NATIONAL FISHERIES INSTITUTE

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

Re: Docket No. 02N-0277; Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sir or Madame:

The National Fisheries Institute (NFI) appreciates this opportunity to submit comments regarding the Food and Drug Administration's (FDA) proposed rule implementing § 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) on maintenance and inspection of records for foods. 68 Fed. Reg. 25188 (May 9, 2003).

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.

NFI commends the FDA for allowing pre-proposal comments on the recordkeeping provisions of the Bioterrorism Act and its efficiency in developing the proposed regulation promptly to maximize the consideration of further comments. NFI supports the purposes of the Bioterrorism Act and the proposed rule (i.e. to enhance protections against bioterrorism through the food supply). NFI believes that the final rule should allow FDA the ability to respond where there is "reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death," without imposing unnecessarily burdensome requirements that restrain trade or exceed applicable constitutional limits on FDA's authority. NFI's recommendations to FDA on the establishment and maintenance of records are summarized as follows:

- Exclude food packaging materials beyond immediate food-contact packaging from the scope of the record keeping regulation;
- Modify the definition of perishable food;
- Eliminate the lot tracking proposal which would impose an enormous burden on industry;

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- Simplify the information requirements to facilitate the food industry's ability to effectuate recordkeeping;
- Eliminate redundant recordkeeping; and
- Change the records access time requirement from 4 and 8 hours, for business and non business hours respectively, to within a time frame not to exceed 24 hours.

General Provisions

Definitions, Section 1.328:

Proposed section 1.328 defines "food" as having the meaning given in section 201(f) of the act, which is: ``(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." FDA also is proposing to include some examples of products that are considered food under section 201(f) of the act. Examples listed in the proposed rule include: Fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; etc. ``Substances that migrate into food from food packaging" include immediate food packaging or components of immediate food packaging that are intended for food use.

In defining the terms "food" and "packaging", FDA asks whether or not outer packaging should be covered. NFI believes that the inner packaging, which is in direct contact with the food, provides a barrier to contamination from outer packaging components. Therefore, NFI agrees with FDA's conclusion that shipping containers and outer packaging, not in direct contact with food, poses only a small risk from contamination and should be omitted from recordkeeping requirements.

Guidance documents addressing the provisions of the records rule should make clear that not all ingredients covered in the definition of food, thus, requiring records, are ingredients that must be included in food product labeling. For example, processing aids and other incidental additives may require records under the new rules but this requirement does not change existing policy that exempts them from ingredient labeling. Likewise, the provisions of the recordkeeping rule should not change existing policies governing product identity labeling.

"Perishable food" is defined as food that is not heat-treated, not frozen, and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 days under normal shipping and storage conditions. The FDA is establishing this definition for the purposes of establishing a shorter record retention time than for nonperishable food. NFI supports the establishment of a shorter records retention time for perishable food but believes the proposed definition is too restrictive.

The definition for perishable food should cover, in most cases, refrigerated food of limited storage life, as opposed to frozen and shelf stable food that has longer shelf life. There are many examples of "prepared" foods that have limited shelf life but do not meet the FDA definition because they are heat-treated. The seven-day shelf life provision is also too restrictive for many limited shelf life products (e.g. less than 45 days) such as refrigerated surimi seafood, cooked crustacean meat (e.g. crab meat, which must be cooked to facilitate removal from the crab) and smoked fish. Raw fish often meet the seven-day requirement but there are species and marketing conditions that yield somewhat longer periods of shelf life. These raw refrigerated fish might not meet FDA's proposed definition. FDA should revise the definition of perishable food to "refrigerated foods of limited shelf life (_____ days)," with the blank to be determined by survey of refrigerated foods.

FDA also asks whether a producer would know whether the food it sells will be processed into a nonperishable food. NFI members indicate they may know in some circumstances but buyers do not always disclose how the product will be used and may utilize it in more than one way. Therefore, producers of perishable food will have to retain records for the longer period of two years, if they are held accountable for the further distribution and use of their products as nonperishable food.

Existing Records, Section 1.330

This section clarifies that it is unnecessary to duplicate records, if the existing company records contain all of the information required by the new rule. NFI supports FDA's intent to allow firms to use existing records on this basis. FDA asked whether or not it should include a model form in the final regulation. NFI believes it might be helpful for some firms to work from an all-inclusive form but not necessarily beneficial or needed for other firms. FDA could provide a sample form as an appendix to the regulation but the regulation and guidance created to implement it should make clear that it is not mandatory to use it.

