

Guidance for Industry¹

Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products

Draft Guidance

This guidance document is being distributed for comment purposes only.

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Comments and suggestions regarding this draft document should be submitted to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with Docket No. 00D-1555. For questions regarding this draft document contact Mary I. Snyder, 202-418-3133.

Additional Copies: World Wide Web/CFSAN home page at <http://vm.cfsan.fda.gov/~dms/guidance.html> or from the Industry Activities Staff, Office of Constituent Operations, Center for Food Safety and Applied Nutrition, 202-205-5251.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

¹This draft guidance represents the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

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Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products

I. Basis for Official Review Of Seafood HACCP Records and Plans

FDA's Seafood HACCP program is set forth at 21 CFR part 123. These regulations require processors of fish and fishery products to operate preventive control systems for human food safety that incorporate seven principles of HACCP. Among other things, processors must establish "critical control points" in their operations where they can most effectively maintain the safety of their products, systematically monitor the operation of those critical control points to ensure that they are working as they should, and keep records of the results of that monitoring. Processors must also develop written HACCP plans that describe the details and operation of their HACCP systems. Each processor may tailor its HACCP system to meet its own circumstances. The regulations require processors to make their HACCP records and plans available "for official review and copying at reasonable times" (§ 123.9 (c)). Finally, the regulations provide that fish and fishery products are adulterated under section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the act) if their processor fails to have and implement a HACCP plan when one is necessary, or otherwise fails to meet any of the requirements of the regulations, including allowing the official review of records (§ 123.6(g)).

The best way for a regulatory authority to determine whether a processor is effectively operating a HACCP system is by inspecting the processor to assess whether the system is operating properly and is appropriate for the circumstances. Review of

monitoring and other records generated by the HACCP system is a critical component of an inspection because it allows the inspector to match records against practices and conditions being observed in the plant and it discourages fraud. Thus, FDA always has intended that its review of processors' HACCP plans and records would occur as part of an inspection of a processor's entire HACCP system. Other provisions in the regulation and statements in the preambles to the proposed and final rules make this plain. For example, § 123.9(b)(3) requires that records stored away from the premises due to seasonal closure be returned to the plant so that they may be officially reviewed during an inspection of the processing conditions. Moreover, FDA opted not to preapprove HACCP plans, on the grounds that such matters, including recordkeeping, should be evaluated under actual operating conditions during an inspection (see the preamble to the final regulations (60 FR 65170, December 18, 1995)).¹

In sum, § 123.9 (c) requires HACCP records and plans to be made available to FDA during an inspection.

II. Failure to Provide Records During an Inspection

During the course of FDA inspections of domestic processors of fish and fishery products, a question that has surfaced, although infrequently, has been whether a processor may provide FDA with HACCP records or plans after the inspection. As explained above, the HACCP regulations require records and HACCP plans to be available for review during an inspection. The agency expects that it will regard the failure to provide records and plans by a domestic or foreign processor as a significant

1. When making this decision, the agency distinguished the review of HACCP records and plans from the review of certain records pertaining to the processing of low-acid canned foods (LACF) and acidified foods that FDA conducts independently of a visual inspection of processing facilities. FDA pointed out that it can effectively review LACF and acidified food records outside of an inspection because, unlike HACCP records and plans, these records are relatively limited in scope and lend themselves to a paper evaluation (60 FR 65170-71). Processors of these products including foreign processors that ship to the U.S., must submit records relating to their scheduled processes to FDA as a condition of doing business in

program violation, even if a firm volunteers the documents after the inspection. As explained above, FDA can best assess compliance of HACCP plans and records when they are reviewed on-site at the facility; review off-site will generally not allow FDA to determine that the plan is being followed and information recorded when required.

III. Failure to Allow an Inspection

For domestic processors, failure to allow an inspection would not only violate the HACCP regulations; it is also a prohibited act under 21 U.S.C. 331(f). Moreover, if a domestic processor refuses an FDA inspection, FDA can obtain an inspectional warrant from the U.S. district court in which the processor is located.

Failure to allow an FDA inspection by a foreign processor can also result in a regulatory response. The definition of "processor" at § 123.3(l) specifically includes persons in foreign countries. Thus, like domestic processors, foreign processors who ship to the U.S. must operate under conditions that satisfy FDA's HACCP regulations, including the requirement that records be made available during the course of an FDA inspection²

During FY 1999, FDA conducted in 4 countries 38 inspections of foreign processors of fish and fishery products that export to the U.S. These inspections, which were coordinated with the host governments, were for the purposes of determining compliance with the Seafood HACCP regulation, and providing feedback and assistance to both the industries in those countries and the host governments on how to meet U.S. requirements and operate effective HACCP systems. In the long term, some of these inspections were also intended to help the host country to achieve equivalence with the U.S. system. A number of similar inspections are planned for FY 2000.

As a result of certain misunderstandings, some processors in one country refused to schedule FDA inspections. Accordingly, FDA has determined that it needs to clarify what the result of a refusal of inspection by foreign processors can be under the Seafood HACCP regulations.

