United Fresh Fruit &
Vegetable Association

April 4, 2003

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 Bioterroism Preparedness and Response Act of 2002. (68 Federal Register 5377; February 3, 2003); Submission of comments.

Dear Sir or Madam:

The United Fresh Fruit & Vegetable Association (United) is pleased to provide comments on the proposed rule for the Registration of Food Facilities contained in Docket Number 02N-0276. This proposed rule was developed by the Food and Drug Administration (FDA) to fulfill their obligation set forth by the provisions of Title III, Subtitle A, Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act"). The summary of the Bioterrorism Act legislation is as follows:

- Amends the Act by adding new section 415 to require registration for food facilities. Requires the owner, operator, or agent in charge of a domestic or foreign facility to submit a registration to the Secretary. For a foreign facility, the registration must include the name of the U.S. agent for the facility.
- The registration shall contain information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business and, when determined necessary by the Secretary through guidance, the general food category as identified under 21 CFR 170.3.
- Requires the registrant to notify the Secretary in a timely manner of changes to such information.
- Requires the Secretary to notify the registrant of receipt of the registration and to assign a registration number to each facility.
- Requires the Secretary to compile and maintain an up-to-date list of registered facilities. Protects the list and any registration documents from disclosure under Section 552 of Title V, U.S. Code.
- Defines facility as any factory, warehouse, or establishment of an importer that manufactures, processes, packs, or holds food. Specifically excludes farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer; and fishing vessels (except such vessels engaged

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- in processing as defined in 21 CFR 123.3(k). Limits foreign facilities to those that manufacture, process, pack, or hold food only if food from such facility is exported to the U.S. without further processing or packaging outside the U.S.
- Amends Section 801 to require that an article of food offered for import from an unregistered foreign facility be held at the port of entry until the facility is registered.
- Authorizes the Secretary to provide for and encourage the use of electronic methods of registration; however, paper registration is allowed.

Introduction

United is a national trade association representing member growers, shippers, packers, processors, marketers and distributors of fresh produce in the United States. United members provide the leadership to shape business, trade and public policies that drive our industry. Working with thousands of industry members, United provides a fair and balanced forum to promote business solutions; helps build strong partnerships among all segments of the industry, promotes increased produce consumption; and provides scientific and technical expertise essential to competing effectively in today's marketplace.

The dramatic impact of the terrorism attacks of September 11, 2001 has led to a new focus in public policy aimed at promoting greater safety and security and preventing terrorist action. As our members provide over 1,000 different fresh fruits and vegetables to American consumers from both domestic growers and around the world, we take our responsibility for prevention, detection, and all necessary actions to protect consumers from intentional contamination of our products seriously.

We encourage FDA to issue final regulations that allow flexibility and take into account the produce industry’s diversity of products and complexity of global production and distribution. Flexibility is critical in that many prescriptive recommendations would be inappropriate or not applicable to our diverse industry.

We commend the U.S. Food and Drug Administration (FDA) for its leadership in working with the private sector, including our industry, to ensure that appropriate steps are in place to minimize the potential of terrorist action to contaminate foods. However, let us keep in mind the American food supply continues to be the safest in the world. Continuing to ensure the safety and security of fresh fruits and vegetables whether produced domestically or abroad is a top priority of the entire produce industry. With this in mind, we have serious reservations about certain provisions of the proposed rule for Registration of Food Facilities.

Statutory Authority for Registration Information

The proposed rule would require registrants to submit more information than is required by the Bioterrorism Act. For example, under the Bioterrorism Act, all foreign facilities required to register must designate a U.S. agent and must submit the name of their U.S. agent. While the Bioterrorism Act requires only the name of the U.S. agent, the proposed rule would require the name, address, phone number, fax number (if available), and email address (if available) of the U.S. agent. By requiring more information than is specified in the Bioterrorism Act, United believes FDA is exceeding its statutory authority. Is the proposed collection of information necessary for the

proper performance of FDA's function and does this information have practical utility? The FDA should request only information necessary for oversight. In addition, the proposed registration process has clearly not fully considered the costs and difficulties that electronic registration poses to small domestic and international suppliers in remote areas of the world. We anticipate that many in the food industry will prefer electronic filing, but that some, particularly small businesses, may not yet have that capability to perform electronic filing. Allowing the option of paper submission is critically important for businesses lacking internet access.

