



CALIFORNIA GRAPE & TREE FRUIT LEAGUE

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

Dear Sir or Madam:

The California Grape & Tree Fruit League would like to provide comments on the Interim Final Rule for the Registration of Food Facilities contained in Docket Number 02N-0276. This Interim Final Rule was developed by the Food and Drug Administration (FDA) to fulfill its obligation set forth under the provisions of Title III, Subtitle A, Section 305 of the Public Health Security and Bioterrorism and Response Act of 2002 ("Bioterrorism Act").

The California Grape & Tree Fruit League is a statewide association of growers, packers, shippers, and marketers of table grapes and deciduous tree fruit. The League's members collectively account for about 85 percent of the total annual production of these commodities in California. Some of its members also import produce from other nations.

The League appreciates efforts by the U.S. Congress and FDA to enhance the security of the nation's food supply against potential terrorist activities. The U.S. produce industry has focused on food safety issues for many years and some sectors have already established effective and rapid trace-back systems to facilitate product tracking in case any problems arise.

In the Bioterrorism Act, Congress directed FDA to develop a system to register food facilities "...engaged in the manufacturing, processing, packing, or holding of food for consumption in the United States." However, Congress specifically stipulated that "facilities" do not include farms. In the League's view, Congress clearly intended to focus the registration process on firms that aggregate commodities from multiple farms to pack, process, store, or distribute the products. In the fresh fruit industry, this would imply that packinghouses, commercial cold storage plants, and food processors would be required to register. This would be the most effective and sensible approach, as packers and cold storage facilities are a critical path in the distribution chain, and the origin of products can be clearly traced by the packers and storage companies.

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The League is quite concerned that FDA may apply a more expansive definition of "processing" and what constitutes a "facility" to include virtually all farming operations located in the U.S. and also every farm overseas that grows products for the U.S. This approach is contrary to the explicit direction of Congress and would place an unnecessary burden on industry.

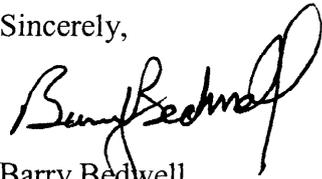
The trace-back systems currently used by much of the produce industry rely on simple, but effective, systems for identifying the origin of products. Federal packaging regulations (and most state packaging regulations) mandate that every carton and every consumer package of produce be labeled with the name and address of the responsible party. Further, packinghouses use lot numbers and pack dates to facilitate product tracking for both financial accounting and food safety trace-back purposes. Some packers also print variety names and other information on the container. In the case of a food safety issue, the shipper name, product lot number, and pack date can be used to quickly identify the source of the product, usually down to a specific field, or even possibly to a small area within a field.

Registering all individual farmers, plots of land, harvesters, field crews, mobile field packing stations, trucks, pest control advisors, and pesticide applicators would require a great deal of time and effort. Further, keeping all of the contact information current would be a monumental task. The registration process could become an end unto itself, distracting FDA regulators from the larger objective of assessing risks and dealing with bioterrorist attacks against the food supply.

In the League's view, a more effective approach will be to focus on the critical nodes in the supply chain where product is aggregated, stored, and distributed. The League strongly suggests that FDA consult with USDA and industry to develop definitions for farms, processing activities, and storage facilities that will fulfill FDA's obligation to Congress in the most efficient and cost effective manner. The League would be glad to meet with FDA staff and explain the trace-back systems currently used by California fruit shippers.

The League appreciates the opportunity to submit its views on this subject. If you have any questions about these comments, please contact me.

Sincerely,



Barry Bedwell
President