

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMP

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[Docket No. 00D-1555]

**Draft Guidance for Industry on Refusal of Inspection or Access to HACCP Records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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products.” This draft guidance sets forth the agency’s interpretation of its Hazard Analysis Critical Control Point (HACCP) regulations for fish and fishery products as they pertain to the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 is issuing this clarification because some domestic firms have questioned whether records can be made available after an inspection (rather than during) and some foreign firms have canceled scheduled inspections by FDA, but offered to make records available for review. This guidance applies to foreign processors that export fish and fishery products to the United States as well as to domestic processors.

DATES: Submit written comments on the draft guidance by *[insert date 30 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

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ADDRESSES: Copies of this draft guidance for industry are available on the Internet at <http://vm.cfsan.fda.gov/dms/guidance.html>. Submit written requests for single copies of the draft guidance to the Industry Activities Staff, Office of Constituent Operations (HFS-565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary I. Snyder, Center for Food Safety and Applied Nutrition (HFS-415), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3133.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft 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 is intended to clarify that on-site 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 (21 CFR part 123). These regulations require processors of fish and fishery products to operate preventive control systems for human food safety that incorporate the principles of HACCP. 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)). The agency expects that it will regard the failure to provide records and plans by a domestic or foreign processor as a significant program violation, even if a firm volunteers the documents after the inspection.

FDA believes that 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.

For domestic processors, failure to allow an inspection would not only violate the HACCP regulations; it is also a prohibited act under section 301(f) of the act (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 United States must operate under conditions that satisfy FDA's HACCP regulations, including the requirement that records be made available during the course of an FDA inspection.

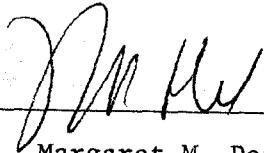
This draft guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on refusal of inspection or access to HACCP records that pertain to the safe and sanitary processing of fish and fishery products. 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 statutes and regulations.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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 draft 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.

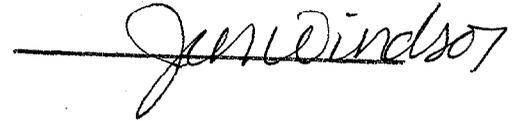
Dated: 10-30-00

October 30, 2000



Margaret M. Dotzel
Associate Commissioner for Policy

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