Flexibility for the Registration Process

Regulations should not impose unnecessary and burdensome requirements on registrants. The registration process needs to be as simple as possible and not unnecessarily disrupt the flow of commerce. United strongly urges FDA to allow appropriate flexibility to enable companies to register as best suits their corporate structure. Some companies, which own or operate multiple facilities, may wish to have a single individual undertake the responsibility to register all of the company's facilities. While others may opt to delegate the registration responsibility to each of its facilities. The regulations need to permit both approaches. We believe this would assist the agency and companies in submission of registrations and updates. In the event that a food security threat or crisis or potential contamination occurs, the corporate headquarters of a firm would want and need to be contacted.

In addition, FDA should permit trade associations, commodity groups or parent companies the ability to register for facilities within their organizations. United would also request that FDA consider an exemption for storage facilities that are temporarily leased and are under the management of a nearby registered firm, if product is stored there for 90 days or less. By providing the flexibility to manage the FDA registration process as appropriate for their company, the burdens on business will be reduced and compliance will increase.

The proposed rule would require that registration information be updated within 30 days after any change in such information. This timeframe does not appear to be feasible for our industry. The regulations should state that a registrant should amend a registration within 30 days of the date on which a *significant* event occurs. Significant events would include a change in ownership of a facility, location of a facility or the closing of a facility. Updates on registration is a burden for a firm when there is a management change, an area code change, a product or trade name addition or subtraction or changes in a product line. While some of these are minor changes the proposal would require the information to be updated within 30 days of the change. There should be some exemptions to the 30-day update requirement for minor changes and optional information provided. Registrants should be permitted to notify FDA of these changes biannually or annually.

Also, FDA needs to adopt appropriate procedures to ensure that confidential business information shared by companies on the registration forms is protected from public disclosure when in FDA's possession and when in the possession of other governmental entities with which FDA may have shared the information. Further clarification is needed from FDA in this area. The electronic registration system should be absolutely secure. The reliability and security of the newly proposed electronic registration system will be critical to maintaining trade and the free flow of produce.

The 60-day period for filing registrations, as suggested by FDA officials, appears to be reasonable in concept; however, with the number of facilities anticipated to register between October and December, this may not be a sufficient timeframe to allow for the smooth conduct of the registration. Thousands of covered facilities registering simultaneously will result in gridlock of any registration system, paper or electronic. We suggest FDA consider try having the registration system functional by August 1, 2003 to allow more time for companies to register in advance of the December statutory deadline.

“Farm” Definition

We commend FDA for putting forth such an exemption; however, the definition of a “farm” outlined by FDA in the proposed rule is far too narrow in scope to cover all the parameters of farming operations in the produce industry. Historically, farming has played an important role in our development and identity as a nation. The official definition of a farm in the United States is determined by the U.S. Department of Commerce and as might be expected, this definition has a commercial orientation. Variations of this official definition have been around since 1850 when the first census of agriculture was taken. According to U. S. Department of Agriculture’s National Agricultural Statistics Service, since 1974, a farm has been defined as "any establishment from which $1,000 or more of agricultural products were sold or would normally be sold during the year." Generally, FDA has defined exemptions, related to the produce industry, in the Food, Drug, and Cosmetics Act (FD&C Act) based on the definition of a "raw agricultural commodity." According to the FD&C Act, the term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. To assist in defining a farm for the purpose of the Bioterrorism Act, we again recommend FDA use a definition for agricultural operations similar to that set forth in the California Food and Agriculture Code:

> “For purposes of this section, the term "agricultural activity, operation, or facility, or appurtenances thereof" shall include, but not be limited to, the cultivation and tillage of the soil, dairying, the production, cultivation, growing, and harvesting of any agricultural commodity including timber, viticulture, apiculture, or horticulture, the raising of livestock, fur bearing animals, fish, or poultry, and any practices performed by a farmer or on a farm as incident to or in conjunction with those farming operations, including preparation for market, delivery to storage or to market, or delivery to carriers for transportation to market.”

The definition of “farm” should also include typical post-harvest operations, such as packing/packaging, washing, grading, waxing, sizing, cooling, conventional storage, controlled-atmosphere storage, transportation to and from the fields or farm, transportation to storage or processing facilities, and packing or holding activities that are incidental to farming. The definition in the proposed regulation also includes “facilities that pack or hold food, provided that all of the food used in such activities is grown or raised on that farm or is consumed on that farm.” By including these facilities under the “farm” exemption, FDA accurately recognizes activities that are “incidental to farming” in which “most farms engage in (e.g. holding and packing of harvested crops).” The holding and packing of harvested crops are traditional farming practices, and such activities should continue to be included in the “farm” definition in the final rule. We request that FDA further provide clarification to the “farm” definition by acknowledging that post-harvest activities, if all food is grown on the farm, also fall under the scope of “activities incidental to farming.”

