DATE: July 8, 2003

TO: Dockets Management Branch (HFA-305)
Food and Drug Administration
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FR: Tom Lovelace
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RE: [Docket Number 02N-0275] Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Fresh Express respectfully submits the following comments regarding the proposed regulations for the detention of food as they relate to the fresh fruit and vegetable industry.

We take the issue of potential terrorist acts against the food supply and food security very seriously. We have instituted measures in security awareness and practices for all our processing locations.

If you have any questions or would like to discuss submitted Fresh Express comment further, please feel free to contact me at (817) 849-3421.

Very truly yours,

Tom Lovelace
Chief Executive Officer

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Relevant Background

Fresh Express is the share leader of the value-added ready-to-eat fresh salad category and operates in both the retail and foodservice segments. In all, Fresh Express offers retail and foodservice customers over 500 separate food items manufactured in six strategically located facilities in the United States. Fresh Express pioneered the packaged salad category at retail and continues to lead the industry in technological, product and food safety programs and innovations. As our core mission, Fresh Express strives to provide consumers and customers with the highest quality, freshest and safest products possible in the marketplace.

We offer the following comments to be considered in establishing the regulations for the establishment and maintenance of recordkeeping requirements:

1. **Administrative Detention Procedure:**

   a. Standard of determination based on "credible evidence". This is a lead concern for any detention or seizure action. The term "credible evidence" is vague and open to interpretation.

      Recommendation: Specific guidelines should be developed to clearly define what "credible evidence" is. There must be assurance of the existence of a clear and present danger or threat before a detention is considered. In particular, the FDA should have clear evidence such as laboratory analysis to confirm the presence of an adulterant and/or affidavits sworn to under penalty of perjury. "Credible evidence/information" should be similar to a "probable cause" standard and more than mere speculation or an anonymous telephone tip.

   b. Invocation of Administrative Detention Authority in Recall Situations. The legislative history of the Bioterrorism Act suggests that the credible evidence or information standard refers to intentional acts of bioterrorism. The FDA may potentially want to apply an administrative detention authority in situations not involving intentional acts of bioterrorism, such as a case of a Class I recall "situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." See 21 C.F.R. § 7.3(m)(1). The FDA may potentially make use of an administrative detention to replace the issuance of Class I recalls.

      Recommendation: The United States Congress' intent in promulgating the Bioterrorism Act of 2002 was to provide the FDA with sufficient statutory authority to invoke administrative detention only in cases where there is credible evidence/information of intentional activity against the food supply. Administrative detention should only be used in extraordinary cases involving intentional acts of bioterrorism against the food supply. Administrative detention should not be used in Class I, II or III recall situations involving unintentional acts of food adulteration.

   c. Notification of Administrative Detention. If administrative detention is invoked, the FDA will also have the ability under the new recordkeeping provisions of the Bioterrorism act to determine to whom a potentially violative product has been shipped. The FDA may thereby issue written notices to receivers to detain potentially violative product at multiple locations.

Recommendation: Procedural safeguards should be put in place to protect both manufacturers and their customers during what is essentially a seizure-type action. It is recommended that the regulation be revised to assure, similar to FDA seizure authority under the Food Drug & Cosmetic Act and relevant court rules, that notice of detention be required to be accompanied by personal service upon the responsible party at individual locations.

2. **Period of Detention.** A major concern for perishable product, such as fresh cut salads, is that the detention period of 20-30 days well exceeds the shelf life of the perishable product.

Recommendation. The period of detention for perishable commodities, including fresh fruits and vegetables shall not exceed 7 days. Because of the short shelf life, any time after the 7-days detention period would make the product unmarketable, even if released, and would thereby amount to a seizure.

3. **Appeals Procedure Perishable Foods.** Another significant concern is that the appeals procedure may cause undue delay in the detention process.

Recommendation: We request the following procedures for the appeals process.

a. FDA determination should be within 3 days of detention order issued or appeal filed. This is based on the premise that in order for a detention order to be issued, there must already exist substantial credible evidence.

b. Request for hearing – is automatically offered within 24 to 48 hours, as requested by the appellant.

4. **Definitions.** The definitions should be harmonized with the definitions provided under the Perishable Commodities Act. We request the following definition offered for comment be included:

a. "Perishable Food" - shall include fresh fruits and vegetables of every kind and character where the original character has not been changed. The effects of the following operations **shall not** be considered as changing a commodity into a food of a different kind or character: water, steam, or oil blanching, chopping, color adding, curing, cutting, dicing, drying for the removal of surface moisture; fumigating, gassing, heating for insect control, ripening and coloring; removal of seed, pits, stems, calyx, husk, pods, rind, skin, peel, et cetera; polishing, precooling, refrigerating, shredding, slicing, trimming, washing with or without chemicals; waxing, adding of sugar or other sweetening agents; adding ascorbic acid or other agents used to retard oxidation; mixing of several kinds of sliced, chopped, or diced fruits or vegetables for packaging in any type of containers; or comparable methods of preparation. (For example, fresh iceberg lettuce, romaine and carrots would be included, as well as fresh cut and packaged salads, green beans would be covered, frozen or canned green beans would not; fresh oranges would be included, frozen concentrated orange juice would not.)

5. **Perishable Foods**. If the above definition is not included, then the detention period and the entire appeals process for perishable foods which exceed the 7-day quality standard, as defined in the proposed FDA regulations, should be reconsidered:

Recommendation: For perishable foods with a shelf life of between 8-30 days:

a. Detention Period - the detention period for this category of perishable foods should not be more than 7 days. Simply, any detention longer than the proposed 7-day period would constitute a seizure.

b. Appeal. The appeals process should be as follows:

i. Written appeals - within 2 days of detention order
ii. Hearing - held within 2 days from appeal
ii. FDA decision - on appeal issued 4 days after detention order or from the date appeal is filed

Thank you for the opportunity to comment on the proposed regulations.

Respectfully submitted,

Tom Lovelace
Chairman and CEO