DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1555]

Guidance for Industry on Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of guidance for industry entitled ''Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products.'' This guidance sets forth the agency's interpretation of its Hazard Analysis Critical Control Point (HACCP) regulations for fish and fishery products as they pertain to the inspection of facilities and records. The agency is clarifying that a processor's refusal to allow FDA to inspect its processing facilities, or to provide HACCP records or plans to an inspector during an inspection, violates the regulations and thus may trigger a regulatory response by the agency. FDA determined that there was a need for clarification because some domestic firms questioned whether records can be made available after an inspection (rather than during) and some foreign firms canceled scheduled inspections by FDA, but offered to make records available for review. This guidance is for domestic processors and for foreign processors that export fish and fishery products to the United States.

DATES: Submit written comments on agency guidance documents at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Industry Activities Staff, Office of Constituent Operations, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington DC 20204. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Anthony P. Brunetti, Center for Food Safety and Applied Nutrition, (HFS–415) Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3150.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products.'' FDA seafood safety regulations require processors of fish and fishery products to operate preventive control systems for human food safety that incorporate the principles of HACCP (part 123 (21 CFR part 123)). The regulations further provide that fish and fishery products are adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(4)) 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)). Processors must make their HACCP records and plans available ''for official review and copying at reasonable times'' (§ 123.9 (c)). This guidance, previously made available in draft for public comment, is intended to clarify that onsite inspection of a processing facility and concurrent review of HACCP records are essential elements of FDA's Seafood HACCP program as set forth at part 123. Thus, the failure to provide records and plans by a domestic or foreign processor during an inspection violates the regulation, even if a firm volunteers the documents after the inspection. FDA believes that violations of these provisions are significant.

In the **Federal Register** of November 14, 2000 (65 FR 68150) FDA published a notice announcing the availability of the draft version of this guidance and requested the submission of written comments by December 14, 2000. One comment was received in response to the draft guidance. That comment expressed concern that FDA is modifying the regulation so that offsite storage of HACCP records will no longer be permitted. FDA disagrees. This guidance does not change any provision of the regulation, but seeks to clarify those provisions dealing with inspections and records availability. The provision in question, § 123.9(b)(3), allows a processor to store records offsite under two circumstances: (1) The facility is closed for prolonged periods between seasonal packs, or (2) the facility is a processing vessel or remote site with limited storage capacity. However, 123.9(b)(3) requires that records be returned to the processing site immediately for official review upon demand (e.g., within 24 hours). As made clear by this requirement for immediate return, this provision does not contemplate that records would be made available for review offsite or after the inspection is completed. Thus, the guidance does not affect offsite storage of records under § 123.9(b)(3). The guidance addresses the circumstances in which processors want to submit HACCP records to FDA for review only after an onsite inspection has been conducted without access to records.

This guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on refusal of inspection or access to HACCP records that pertain 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 approach satisfies the requirements of the applicable statute, regulations, or both.

II. Comments

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). 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. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://vm.cfsan.fda.gov/dms/guidance.html.

Dated: July 11, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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