NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

July 8, 2003

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Dockets Management Branch
(HFA – 305)
Food and Drug Administration
5630 Fishers Lane
rm. 1061
Rockville, MD 20852

Re: 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; 68 Federal Register 25241; May 9, 2003.

John R. Cady
President and
Chief Executive Officer

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Washington, DC 20005
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Dear Sir or Madam:

The National Food Processors Association submits the following comments on the FDA proposal on Administrative Detention referenced above.

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, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, 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, snacks, drinks and juices, or provide supplies and services to food manufacturers.

FDA has proposed these regulations to implement the Administrative Detention provisions of Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2003 (hereafter the Bioterrorism Act). The Bioterrorism Act authorizes the use of administrative detentions and requires regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order. NFPA strongly supports the appropriate exercise of FDA's detention authority to prevent or stop the possible introduction into commerce of food that is likely to cause serious adverse health consequences or death to humans or animals. This authority is a powerful tool for protecting the public.

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We would expect the Agency to activate these regulations only when other avenues of preventing the product from moving in commerce are not available, including voluntary holding of the product by a responsible party. Prior to the provision of this new detention authority, the food industry has demonstrated the desire and ability to act quickly and responsively to prevent the public from being exposed to potentially harmful food. This is demonstrated by industry voluntary cooperation in Class I recall situations and self-initiated actions that occur without FDA involvement. It has been and remains in the interest of the food industry to take responsible and timely action to ensure the safety of the U.S. food supply. NFPA strongly believes FDA's use of administrative detention authority should rarely be necessary. As noted in the preamble (68 FR 25251), FDA previously would have requested a voluntary recall of the suspected product; developed enough evidence to move directly to seize the food; or referred the matter to the appropriate State authority for most cases involving purely intrastate commerce. We believe that the request for a voluntary recall still represents the most viable option for a majority of these situations, with detention being considered as the second option.

Defining Scope of Administrative Detention Authority

The Bioterrorism Act authorizes FDA to detain food under circumstances presented during an inspection, examination, or investigation if an officer or qualified employee of FDA has "*credible evidence or information*" indicating that the article presents a threat of serious adverse health consequences or death to humans or animals. These criteria come directly from section 303 of the Bioterrorism Act. However, the statute does not define the evidentiary standard of "*credible evidence or information.*" The proposal observes that no precise definition of this legal standard exists but refers to common English language usage in noting that "credible" sometimes means "worthy of belief or confidence; trustworthy." The statute and proposal authorize detention only of food that *"presents a threat of serious adverse health consequences or death to humans or animals,"* and the Agency equates this standard to the same one applied to Class I recalls for which the public need for administrative detention is not established. NFPA encourages FDA to proceed with plans to issue guidance or rules to elaborate on the standards in the Bioterrorism Act.

Perishable Food Definition (21 CFR §1.377)

The Bioterrorism Act does not define perishable food. FDA proposes to define perishable food as:

> "*Perishable food* means 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."

Discussions with FDA indicate the 7-day limitation refers to the shelf life of the food from time of production not the shelf life remaining from the date at which the product may be made subject to a detention order. FDA has provided limited discussion on which product categories would fit this definition.

NFPA urges FDA to adopt a more expansive definition of perishable foods. The intent of "perishable food" being included in this Bioterrorism Act provision was to provide for an expedited detention review process for foods having a short-term shelf life. Such foods may have received a mild heat treatment (i.e., pasteurization) and be stored under refrigeration to achieve a shelf-life in excess of 7 days; likely in the range of 14 to 90 days. NFPA proposes to define perishable food as:

> "*Perishable food* means food that may have been heat-treated or otherwise preserved so as to prevent the quality of the food from being adversely affected for a period of 90 days or less under normal shipping and storage conditions."

Products included in this revised definition include raw agricultural commodities, refrigerated pasteurized products (milk and milk products, juice and juice concentrates), packaged produce, etc. that have a short shelf life and need to move expeditiously through marketing channels to the consumer. Even under this revised definition the detention of a perishable food which has less than 14 days shelf life remaining (not from date of production) will essentially prevent the product from reaching the market even with an expedited review of the detention order and a finding in favor of the owner of the food.

Procedures for Detention (21 CFR §1.378)

At §1.378 FDA proposes "An officer or qualified employee of FDA may order the detention of any article of food...if the officer or qualified employee has credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals."

