufficiently Protect Consumers



G A O

Accountability * Integrity * Reliability

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more serious violations. Table 1 summarizes the type and estimated frequency of the violations identified by FDA inspectors.

Table 1: Estimated Percentage of Occurrences of Nine Types of Serious HACCP Violations in Fiscal Year 1999 Inspection Records for Three FDA Districts

Type of violation	Estimated percentage of occurrences ^a
Inadequate identification of hazards	16
Inadequate identification of critical control points	21
Inadequate identification of critical limits	23
Inadequate written monitoring procedures	16
Inadequate implementation of monitoring procedures	21
Inadequate identification of corrective action procedures	21
Inadequate corrective actions	12
Inadequate monitoring records	31
Inadequate corrective actions records	9

^aSee appendix 1 for sampling errors for these estimates. These estimates are based only on cases for which the product had a HACCP plan. The only exception was the estimates of the inadequate identification of critical control points, which is based on cases for which the product had a HACCP plan and for which the 1999 version of Form 3501 (Domestic Seafood HACCP Report) was used to record the inspection results. Each case could be subject to more than one type of violation.

The potential health risks associated with these violations are significant because they can involve the failure to establish critical limits for high-risk products, such as cooked ready-to-eat seafood. The failure to establish cooking critical limits for cooked ready-to-eat products can allow pathogens such as listeria monocytogenes to survive, and possibly cause listeriosis—a serious and often fatal condition to humans. FDA’s compliance data for fiscal year 1999 show that 40 percent of the HACCP plans covering cooked ready-to-eat products did not establish adequate time and temperature critical limits to prevent, reduce, or eliminate these types of hazards.

Even if the plans were complete, according to FDA requirements, they would still omit a serious hazard because methylmercury, a highly toxic substance, is not identified or covered in FDA’s seafood guide as a hazard reasonably likely to occur. According to a July 2000 National Research Council report, contaminated fish is the major source of human exposure

to methylmercury in the United States and can cause, among other things, serious neurological problems, such as mental retardation in young children. The risk to public health posed by methylmercury is based on how much of the contaminant is in fish and how much fish people eat.

FDA's guidance to industry does not discuss the identification and control of methylmercury even though FDA's tests for methylmercury in shark and swordfish found that 9 of 18 samples analyzed in 1998 and 1999 met or exceeded FDA's 1.0-part-per-million action level.¹⁷ These test results pertained to imported products.

FDA officials said that most commercial seafood species have very low levels of methylmercury. They also said that the species that contain the highest average amounts of methylmercury—shark and swordfish—are expensive and, therefore, consumed infrequently. Thus, FDA considers that, in most species, methylmercury is not a hazard that is reasonably likely to occur and that HACCP controls are not needed. Furthermore, FDA's position is that if there were an industrial incident or similar event that could raise the levels of mercury in commercial seafood, they would examine whether HACCP controls are warranted and issue new guidance as necessary.

FDA has been evaluating new data on the health effects of methylmercury from the consumption of fish. However, the agency has not established a timeline for completing its evaluation. Moreover, FDA officials stated that the agency is unlikely to include any guidance to industry in the next edition of its Fish and Fisheries guide to be issued in calendar year 2001. In the meantime, FDA advises industry and inspectors not to identify methylmercury as a hazard reasonably likely to occur. However, before HACCP's implementation, FDA's draft Fish and Fisheries Guide identified methylmercury as a potential hazard in certain seafood species consumed by humans, including swordfish and tuna. Furthermore, in 1995, FDA updated its consumer advisory warning pregnant women and women of childbearing age to limit their consumption of shark and swordfish because of potential methylmercury contamination. In January 2000, FDA revised its methylmercury advisory and now recommends that women who are pregnant, or who are of childbearing age and may become pregnant, avoid

¹⁷“Action levels” are agency guidelines that, when exceeded, may pose a threat to public health.

eating the four species of fish known to have the highest levels of methylmercury: shark, swordfish, king mackerel, and tilefish.

