NATIONAL JUICE PRODUCTS ASSOCIATION

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Dockets Management Branch (HFA-305)
Food and Drug Administration -- Rm. 1061
5630 Fishers Lane
Rockville, Maryland 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

Ladies and Gentlemen:

By notice published in the *Federal Register* for May 9, 2003 (68 FR 25242), the Food and Drug Administration ("FDA") published a proposed rule providing procedures relating to the detention of an article of food if an officer or qualified employee of FDA has credible evidence or information that such article presents a threat of serious adverse health consequences or death to humans or animals ("administrative detention").

The following comments on the administrative detention rule are submitted on behalf of National Juice Products Association ("NJPA"), a trade association whose regular membership is comprised of 57 processors of fruit and vegetable juices and juice beverages. Those located in the United States ship and receive juices and juice beverages (in interstate, intrastate and foreign commerce), as well as ingredients used in the production of such food products. Many of NJPA's regular members located in the United States are both importers and exporters of these products, and members located in foreign countries export juices, juice concentrates and other juice beverage ingredients to destinations in the United States. Many of the Association's 51 associate members provide equipment, packaging, supplies and ingredients to juice processors in the United States, and also import juices and juice beverage ingredients into the United States. NJPA's member companies are located primarily throughout the United States, Canada and Central and South America, and represent a majority of the juice and juice beverage processors in the United States. Most of the Association's member companies would be affected by FDA's adoption of the proposed administrative detention rule.

02N-0275

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General Comments

The proposed rules have been published to implement the provisions of Section 303 of the Bioterrorism Act[1] relating to administrative detention, which FDA recognizes as self-implementing. FDA states (68 FR 25243) that, because of the authorities available to the agency and to the U.S. Customs Service to control imported food, "FDA does not expect to frequently use administrative detention under section 303 of the Bioterrorism Act to control imported food." FDA also points out with respect to all food (68 FR 25251) that prior to the Bioterrorism Act's expanded grants of authority, its receipt of credible evidence or information that a food presented a threat of serious adverse health consequences or death to humans or animals would have resulted in a request for voluntary recall of the food, the development of enough evidence to seize the food, or the referral of the matter to the appropriate state authority for most cases involving purely intrastate commerce.

While NJPA is supportive of FDA's exercise of the new administrative detention authority in cases where the standard set forth in Section 303 is met, NJPA is also hopeful that FDA will do so only in cases where other options for stopping the movement of the product would be unavailable. The food industry has historically had every desire to prevent, and has acted to prevent, the distribution of food that would be harmful to the public health, and NJPA is hopeful FDA would continue to use the voluntary recall of product to effect the same outcome as would be provided by the exercise of its new administrative detention authority.

"Perishable" Food

The proposed rule proposes to define "perishable food" 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."[2] This definition's importance for purposes of the administrative detention rule is twofold. First, it determines when FDA must use the expedited procedures in proposed §1.383 if the agency initiates a seizure action against an article of food under Section 304(a) of the Act.[3] Second, it affects the times within which an affected person must file an appeal of a detention order and within which an informal hearing (if any) must be held under proposed §1.402.

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1 Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, June 12, 2002.

2 This is the same definition contained in the proposed rule relating to Establishment and Maintenance of Records in Docket No. 02N-0277 (see Footnote 4, *infra*). NJPA will submit similar comments in response to that proposal.

3 Federal Food, Drug and Cosmetic Act, as amended.

NJPA disagrees with the seven-day aspect of the proposed rule's definition of the term "perishable." Section 304(h) of the Act, as added by Section 303 of the Bioterrorism Act, authorizes the administrative detention of food as to which the statutory requirements for detention are met for "a reasonable period, not to exceed 20 days," with a possible detention of up to 30 days under certain circumstances, to enable the agency to institute a seizure or injunction action under the Act. It also requires FDA to provide by regulation for procedures for instituting either such action on an expedited basis with respect to perishable foods. This is the only mention of "perishable foods" in the new administrative detention portion of the Act.

