



Blue Diamond Growers

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June 4, 2003

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

Attn: Docket No. 02N-0277

Re: Proposed rule to implement section 306 (establishment, maintenance, and availability of records) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). 68 Fed. Reg. 25, 188 (May 9, 2003)

Blue Diamond Growers is a grower-owned cooperative of nearly 4,000 California almond growers who represent about two-thirds of all almond growers who commercially produce almonds in the western hemisphere.

California grows 100 percent of the total U.S. supply of almonds. California will produce 87 percent of the world supply of almonds 2003-2004. Spain and Italy respectively grow the majority of the rest of the total world supply. Morocco, Israel, Afghanistan, Chile and Australia grow very small amounts of almonds, but not enough for internal consumption. Almond imports are virtually non-existent.

Almonds are California's largest food export and rank number three among America's top exported consumer foods. California produced 1.1 billion pounds of almonds in 2002-2003, a record. Nearly 80 percent of the total supply is exported to over 95 countries. Western Europe is the largest importer of U.S. almonds (57 percent) with Spain and Germany respectively ranking first and second largest importers. Asia, led by Japan and India, rank the second (26 percent) largest importer of California almonds, followed by the Middle East (8 percent); North America (5 percent); Eastern Europe (2 percent); and others (2 percent).

Blue Diamond Growers works with freight forwarders which use the AES Direct system which is the U.S. Census Bureau's free Internet based system for filing Shippers' Export Declaration (SED) information to the Automated Export System (AES). It is the electronic alternative to filing a paper SED.

The AES Direct significantly streamlines the export reporting process by reducing the paperwork burden on Blue Diamond, reducing costly document handling and storage, and ensuring timely filing of export information. It allows easy access to all government agencies who seek export

**02N-0277**

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The Almond People ®

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traffic information. It is certified to U.S. Government Standards for data security and encryption. It also meets record keeping requirements of the U.S. Customs Service where data is stored for retrieval for the statutory 5-year period.

The Blue Diamond cooperative has served its grower-members since May 1910, establishing a renowned reputation for producing a quality product under the Blue Diamond name. It has opened virtually all of the 95 markets to the California almond industry beginning with establishing an overseas office in Japan in the early 1960s. Blue Diamond worked with USDA to establish the Federal Marketing Order in the 1950s which regulates the almond industry.

Food safety is a top priority of Blue Diamond from on farm production through the food chain to the final consumer. Blue Diamond supports the Food and Drug Administration's proposed Public Health Security and Bioterrorism Preparedness and Response Act, but would like to comment on Section 306 of the proposed act.

The establishment and maintenance of records sufficient to identify the immediate previous source and immediate subsequent recipients of food is technically difficult to fully comply with. Blue Diamond's record keeping system will fully comply with the requirement to identify shipments of its food products to its customers.

However, tracking food product back to a specific farmer, once it has passed its testing stage for physical contamination, will not be possible without significant cost, facility changes and modification of Blue Diamond's manufacturing infrastructure. During the ninety-day harvest period, between August and November, Blue Diamond's share of the California almond crop is delivered to receiving stations for processing. On average, Blue Diamond Growers will receive over 50,000 separate deliveries of almonds from its nearly 4,000 growers. Each delivery is sampled and tested for physical contamination. The purpose of the incoming testing is to establish the quality level of the product and to identify any deliveries with potential product contamination.

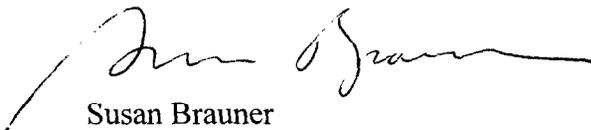
In addition to physical contamination, Blue Diamond randomly tests incoming lots for bacterial and chemical contamination at its on-site laboratory. Any product identified as contaminated in the random testing process is isolated, and either returned to the individual grower or set aside for special treatment or processing. Should there ever be contamination that is believed to be intentional or by suspicious circumstances, the appropriate government authority would be notified immediately.

After the incoming product is satisfactorily sampled and tested at the delivery stage for physical contamination, the raw product is commingled with other growers' products that have similar varieties and quality characteristics. Because Blue Diamond is a cooperative whose growers average 50 acres each, the product must be commingled to be sufficiently available for final packaging of a variety of products. Blue Diamond believes its incoming testing program provides sufficient safeguards to identify and remove any potential physical contamination and chemical and bacterial contamination (via random sampling) that may lead to adulteration of its food and/or serious health consequences to the consumer.

Should Blue Diamond be required to maintain every lot separately throughout its manufacturing processes, the warehousing and inventory systems would have to be completely revamped at a cost of hundreds of millions of dollars to the Blue Diamond cooperative members, most who are small family farmers. The additional capital expenditures and operational costs would potentially destroy the cooperative's way of doing business and the industry that is just returning to economic health after nearly 3-4 years of payments to growers below their cost of production.

Blue Diamond urges the Food and Drug Administration to use discretion in the enforcement of section 306, allowing the California almond industry to use current incoming testing procedures which flags physical and chemical and bacterial (random samples) contamination problems at the individual grower level at the beginning of the manufacturing process. This testing procedure for individual grower contamination would be in lieu of complete trace-back of almonds to the individual grower level once the product has passed its early contamination testing.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Brauner", with a long horizontal flourish extending to the right.

Susan Brauner  
Director, Public Affairs