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Guidance for Industry

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

*Additional copies are available from:
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<http://www.cfsan.fda.gov/guidance.html>*

You may submit written or electronic comments regarding this guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
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This guidance represents the Food and Drug Administration's (FDA'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. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. Introduction

The Food and Drug Administration (FDA) is providing this guidance for seafood processors and other entities that are interested in obtaining “export certificates” for fish or fishery products that are required by countries in the European Union (EU) or the European Free Trade Association if certain U.S. products are to be shipped to the EU or the European Free Trade Association EFTA.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or

¹ This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

The EU has required that “Health Certificates” (hereinafter referred to as EU Export Certificates) accompany all shipments of fish and fishery products that are shipped to the EU or EFTA since 1993. At that time, FDA voluntarily began issuing such EU Export Certificates free of charge. When FDA agreed to begin issuing EU Export Certificates, FDA anticipated that this would be an interim program and issued approximately 3,000 certificates annually. FDA now issues over 30,000 certificates each year for shipments of fish and fishery products to the EU and EFTA member countries.

Since 2003, FDA has experienced significant increases in food safety responsibilities and concomitant declines in resources available for food safety. In order to carry out public health activities and regulatory oversight that are intended to protect the U.S. consuming public, FDA has found it necessary to focus these resources to higher priority programs (based on public health significance) and has determined that it can no longer justify the use of its limited food safety resources for issuance of EU Export Certificates, especially when another agency has resources available to issue these certificates and has as part of their mission the issuance of such certificates. Therefore, FDA intends to proceed with a Certification Referral Program to the National Oceanic and Atmospheric Administration Seafood Inspection Program (NOAA SIP) to include all fish and fishery products for export to EU or EFTA member countries. Thus, on

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February 17, 2009, FDA intends to discontinue its issuance of EU Export Certificates and intends to refer to NOAA SIP any requests for such certificates that are sent to FDA.

FDA also intends, however, to continue producing its EU Export Certificate List, which identifies all fish and fishery product establishments in the U.S. that are in regulatory good standing with FDA and that seek to export fish and fishery products to the EU and EFTA that NOAA SIP could consult to determine whether particular fish and fishery product establishments are in regulatory good standing with FDA when issuing EU Export Certificates.

III. How to Obtain EU Export Certificates

Establishments seeking EU Export Certificates should contact NOAA SIP. See the appendix to this document for a list of NOAA SIP offices and contacts.

IV. Appendix

NOAA SIP Office and Contacts for EU Export Certificates

NOAA Seafood Inspection Program – Headquarters

NOAA Seafood Inspection Program

1315 East-West Highway

Silver Spring, MD 20910

Telephone: 301-713-2355

Fax: 301-713-1081

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Northeast Inspection Branch

NOAA Seafood Inspection Program

11-15 Parker Street - Room 213

Gloucester, MA 10930

Telephone: 978-281-9228

Fax: 978-281-9134

Southeast Inspection Branch

NOAA Seafood Inspection Program

9887 4th Street North, Suite 220

St. Petersburg, FL 33702

Telephone: 727-570-5383

Fax: 727-570-5387

Western Inspection Branch

NOAA Seafood Inspection Program

7600 Sand Point Way, N.E.

Bldg 32, Room 286A

Seattle, WA 98115

Telephone: 206 526-4259

Fax: 206 526-4265

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More information about NOAA Seafood Inspection Program may be found at

<http://seafood.nmfs.noaa.gov/>.