Requirements to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Source and Subsequent Recipient of All Food Sections 1.337 and 1.345

FDA proposes in these sections to require nontransporters to establish and maintain records for all food received from and sent to nontransporter previous source and nontransporter recipient, respectively and transporters who delivered food coming to and leaving the facilities. FDA indicates the records must include information reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product.

NFI believes that FDA has exceeded the provisions of the Bioterrorism Act and placed a large impracticable requirement on firms by proposing to mandate that records link incoming ingredients to outgoing lots of finished products. The Act allows FDA to

establish by regulation recordkeeping requirements to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. However, there is no wording in the Act to indicate intent to link specific lots of incoming ingredients with specific lots of outgoing food.

There are numerous examples in food production where the commingling of ingredients would make compliance with this requirement very difficult, if not impossible. Continuous blending operations, such as surimi and surimi analog production, utilize large hoppers with continuous feed. One would need to estimate how addition of ingredients there translates into the hour code on the production floor. A similar situation would exist for some breading operations that utilize bulk hoppers for batter rather than adding ingredients on the production floor. These and other examples of food manufacturing involving the commingling of ingredients would require development of expensive new record keeping systems throughout the food industry without being required by the Act or improving public health protections.

The information requirements in these Sections exceed the information necessary for firms to collect and retain and are redundant. The information in 1.337 and 1.345 (a) (1) and (2) are available to the FDA through the plant registration process, therefore, it is unnecessary for firms to keep individual contact names and contact information for each transaction. The name and addresses of firms are available on most invoices and bills of lading. These records should suffice because FDA can the access the additional information via the registration database. Conversely, FDA could allow registration numbers to be recorded as a substitute for this information.

Regarding the information on transporters to be recorded by nontransporters, the relevant transporter information may or may not be on the paperwork at the time that the items are received. In addition, some transporters utilize owner-operators rather than company-owned vehicles. Therefore, if transportation information is required to be retained by the recipient, the transportation company's information should be sufficient, and that company should be required to trace which subcontractor made the delivery.

The requirement that the manufacturer who ships a food and the recipient of the food (nontransporter) who receives it both retain detailed information about the transporter of a food is redundant. FDA should re-examine its information needs and keep them as simple as possible. FDA should be able to effectively trace food with only one or the other firm recording the transporter information, since FDA will in most instances be cable of imposing record keeping requirements upon almost all commercial food transactions in the U.S., including the responsible transporting companies.

Records Availability, Section 1.361

FDA's current experience indicates that the normal response time for requested records is 2-3 days. The agency's interest in reducing this time is understandable but NFI believes the agency has placed an unrealistic time frame on record availability.

FDA's definition of "business hours" does not correspond to some facilities' actual business hours. For instance, some NFI members indicate that all office personnel, who would know how to access the records, are gone by 4:30 p.m., but FDA considers business hours to extend until 6:00 p.m. The upshot of these limits is that several management personnel from each facility would have to be familiar with and able to access records from the filing system, to cover for the hourly people who would ordinarily do this type of work but who would not be expected to come in at off-hours on a moment's notice. The FDA proposal presumes incorrectly that such personnel are still working at 6:00 p.m. and are available around the clock. Given the severity of the penalties for non compliance with records access and the inevitability of unavoidable delays that can occur both during and, especially, after business hours, NFI recommends FDA establish a more realistic and achievable time requirement of 24 hours from the time of request in all situations.

FDA guidance for internal implementation of the new rule should carefully address the last two elements of the standard for records access (i.e. the reasonable belief that an article of food is adulterated and presents a serious risk of adverse health consequences or death to humans or animals). Invoking the records access requirement should be reserved for those cases in which there is a strong probability of a serious problem with an article of food that exposes consumers to serious threats to their health if the food is consumed. NFI suggests that FDA adopt internal procedures similar to those proposed for administrative detention where a request for records is approved by the District Director or acting District Director.

NFI appreciates FDA's consideration of these comments and is to cooperate in the implementation of this new requirement.

Sincerely

Robert L.Collette
V.P. of Science and Technology