NJPA does not believe that whether a food has been subjected to heat treatment or thermal processing should be a factor in differentiating between perishable and non-perishable food. NJPA members consider as "perishable" those juice products which have a shelf-life of 90 days or less. These products would include "chilled" juices and juice beverages which, although they may have been pasteurized, are transported and stored under refrigeration. Under these conditions, their shelf lives would exceed seven days, but generally be 90 days or less. These retail products must move quickly through the distribution chain to their ultimate consumer outlets (*i.e.*, supermarkets or other retail outlets, or institutional providers) if they are to retain their value. The vast majority of these consumer outlets require these products to have a shelf life in excess of that which would remain if the products were to be administratively detained for a 20-day or 30-day period, only to be found not to be adulterated. Thus, much if not most of this type of product would lose all of its value in the market if not treated as "perishable" under the proposed administrative detention rule.[4]

As NJPA has suggested for different reasons in its comments on FDA's proposed rules relating to the establishment and maintenance of records under the Bioterrorism Act,[5] NJPA supports the following revised definition of the term "perishable food" for purposes of the administrative detention rule:

> *Perishable food* means food that ~~is not heat treated, not frozen, and not~~ may have been thermally processed or otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held ~~longer than 7~~ for 90 days or less under normal shipping and storage conditions.

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[4] The drop in value of these "chilled" juice products far exceeds the 1% to 3% per day estimates used by FDA in its analysis of economic impact. See 68 FR 25257.

[5] Docket No. 02N-0277, *Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, 68 FR 25188.

Administrative Detention Criteria

Proposed §1.378 states that "[a]n officer or qualified employee of FDA may order the detention of food" that is found to meet the statutory criteria for detention set forth in new Section 304(h)(1)(A) of the Act. Both new Section 304(h)(1)(B) of the Act and proposed §1.391 of the administrative detention rules provide that a detention order must be approved by "an authorized FDA representative," who must be the FDA District Director in whose district the involved article of food is located, or an FDA official senior to such director. FDA should clarify that the detention authority contained in proposed §1.378 can be exercised by the "officer or qualified employee of FDA" mentioned in that section only after the approval required by proposed §1.391 has been obtained. Likewise, proposed §1.391 should be modified to state that the "authorized FDA representative" mentioned in the proposed rule may approve a detention order only if the "officer or qualified employee" mentioned in proposed §1.378 "has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals."

Detention Period

Section 303 of the Bioterrorism Act authorizes detention, if the statutory standards therefor are met, "for a reasonable period, not to exceed 20 days." This 20-day period may be extended if "a greater period, not to exceed 30 days, is necessary to enable the Secretary to institute an action" with respect to the article of food via seizure or injunction. NJPA assumes that any testing which might be required to confirm the "credible evidence" which resulted in FDA's initial issuance of a detention order would normally be completed within the 20-day period mentioned in the statute and the proposed rules. NJPA would also expect that no extension of the detention period would be deemed justified or "necessary" in the event it was shown that the testing of the affected product had not been conducted expeditiously, or that it could have been completed within the 20-day period had it been accorded appropriate priority.

Information in the Detention Order

Proposed §1.393 sets forth FDA's proposal with respect to the information to be contained in a detention order. Among the proposed information is "[a] brief, general statement of the reasons for the detention." See proposed §1.393(b)(6). NJPA submits that this brief general statement should include, at a minimum, a description of the "credible evidence or information" that resulted in the issuance of the detention order. Without such information, the owner of the detained article would be denied information critical to its conduct of its own investigation, and its ability to take a meaningful appeal of the detention order

would be severely hampered or denied. Even if the "credible evidence" that resulted in issuance of the detention order is "classified information" (see proposed §1.406), the detention order should set forth the reason FDA believes the article of food subject to the order "presents a threat of serious adverse healh consequences or death to humans or animals."

NJPA hopes FDA will find the foregoing comments useful as the proposed rule is finalized later this year. If we can provide any additional information in this regard, or be of assistance in any other way, please do not hesitate to contact me at 813-273-4321 or aw@macfar.com.

Respectfully,

Ansley Watson, Jr.
Executive Director

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