



December 22, 2004

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

Re: Docket Number 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

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
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NFPA appreciates the opportunity to comment on the draft Level 1 guidance referenced above. We recognize the resource demands on both FDA and the food industry in meeting international certification requirements. However, NFPA supports FDA's continued role, as the competent authority, in developing the EC facility listing and in certifying fish and fishery products outside the scope of the proposed referral program.

Need for a Referral Program

NFPA recognizes the significant resources necessary for the issuance of Health Certificates needed for the export of US Fish and Fishery products to the EU, EU

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Accession Partnership Countries, and members of the European Free Trade Association (EFTA). We agree that this poses a particular hardship with respect to the issuance of certificates for live and perishable products that require expeditious delivery to maintain market value. Referral of the certification process for live and perishable fish and fishery products to NOAA's Seafood Inspection Program (SIP) would free up valuable FDA resources required for the agency's increasing demands to ensure its public health mandate continues to be carried out.

The scope of the referral program is appropriately limited to live and perishable (fresh) fish and fishery products. The referral of these time sensitive certificates will accomplish FDA's objective of freeing resources required for certification of these specific products. As such, even if the 24-month referral program is a success, we do not see a need to extend the referrals to products that are not as time-sensitive. **We emphasize the importance of FDA continuing to issue EU Health Certificates for all other products currently covered by the EU certification program. The continuation of the program by FDA ensures that FDA continues to be recognized as the US regulatory authority for fish and fishery product safety.**

Agency Roles

FDA

NFPA fully agrees with FDA's assertion that the Agency continue to be recognized as the primary competent authority for all EU-related Export Certificate services for fish and fishery products covered by this Referral Program. As the lead agency for enforcement of food safety rules for fish and fishery products in the United States, it is important and appropriate that the FDA continue to be recognized internationally as the agency responsible for the safety of products manufactured in the United States.

As FDA intends to continue to establish criteria and evaluate firms for eligibility for inclusion on the EU Certificate Lists, it is apparent that the largest savings in resources attributed to the proposed program will be realized through the referral of the administrative tasks of reviewing certificates for perishable products for completeness, verifying the establishment is listed by FDA as eligible, as well as signing, stamping, and returning the completed certificate to the applicant. NFPA strongly agrees with FDA's strategy for the program, as it leverages systems already in place, reduces redundancy of inspection(s), ensures the validity of certificates, and facilitates the process of certificate issuance for all parties involved – FDA, NOAA SIP, and the exporting establishment. SIP services should also continue to remain available to processors with more specific marketing or certification needs.

Section II.3 of the proposal expresses FDA's intent to continue to provide EU Export Certificate services for shipments of fish and fishery products other than live and perishable (fresh) products, such as frozen, canned, dried, vacuum packed, and other value added fish and fishery products. The referral of certification for time sensitive products (live and perishable) relieves the majority of the resource demands for this activity, thereby freeing the necessary resources for FDA to continue to provide EU export certification services for all other products that it currently oversees. Resource issues aside, we believe the most appropriate entity for issuing

health certificates is the competent authority for assuring the safety of fish and fishery products in the United States.

NOAA SIP

The NOAA SIP programs offer an extended and valuable range of services to domestic and international producers of Fish and Fishery products, including export certification for these products destined for the EU, EU Accession countries, and EFTA members.

Under the referral program proposal, EU Health certificates for live and perishable products will be provided by the NOAA SIP, essentially using the EU Certification List posted by FDA for verification of eligible establishments. For the purpose of the referral program, this is clearly intended to be an administrative function as described above, and should not require any additional in-plant inspection, beyond what is already provided by FDA to ensure product safety. The proposal sufficiently delineates other NOAA SIP services that may be optionally requested for "non-referral program EU Export certificates." The distinction for referral program EU Health Certificates, versus EU Export Certificates issued by NOAA SIP under pre-existing services, is important to ensure the effectiveness and efficiency of the referral program, and to minimize impact on establishments that begin to use the NOAA SIP as FDA refers them.

The proposal also indicates information will be provided to FDA whenever NOAA SIP has information that an establishment seeking certification under this referral program should no longer be in regulatory good standing with FDA, e.g., where NOAA SIP has reason to believe that conditions in the establishment have deteriorated substantially since the most recent FDA. As in separate comments submitted for docket # 2004D-0509, NFPA agrees this information may be of value in determining the status of processors, and their eligibility for inclusion on the EU Export Certificate list. However, 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.

Conclusion

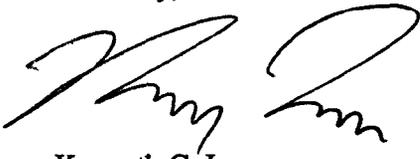
The industry supports FDA's efforts to manage and allocate resources to more effectively carry out the agency's public health mandate, while attempting to accommodate efforts to ensure the smooth flow of trade in fish and fishery products to the EU and minimize the economic impact on the industry. Based on these efforts, we agree the proposed referral program is merited, with the following considerations:

- The authority for verifying food safety remains with FDA, and the referral program certification relies strictly on an establishment's eligibility for inclusion on FDA's EU Export Certificate lists;
- The EU Certificate referral program remains limited in scope to live and perishable (fresh) products, and FDA continues to provide EU health certification for other fish and fishery products as the primary competent authority responsible for the safety of commercial fish and fishery products in the United States.

- The referral program is appropriately viewed as a delegation of an administrative function from FDA to the NOAA SIP without imposing additional inspections or requirements on the industry.
- The effective date for the referral program provides enough time for establishments exporting live and perishable products to the EU to familiarize themselves with the guidance, and to make necessary arrangements to begin applying for EU Health Certificates from the NOAA SIP.

NFPA appreciates the opportunity to comment on this important guidance proposal.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ken Lum', with a large, sweeping flourish at the end.

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