



**NATIONAL
FISHERIES
INSTITUTE**

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April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0276

Re: FDA Docket No. 02N-0276, Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sir or Madam:

The National Fisheries Institute (NFI) would like to offer the following written comments on the proposed "Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002."

The NFI is the nation's leading trade association for the diverse fish and seafood industry operating in the United States. The NFI represents fishing vessel owners, processors, importers, exporters, distributors, aquaculturists, seafood retailers and restaurants. NFI is committed to assisting our member companies in providing consumers with wholesome and diverse seafood choices. The NFI promotes safe, sustainable, and affordable seafood as the daily protein food of choice for feeding the world.

The NFI has assessed the feasibility and practicality of the proposed regulation. While this assessment is not exhaustive, we have a number of insights and cautions to share after examining this far-reaching and controversial regulation.

The NFI believes that databases currently maintained by the FDA and U.S. Customs contain a majority, if not all of the information specified in the proposed "Registration of Food Facilities" regulation. We do not believe that the FDA has fully considered how the current OASIS system could be integrated with databases maintained by the U.S. Customs Service to capture and use this information [It is our understanding that the U.S. Customs' Automated Commercial System (ACS) has already been provided with funding to transition to a new "Automated Commercial Environment" (ACE)]. It is NFI's opinion that database upgrades already budgeted and planned for should be expanded and upgraded to accommodate the regulation's requirements and also integrate the dual needs of FDA and Customs. This would surely be more logical, efficient and

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much less expensive than spending millions of dollars to create a new, complex and untested system that is in ADDITION to the current OASIS and U.S. Customs databases. Under the current proposal these two governmental agencies will have three huge databases that may not be able to share information, efficiently update data across the platforms or even “talk to each other.” NFI believes that the database system(s) as currently proposed will be unworkable and will be quite chaotic and frustrating, especially during the initial registration phase (October 15 through December 15, 2003).

After upgrading and integrating the FDA and Customs databases, it can be determined at that point if further information on food processing facilities is needed from the industry and that can then be obtained.

In addition to this major concern we would also like to comment on several other areas. NFI has heard from a number of international member companies as well as representatives of trade associations in other countries that object, on principle, to having an agent or representative in the USA as a contact point for communication with the FDA. In addition to the considerable cost considerations, they have expressed concerns about commercial confidentiality and related implications.

The proposed regulation states that foreign facilities must be registered by owners, operators or “agents.” NFI believes that much more planning and consideration should be given to defining, for purposes of this regulation, who an “agent” is or will be. For instance, could an importer of record in the US register the companies/plants whose products they import?

NFI is aware of foreign Customs Brokers/freight forwarders that coordinate the shipping and importing into the US of fisheries and food products. The majority of these organizations have excellent communications capabilities (phone, fax, e-mail/internet, etc.), translators speaking English and the native language, office staffing for several time zones or even “around the clock,” and a familiarity with the food processing and business practices in their areas. It is NFI’s contention that the current proposed regulation should be changed to allow for these types of agencies and organizations to act as “agents” for companies in their country and/or geographic region, even though a majority do not have a US office nor could be considered a “US Agent” as such. It is our view that their contacts and communication capabilities would be equal to, if not superior to US agents representing companies/facilities in a country where the US agent may have little expertise and may not even speak the local language.

A second potential problem area is the registration of factory (processing) fishing vessels. Many of these vessels, regardless of country of registry, fish in a number of different locations and sovereign jurisdictions, as well as on the “High Seas” throughout the year. These vessels have a “Home Port” designation but no fixed or permanent address. This situation will need to be considered and provided for in advance of the initial registration, as continually updating the registration of a vessel throughout the year would be unworkable for both the individual company and the FDA.

NFI's final area of concern is that significant quantities of certain seafood products are imported from small ships and regional facilities in remote areas of the world. Communication and information flow to and from these areas may be quite slow or restricted. It is almost inevitable that some seafood imports will arrive in the U.S. from unregistered firms because they simply were not aware of the new regulation. The NFI believes that planning for and accommodating this fact is necessary. A "transition period" needs to be put in place, during which time unregistered companies/facilities could be informed of the new registration requirement without having their imported products detained.

The proposed FDA regulation mentions moving and holding detained cargo in a "secure location" – does this have to be a Customs bonded facility? Also does the agency have adequate cold storage facilities (both frozen and refrigerated product) to adequately accommodate an initial "surge" of unregistered seafood products? This potential situation also needs to be addressed prior to implementation of the proposed registration.

The NFI appreciates this opportunity to comment and looks forward to further dialogue with the Agency on this issue.

Sincerely,

A handwritten signature in cursive script that reads "Robert Collette".

Robert Collette
Vice President,
Science and Technology