FDA's Seafood HACCP regulations deem fish and fishery products to be adulterated under § 402(a)(4) of the act if the processor of those products fails to have and implement a HACCP plan when one is necessary or otherwise fails to meet any of

² Section 123.9 (c) of FDA's Seafood HACCP regulations states that a processor's HACCP records and plans must be available for "official review." While official review may include review by regulatory agencies other than FDA, including those of the foreign country in which the processor is located, it always includes FDA for purposes of food to be exported to the United States.

the requirements of the regulations, including allowing the official review of records during an inspection (§ 123.6(g)). Thus, when a processor does not allow FDA to review records during an inspection, FDA believes that the processor's products are, or appear to be, adulterated under the HACCP regulations.

FDA notes that except in circumstances where there is a public health emergency or the Agency receives information that would indicate the appearance of adulteration of products shipped to the U.S., foreign inspections are generally scheduled well, e.g., weeks, in advance. Thus, FDA believes that taking action under § 801 is appropriate if companies do not accommodate FDA's inspectional request. Examples of circumstances in which FDA believes a foreign processor's refusal to permit inspection may result in an enforcement action by FDA include:

1. A processor is provided notice of at least one day for an inspection and the processor refuses to allow inspection in the absence of any mitigating factors.
2. A processor permits inspection of the facility but does not allow access to HACCP plans or records during the course of the inspection.

However, FDA recognizes that there may be valid reasons why an inspection cannot be scheduled, or if scheduled, cannot be accomplished and that, as a matter of policy, it should consider refraining from action under § 801. Thus, the agency acknowledges that there may be circumstances that it may take into consideration when determining whether to take action due to a foreign processor's refusal. Examples of circumstances that might not result in FDA enforcement action include:

1. A processor has a schedule conflict but is willing to allow inspection at an alternative time and date on the itinerary of the scheduled FDA (foreign) inspection trip that is feasible from FDA's standpoint.
2. A processor is temporarily not shipping to the U.S. because the facility is undergoing major construction.
3. A processor is not operating because of a national or religious holiday and an alternative time and date on the itinerary of the scheduled FDA inspection trip is not feasible.
4. An "Act of God," major calamity, or country emergency makes a scheduled inspection impossible and an alternative time and date on the itinerary of the scheduled FDA inspection trip is not feasible.

FDA also may decide to notify a foreign processor in writing of our intent to issue an import alert because the firm has refused inspection or HACCP records and plan review. A written notice may be warranted if the agency has reason to believe that the foreign processor did not understand fully the U.S. legal and regulatory requirements related to FDA's inspection procedures as they apply in the processor's country, or the consequences of refusing inspections or records review. The agency is aware that the information about U.S. requirements that is made available to foreign processors by different governments may vary significantly in the details provided. Instances of this kind of misunderstanding have caused processors to refuse to schedule FDA inspections. In such cases a written notice from FDA before an import alert is issued may serve to clarify the issues and provide an opportunity for the firm to accept inspection and provide the required HACCP documents.

If the processor does not respond in writing with an adequate reason for its refusal within the time frame provided in FDA's letter, FDA may issue an import alert. If, within the time frame, the processor does provide reasons acceptable to the agency, FDA may forego an import alert and reschedule the inspection. If it is impractical for the agency to perform the inspection itself, due to resource constraints or other reasons, the inspection may be performed by a third party satisfactory to the agency. In that case, FDA should be provided with documentation of the inspection that enables the agency to adequately evaluate the findings. Because third parties, such as the National Marine Fisheries Service of the U.S. Department of Commerce, often provide services for a fee, the processor may have to pay for the inspection.

If an import alert has been issued for refusal to permit inspection or review of HACCP records and plans, the processor should write to the FDA (Mary I. Snyder, Center for Food Safety and Applied Nutrition, (HFS - 415) Food and Drug Administration, 200 C St. SW., Washington, DC 20204) to request removal from the import alert. The request should indicate a willingness to permit immediate on-site inspection by FDA. Again, FDA may conduct the inspection or suggest that a satisfactory third party conduct it. A processor should respond promptly to any recommendations made as a result of the inspection. The processor should describe the corrective actions it took or will take and provide adequate and timely documentation of those corrections.

Foreign processors should note that a determination of adulteration under these circumstances cannot normally be overcome solely by a review of HACCP records and plans. As explained above, FDA can best assess compliance when HACCP plans and

records are reviewed on-site at the facility; review off-site generally will not allow FDA to determine that the plan is being followed and information recorded when required.

Finally, although the Seafood HACCP regulations impose obligations on importers to take “affirmative steps” to ensure that the fish and fishery products they are importing comply with U.S. HACCP requirements, FDA does not view affirmative steps required of importers to be equivalent to inspections by experienced government inspectors. Rather, the affirmative steps set forth the ways importers can meet their legal responsibilities of ensuring that food they import meets the food safety requirements of the act. Consequently, a processor that does not allow FDA to conduct an “official review” as required by the Seafood HACCP regulations may not justify its behavior on the grounds that importers who purchase from it are adequately performing affirmative steps.

This draft guidance represents FDA’s current thinking on refusal of inspection or access to HACCP records pertaining to the safe and sanitary processing of fish and fishery products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations. The draft guidance is being distributed for comment purposes in accordance with FDA’s GGP’s (65 FR 56468, September 19, 2000); the draft guidance has been designated as Level 1 guidance.