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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2004D-0510]

Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Live and Perishable Fish and Fishery Products for Export to the European Union and the European Free Trade Association

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or agency) is announcing the availability of the draft guidance entitled "Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Live and Perishable Fish and Fishery Products for Export to the European Union and the European Free Trade Association." The draft guidance proposes a 24-month Referral Program in which European Union (EU) Export Certificates for all shipments of live and perishable fish and fishery products destined for the EU, EU Accession Partnership Countries, and members of the European Free Trade Association (EFTA) would be issued by the National Oceanic and Atmospheric Administration Seafood Inspection Program (NOAA SIP) under the Agricultural Marketing Act (AMA). This draft guidance is not final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by [*insert date 30 days after date of publication in the Federal Register*].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.

ADDRESSES: Submit written requests for single copies of this draft guidance to Bruce Wilson, Center for Food Safety and Applied Nutrition (HFS-417), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1425, e-mail: *bwilson1@cfsan.fda.gov*. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments concerning the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Tim Hansen, Center for Food Safety and Applied Nutrition (HFS-415), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1405, e-mail: *thansen@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Since 1993, the EU has required that an EU Export Certificate accompany all shipments of fish and fishery products that are shipped to the EU. For fish and fishery products generally, the certificates that FDA signs essentially attest that the products have been produced in accordance with a Hazard Analysis Critical Control Point (HACCP)-based safety system that is at least equivalent to the EU system of control. The FDA HACCP regulations have been deemed

by the European Commission to be equivalent, in principle, to the EU system of control. In 1996, the EU also began requiring a different certificate specifically for shipments of live molluscan shellfish (e.g., oysters, clams, mussels). These certificates are based partly on equivalence to, and partly on consistency with, EU requirements.

In 1993, to ensure the smooth flow of trade in fish and fishery products to the EU, FDA began signing certificates for shipments of fish and fishery products to the EU. FDA also signs certificates for shipments of fish and fishery products to EU Accession Countries and EFTA Members. A certificate is issued if it is determined that the establishment¹ is in regulatory good standing with FDA. The NOAA SIP of the U.S. Department of Commerce also signs EU Export Certificates as one service that it offers U.S. seafood processors and other entities in its voluntary, fee-for-service seafood inspection program.

The demand for EU Export Certificates by industry has risen dramatically in recent years and has caused significant resource allocation problems for FDA. The diversion of resources to lower priority, discretionary activities diminishes the agency's ability to carry out public health activities and regulatory oversight that are intended to protect the U.S. consuming public.

II. Significance of Guidance

In order to expedite the exportation of live and perishable fish and fishery products, FDA is considering what parts of its current EU certification activities related to fish and fishery products could be conducted by NOAA SIP. FDA is, therefore, proposing to operate a Referral Program for a 24-month

¹ "Establishment" refers to any structure, or structures, under one ownership at one general physical location, or, in the case of a mobile establishment, traveling to multiple locations, that manufactures/processes, packs, or holds food. Transport vehicles are not establishments if they hold food only in the usual course of business as carriers. An establishment may consist of one or more contiguous structures, and a single building may house more than one distinct establishment if the establishments are under separate ownership.

period to test the viability and effectiveness of such an arrangement. During this period, EU Export Certificates for all shipments of live and perishable fish and fishery products destined for the EU, EU Accession Partnership Countries, and EFTA Members would be issued by the NOAA SIP under the AMA. The basis for issuing EU Export Certificates under the Referral Program would be, as it is now, whether the establishment or establishments in question are in regulatory good standing with FDA. FDA intends to cease to issue EU Export Certificates for live and perishable fish and fishery products during this period. FDA seeks comment on this referral program, including whether it should be expanded beyond live and perishable to all shipments of fish and fishery products destined for the EU, EU Accession Partnership Countries, and other countries with certificate requirements. During this 24-month period, however, both agencies intend to continue to issue EU Export Certificates for shipments of canned, frozen, dried, vacuum packed, etc., products, as requested by appropriate parties.

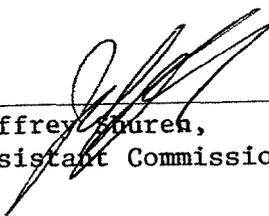
III. Electronic Access

An electronic version of this guidance is available on the Internet at <http://www.cfsan.fda.gov/guidance.html>.

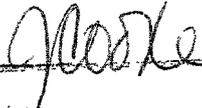
IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/17/04
November 17, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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