



**NATIONAL
FISHERIES
INSTITUTE**

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0275

Re: FDA Docket No. 02N-0275, Administrative Detention of Food for Human or Animal Consumption 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 "Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002."

The NFI is the national trade association for the diverse fish and seafood industry of the United States. NFI is a "water to table" organization representing fishing vessel owners, aquaculturalists, processors, importers, exporters, distributors, retailers and restaurants. NFI is committed to assisting our members provide consumers with safe, sustainable, and diverse seafood choices. NFI is the leading voice for promoting safe, sustainable, 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 several insights and cautions to share after examining this regulation.

Provisions of the Administrative Detention regulation are based on rules currently in place and implemented for the administrative detention of medical devices. The NFI does not believe that this is an analogous product type or an appropriate comparison. Medical devices are non-perishable, high value and are shipped in small volumes from a

limited number of very sophisticated suppliers. The NFI believes that the Agency needs to rethink the Administrative Detention provisions and approach for perishable food products. The analysis of these foods and concomitant decisions must be made extremely quickly or else necessary arrangements (such as a reimbursement/insurance fund) must

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be made for affected companies that will completely lose shipments of perishable food products as a result of administrative detention.

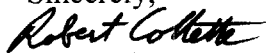
In light of this, the NFI believes that the FDA has wisely decided upon an expedited hearing process for administratively detained perishable foods, but the proposed process is not rapid enough. As stated in the proposed regulation, an appeal hearing must be requested within two days of receipt of an administrative detention notice, if FDA grants the appeal request, the hearing will be within 2 calendar days (“after the date the appeal is filed”). FDA’s decision is to be issued within 5 days of the date of the appeal filing. This proposed procedure will still take up to 7 days and for highly perishable fresh seafood products this would leave only 2-3 days of acceptable shelf-life remaining. Practically, these remaining days would be used in distribution so that a load of, for example, fresh seafood would, in most cases, be a total loss.

NFI would like to suggest that the FDA provide for an “automatic appeal” on the second day after an administrative detention order is issued, with a decision on the appeal made within 24 hours of the hearing. NFI respectfully requests a codified requirement that the sampling and diagnostic testing (to confirm/deny suspicions of food product tampering) be initiated within 24 hours of the issuance of an administrative detention order. The NFI feels that this request is reasonable, given that this type of incident might well involve matters of national security and/or the economic well-being of an entire sector of the American food supply.

NFI would also like to comment on the procedures and disposition of product during the time it is being held in administrative detention. It may be that entire containers or truckloads of product are detained during an administrative detention investigation. Even if there is food product contamination/adulteration, in many instances it may be only one or a very few cases of the food product(s) and not the entire truckload or container. Thus a majority of the detained food product could be released for entry into U.S. commerce after termination of the Administrative Detention order. The NFI respectfully requests written provisions for maintaining the safety, integrity and quality of food product(s) while under administrative detention. This should include, but not be limited to, the holding of refrigerated and frozen food products at the same refrigerated and frozen temperatures and conditions that are found in U.S. commercial cold storage facilities. It should also include a provision to allow, at the request of the “owner operator or agent in charge,” the freezing of detained “fresh” product that is (or will likely be) detained for 4 or more calendar days.

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

Sincerely,



Robert Collette

Vice President,

Science and Technology