Even when FDA identifies serious violations at a seafood-processing firm, it does not take timely regulatory action to ensure compliance. When interactions between inspection personnel and plant personnel fail to obtain compliance, warning letters are the principal means of notifying the plants of serious violations and achieving prompt corrective action before proceeding to more stringent enforcement actions. Warning letters are to be issued for violations of regulatory significance—i.e., violations that affect product safety and may lead to enforcement action, such as product seizure or injunction, if not promptly and adequately corrected. To ensure the prompt and adequate correction of serious violations, FDA's regulatory procedures manuals state that warning letters should be approved within 15 working days of the receipt of the district office's recommendation.

According to FDA's analysis of 52 warning letters processed in calendar year 2000, 94 percent, or 49, exceeded recommended issuance time frames thus significantly delaying notification to industry of observed problems that needed correction. On average, 73 days elapsed between the receipt of the district offices' recommendation and the approval of the warning letters.

Our analysis of 162 warning letters issued to domestic firms nationwide after inspections conducted in fiscal year 1999 parallels these findings—that is, three-quarters of the letters exceeded the issuance time frames by 30 days or more. More significantly, we found that 67 percent of these letters were associated with high-risk products, including scombrototoxin-susceptible seafood, which, if not properly handled, could cause serious health problems requiring hospitalization, particularly in the case of elderly individuals.

FDA headquarters officials explained that issuance time frames are exceeded primarily because of the need to ensure that recommendations in district offices' warning letters are consistent with agency policy. They explained that changes in agency policy are sometimes necessitated by changes in the science associated with HACCP systems and that, in some cases, a significant amount of time is needed to review new or updated policy to ensure that it is interpreted correctly. Also, a significant number of the recommendations in the domestic warning letters submitted by the districts require changes because the letters did not correctly cite serious or critical deficiencies. FDA district officials cited an increase in the

effectiveness of the federal seafood safety system. If left uncorrected, they will continue to undermine the goal of HACCP systems—that is, controlling hazards in the production process before the product reaches the market. More importantly, U.S. consumers may continue to be placed at risk of contracting foodborne illness from contaminated domestic and imported seafood products.

Without requiring registration of all domestic seafood firms, FDA cannot effectively ensure that all seafood products are processed under the HACCP regulations. Similarly, FDA cannot ensure that all seafood products are operating under HACCP systems if it continues to exclude vessels that meet its criteria for land-based seafood firms. Unless FDA verifies that industry identifies and controls all hazards reasonably likely to occur, it cannot ensure that industry is implementing an effective HACCP system. And without the actual observation of the seafood products selected for inspection, FDA inspectors cannot ensure full compliance with HACCP

requirements. Also, without prompt completion of its ongoing evaluation of methylmercury, FDA is unable to give direction to the industry on whether it should establish HACCP controls for this hazard, thus potentially placing consumers at risk of exposure to unsafe levels of methylmercury.

Furthermore, without FDA's timely notification to industry when deficiencies are observed, serious problems are not corrected promptly. Finally, without baseline data, such as that provided by regular microbial testing, FDA is unable to measure the HACCP program's effectiveness and is unable to identify when and where corrective actions are needed.

Concerning imports, FDA does not have seafood equivalence or compliance agreements with any foreign country, which is one of the most effective methods for ensuring the safety of imports. Lacking such agreements, FDA must rely, in part, on a review of importers' records to ascertain that imported products are processed under an acceptable HACCP system. However, most importers have not had the required documentation to demonstrate that the product offered for entry has been processed under HACCP controls. In addition, by not communicating the results of foreign firms' inspections to U.S. port of entry personnel, the likelihood that unsafe products from these firms are not inspected prior to their release into the U.S. market is increased. Finally, port of entry inspections are insufficient to ensure the safety of imported seafood, are an inefficient use of resources, and have been unable to keep pace with increasing import shipments.