We believe the authority to detain product on the basis of the Bioterrorism Act should be vested at a level higher than what is currently proposed and strongly urge that this section be revised to read an *authorized FDA representative* as defined in §1.377. Detention authority is a powerful tool for FDA and should be used judiciously. Similarly, we believe the procedures called for in the regulations should assure consistent application of the authority to the extent possible. Consequently we suggest §1.378 be amended to read:

> "An authorized FDA representative may order the detention of any article of food...if the authorized FDA representative has credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals."

Or, alternatively

> "An officer or qualified employee of FDA may order the detention of any article of food following approval of the detention order by an authorized FDA representative as provided for in §1.391...if the officer or qualified employee has credible evidence of information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals"

Either alternative wording for §1.378 will provide that a detention order must be approved by an FDA District Director in whose district the article of food involved is located or an FDA official senior to such director consistent with §1.391. This is also consistent with the level at which decisions would be made regarding a conditional release of the detained article to transfer the product to another location or to destroy the product at §1.381(d), which states: "You must submit your request for the limited conditional release of the detained article in writing to the authorized FDA representative who approved the detention order."

Length of Detention Period (21 CFR §1.379)

We support the proposal that FDA may detain an article for not more than 20 days. This should be more than sufficient time for FDA to reach a decision on whether such product, in fact, presents a threat of serious adverse health consequences or death to humans or animals. We agree that an article may be detained for an additional 10 days, but only under certain conditions (i.e., awaiting test results with respect to the suspected health hazard). The company should be immediately informed of any additional time requirement, the reason for the additional time, and the actual time period that will be required (up to 10 days). Any sampling and testing conducted with respect to a detention order should be given top priority at the appropriate FDA laboratory (or FDA contract laboratory) to expedite the process such that the need for an additional 10 days can be eliminated or shortened to less than 10 days. Assuring timely performance of any testing required should minimize the need to add 10 days to the detention period. NFPA encourages FDA to take the steps to ensure an affected company is informed of reasons for an extension. As specified in the Bioterrorism Act, there should be no case when the detention period exceeds 30 days.

When the authorized FDA representative has reason to determine that the detention order should be terminated, thereby releasing the product to the company, the FDA should inform the company within one calendar day of such determination. This will minimize possible loss of market value and allow product to continue into commerce as soon as possible. Accordingly, we suggest the following amendment to §1.379(c):

> "(c) An authorized FDA representative may, in accordance with §1.384, terminate a detention order before the expiration of the detention period. Such termination information shall be provided to the company in writing within one calendar day of the decision by FDA that such order shall be terminated."

Labeling or marking Requirements (§1.382)

NFPA recommends that the expiration date of the detention order and the authorized FDA representative be added to the list of information in §1.382 (d) that shall be included on the official FDA tags or labels to be affixed to the detained articles. The amended section would read as follows:

> "(d) The detention order number, the date and hour of the detention order, the detention period, the expiration date of the detention order, the name of the officer or qualified employee who issued the detention order and the name of the authorized FDA representative who approved the detention order."

If the detention period is extended for additional time up to the 10 day limit the detention order and the affixed tags or labels should be amended accordingly.

Requirements for Submitting an Appeal (§1.402)

FDA is proposing that any appeal of a detention order for a perishable food must be filed within 2 calendar days of receipt of the detention order. As noted earlier in these comments, NFPA is requesting a change in the definition of perishable food from 7 days to 90 days. Concurrent with this change we request that the time period for filing a notice of appeal be amended to 4 working days. The paragraph would read as follows:

> "(a)(1) Perishable food: If the detained article is a perishable food, as defined in §1.377, you must file an appeal within 4 working days of receipt of the detention order."

This will provide the firm with additional time to consult with appropriate scientific staff and legal counsel and determine whether or not to file an appeal based on the information available to the firm on the reason for the detention.

Dealing with Classified Information in an informal hearing

NFPA is concerned that the "classified information" clause may lead to withholding information that a company would find necessary for preparing its own evaluation, including sampling and testing of the product, to determine whether the article of food presents a threat of serious adverse health consequences or death to humans or animals. This could hamper any attempt to test product for possible contaminants as well as restrict a company's ability to appeal or request and prepare for a hearing on the detention order. FDA should provide, whenever possible, the specific reason why the Agency believes the article of food presents a threat of serious adverse health consequences or death to humans or animals (i.e., "product may be contaminated with x").

NFPA appreciates this opportunity to comment on the provisions of this important rule and stands ready to answer any questions you may have.

Sincerely,

John R. Cady