

WORLD TRADE ORGANIZATION

G/SPS/N/USA/353/Add.1
26 July 2001

(01-3712)

Committee on Sanitary and Phytosanitary Measures

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NOTIFICATION

Addendum

The following communication, dated 20 July 2001, has been received from the United States.

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

The Food and Drug Administration (FDA) is announcing the availability of guidance (previously notified as G/SPS/N/USA/353) for industry entitled "Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products". This final 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 cancelled 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.

Interested persons may, at any time, submit written comments on the guidance. The full text of this addendum (and the guidance), including instructions for commenting, is available from the address below.

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