“Food” Definition

The definition of “food” in the proposed regulation is far too encompassing. United understands that it would include food equipment and packaging materials. This would include an extensive group of materials and manufacturers and would create substantial burden upon the agency and the food industry needing to submit registrations. If this is necessary may we suggest FDA implement registration requirements over a more extended period of time for these operations.

“Facility” Definition

The proposed definition of “facility” includes mobile facilities. What kind of mobile facilities does FDA have in mind? Can a transportation vehicle (*e.g*., a truck, rail car) ever become a mobile facility? The definition of “facility” indicates that a “mobile facility” requires registration if it “manufactures/processes, packs, or holds food for consumption in the United States.” “Mobile facilities” that hold food and are subject to registration should not include mobile structures that are exclusively used for transporting food, including railcars, airplanes, ships, cars, shipping containers, ocean vessels, and trucks are exempt from registration. The definition of “facility” is still open for interpretation because it implies that a mobile structure under “one management” that holds food is subject to registration. United requests that FDA clarify “mobile facilities” and to specifically exclude mobile structures, which hold food for the lone purpose of its transport.

Requirements pertaining to the listing of a facility’s address should be flexible to accept varied information that is unconventional to format used in the United States. FDA needs to take into account address formats that are unique from the conventional address forms used in the United States. In many international locations, facility addresses may not be listed or recognized by a single street name and number, but rather from a crossing of streets or even from specific reference points that may involve other buildings or landmarks. FDA should not only accept unique address listings from foreign facilities, but also revise the Food Facility Registration Form and its internet version to allow for unconventional address information.

Sites that serve as transitory staging areas where produce is momentarily held prior to transportation should be exempted from the definition of “holding” in the proposed regulation. Given the perishable nature of the product and the desire to rapidly transport the fresh commodity, produce moves from these staging areas as quickly as possible. Therefore, United requests that FDA distinguish in the rule those facilities that serve as staging areas for the next step in the transportation route as separate from facilities that hold food. Clearly the proposed definition seeks to encompass facilities that are designed for the purpose of storing product and where there is *intent* to store the product for a period of time. The definition of “holding” should exclude these transitory staging areas.

A foreign food facility that manufactures/processes, packs, or holds food that will be consumed in the United States must register with FDA, unless the food will undergo further manufacturing/processing or packaging (other than *de minimis* activity, such as labeling) before it is exported to the US. We request FDA clarify what the agency will consider as *de minimis* activity. Can packaging be a *de minimis* activity?

Revocation of Registration and Failure to Register

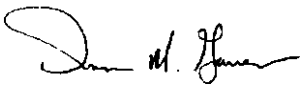
When should a facility's registration be revoked by FDA, and what procedures should FDA be required to follow before revoking a facility's registration? Foods from an unregistered facility may not be imported into the United States. Imported food from an unregistered foreign facility should be held under conditions that maintain the product's marketability. This is particularly critical for perishable fruits and vegetables. Once a registration is submitted on that facility, a registration number should be issued promptly. Especially for perishable products received at port, FDA should provide a mechanism that ensures that registration numbers are issued to previously unregistered facilities within 24 hours, so that such products will not be denied entry into the U.S. market.

Also, we have reservations about the provision of the proposed regulation that makes failure to register a facility a prohibited act. We do not oppose this amendment, but we encourage FDA to communicate clearly to consumers that the food is misbranded due to a failure of a food company to register, not because of an inherent food safety or security risk. Lack of adequate communication may result in false food scares and undermine consumer confidence in the agency.

Conclusion

In conclusion, the registration process should be as simple as possible, and ensure that the implementation of the regulation does not unnecessarily disrupt the flow of commerce. If even a small percentage of produce is delayed or removed from the marketplace, the cost implications could be immediate and dramatic. The produce industry is committed to ensuring the security of its products. The industry is proud of the contribution it makes to the health of Americans by providing wholesome foods essential for good health. It is important to always consider that increasing the consumption of fresh fruits and vegetables is a critical component of public health, and that risk management steps are properly weighed with the public health impact on the cost and availability of fresh produce. Thank you for the opportunity to comment. We look forward to continuing to work together with the FDA on these important matters.

Sincerely,



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