



December 22, 2004

Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

2961 '04 FEB 28 10:19

NATIONAL  
FOOD  
PROCESSORS  
ASSOCIATION

Re: Docket Number 2004D-0509.

**Draft Guidance and Protocol for Industry and Food and Drug Administration Staff. Certification of Fish and Fishery Products for Export to the European Union and European Free Trade Association.**

Dear Sir or Madam:

The National Food Processors Association (NFPA) is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, egg products, snacks, drinks and juices, or provide supplies and services to food manufacturers. In 2005, NFPA will become the Food Products Association (FPA).

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Seattle, WA 98144  
206-323-3540

NFPA appreciates the opportunity to comment on the draft Level 1 guidance referenced above.

Need for Guidance

While FDA has been signing certificates for shipments of fish and fishery products to the EU since 1993, the protocol for certification has not been comprehensively described to the extent that this draft guidance describes the protocol. Seafood processors frequently rely on FDA's EU certification services, and the draft guidance will clarify and facilitate the procedures for those in industry who require certificates, and for those at FDA that administer the program.

FDA Roles

NFPA fully supports the agency's assertion that it continue to serve as the lead competent authority in the U.S. for fish and fishery products. As the lead agency for enforcement of food safety rules for fish and fishery products in the United

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States, it is important and appropriate that the FDA continue to be recognized internationally as the agency responsible for safety of products manufactured in the US, and intended for domestic as well as foreign consumption. The identification of competent national authorities is becoming increasingly important to foreign trade partners for activities related to export certification.

The guidance indicates FDA will “consider the results of inspections conducted by other governmental entities within the U.S. with which FDA has a contract, partnership arrangement, or MOU for a regulatory inspection when making the final determination as to whether or not an establishment is in regulatory good standing.” While we agree this information will be of value in determining the status of processors, and their eligibility for inclusion on the EU Export Certificate list, it is important to ensure that the information provided is evaluated in the context of FDA’s regulatory compliance and enforcement authorities, as other government inspection programs may include quality criteria that are not relevant to FDA’s food safety purview.

#### Eligibility for Inclusion on EU Export Certificate Lists

With regard to the three EU export certificate lists FDA intends to maintain (the Value-Added Processors List, the Value-Added Processing Vessels List and the Other Than Value-Added Processors List), we understand that the guidance is simply formalizing the criteria currently used for categorizing the EU lists at <http://www.cfsan.fda.gov/~frf/sfeuexp.html> . As these lists will be essentially the same as the three currently posted by FDA (The EU Export certificate list for “Establishments”, the EU Export certificate list for “Processing Vessels”, and the EU Export certificate list for “Exporters other than Processors”), we would suggest the terminology used to describe the lists is uniform to enhance clarity of the list classifications. The guidance should also point out that those already on any of the EU export certificate lists need not re-apply unless the nature of their business has changed or additional processing facilities have been added.

In order to be included on the EU Export certificate list, an establishment must be considered to be in “regulatory good standing.” The criteria in section III.B.1. of the guidance states that “An establishment should not be considered in regulatory good standing and should not be issued an EU Export Certificate for any of its products after a Warning Letter has been issued or an FDA legal action has been filed in court, such as an injunction, seizure, or prosecution, under any of the laws or regulations administered by FDA.” It has been our experience that establishments receiving a warning letter are given an opportunity to address compliance issues prior to removal from the list. The guidance should state that the establishment’s action to address the Warning letter should be considered prior to determining whether or not the establishment remains eligible for inclusion on the list.

#### General Comments

The industry appreciates FDA’s continued efforts to ensure the smooth flow of trade in fish and fishery products to the EU, through implementation of the EU Export Certificate program for products exported to the European Union, EU Accession Partnership countries, and members of the European Free Trade Association (EFTA). Notwithstanding the current proposal for a referral program to the NOAA Seafood Inspection Program for live and perishable fish and

fishery products, we commend and encourage FDA to continue the issuance of EU health certificates for other products outside the scope of the referral pilot, including canned, frozen, dried, and other value added forms of seafood products.

We appreciate your consideration of these comments, and trust you will contact us if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ken Lum', written in a cursive style.

Kenneth C. Lum  
Vice President  
National Food Processors Association  
Center for Northwest Seafood