



**Fresh Vegetables, Inc.**

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

**RE: Docket No. 02N-0276. Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. (68 Federal Register 5377; February 3, 2003); Submission of comments- Reg.**

Dear Sir or Madam:

We are very thankful to the Food and Drug Administration for the opportunity to provide comment and feedback on the above referenced proposed rule.

The objective of the Bioterrorism Preparedness and Response Act of 2002 are to improve the ability of the U.S to prevent, prepare for and respond to bioterrorism and other public health emergencies. The FDA in the proposed rule indicates that the facility registration information will help the Agency determine the source and cause of the event and enable the FDA to quickly notify the affected facilities. The proposed registration requirements will only facilitate the FDA in investigating an incident once the Agency becomes aware of it. Furthermore, the registration of food facilities will create a centralized database of critical information pertaining to all food facilities and transportation of food and requires the stringent security protocols to prevent people or entities with ill intent from accessing this information. The lack of a centralized database may actually prove more effective in minimizing the potential terrorist threats on the food supply.

The proposed regulations regarding food facility registration requires registration of facilities beyond that mandated by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. We urge the FDA to limit the scope of the registration to those that conform to the statutory language. The scope of the registration provisions and proposed definitions go beyond the statutory requirements for the Health Security and Bioterrorism Preparedness and Response Act.

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As proposed, all trucks, truck trailers, shipping containers and rail cars will be required to register. The FDA appears to have underestimated the complexity of the registration requirements, the number of facilities that would be required to register, and the reporting burden on facilities and parent firms.

The proposed rule imposes conditions that would limit the exemption for farms. Traditional farming activities of fruits and vegetables such as cutting, trimming and washing performed during or immediately after harvest and placing these products in boxes appears to meet the definition of manufacturing/processing and packing. Farms were specifically exempt from the registration requirements under the statute. However, the FDA definition of manufacturing/processing and packing as proposed imposes a significant burden on all farming activities and would require the registration of land where fruits and vegetables are grown and harvested.

The proposed rule envisions an Internet based electronic registration process. However, the system will be available in October of 2003 giving an eight-week time period for the registration of all facilities. Any flaws or disruption in service of the Internet based electronic registration system will cause serious disruptions to trade and commerce of food products. The FDA should consider the option of making the initial registration process available both through electronic means and by paper registration by the submission of a completed registration form by mail.

The required registration information in the proposed rule includes individual's name, title, office phone, home phone, cell phone (if available) and e-mail address (if available). The address and facility's main telephone number will serve the purpose of the FDA in contacting the facility during an emergency. The personal information is likely to change frequently with personnel changes and job responsibilities and requires numerous updates to the registration form. With the requirement to update any change in registration information within thirty days, these frequent updates could pose undue burden to the industry without significant benefits.

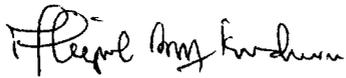
The FDA must establish a clear procedure for change of ownership or management of a facility and the process for making changes to the registration information.

The proposed rule requires that all foreign facilities must identify at least one U.S. agent. Depending on the nature of the business a facility may have numerous U.S. agents. It is unclear what responsibility the designated U.S. agent will have when the transaction made by the foreign facility does not involve the identified U.S. agent.

The FDA proposes that when a foreign facility fails to register, the owner, purchaser, importer or consignee is responsible for placing and paying for the secure storage of the product even though they have no responsibility for the registration of the facility. The FDA must establish a chain of custody and clarify the fiduciary responsibility when products are impounded or placed on hold.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,



Mahipal Kunduru, Ph.D.,  
Director Food Safety and Quality  
Dole Fresh Vegetables Inc.,