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

RE: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The International Banana Association (IBA) is providing these comments to the February 3, 2003 Federal Register notice (Vol. 68, No. 22, pp. 5378-5427) on the proposed rule requiring the registration of food facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

IBA is the trade organization representing the common business interests of the banana industry. IBA members are companies involved in the growing, shipping and importation of bananas into the United States. These members include Banacol Marketing Corporation, Chiquita Fresh North America, Del Monte Fresh Produce Inc., Dole Food Company, Le Best Banana Supply, Pacific Fruit Inc., and Turbana Corporation. Altogether these companies are responsible for importing over 98% of the bananas consumed in the U.S.

IBA members strongly support the goal of the Bioterrorism Act to strengthen the safety of our food supply and the efforts by the Food and Drug Administration (FDA) to implement rulemaking that is consistent with the intent of the law. IBA members have the highest commitment to food safety and their business operations are first-rate in ensuring the quality and security of their fresh products. IBA's comments serve to provide feedback to FDA on the implementation of the Bioterrorism Act in regards to the registration of food facilities. The following six points summarize our comments for FDA's consideration, with an explanation of each point below:

- The definition of "farm" should include typical post-harvest operations, along with packing or holding activities that are incidental to farming;
- The definition of "facility" should not include mobile structures that hold food for the exclusive purpose of its transport, delivering food cargo from and to specific locations in the supply chain, such as cargo containers and ocean vessels;
- The definition of "holding" should not include sites that serve as transitory staging areas for the transportation of food, such as container yards and ports;
- FDA should clarify whether ripening is a "manufacturing/processing" activity, requiring facilities that ripen food to register;

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- Requirements pertaining to the listing of a facility's address should be flexible to accept varied information that is unconventional to the format used in the U.S.;
- FDA should be responsible for costs incurred from mistakes made in the enforcement of the rule that result in the holding of imported food.

§1.227 (c)(3) Definition of "Farm"

IBA agrees with FDA's definition of "farm" including "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)." Banana farms have packing stations that are located directly on the farm, usually at a central location for efficient harvesting operations. 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.

IBA is requesting FDA to 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." In bananas, post-harvest activities, such as the washing of the fruit and treatment against pests, occur in the packing station prior to packing. All post-harvest activities are done *on the farm*. Therefore, the definition of "farm" should include "facilities that engage in post-harvest activities, 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."

§1.227 (c)(2) Definition of Facility

On the farm bananas are packed into boxes, palletized, and loaded into cargo containers on trucks. This begins the banana's journey from farm to retail. The bananas are then transported from Latin America to ripening and distribution centers in the U.S. prior to their display before consumers. The long journey involves multiple transportation steps.

The proposed rule defines a "Facility" as including a "mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States." This definition is confusing when applied to structures that move food from one specific departure point to one specific destination point in the distribution chain. Do the words "multiple locations" indicate that a mobile facility - one that is subject to registration - must travel to several different sites with the same food and either manufacture/process, pack or hold the food while in transit, such as a catering operation?

Cargo containers are used to carry bananas from the farm to the foreign port, and then containers are also used to carry the product away from the U.S. port in route to their sale. In addition, ocean vessels carry bananas between ports either in the same containers onboard the ship or on pallets in the ship's cargo hold.

IBA believes that cargo containers and ocean vessels are outside the intent of the law and FDA's proposed rule, as much of the information sought by FDA is illogical when applied to mobile structures that hold food for the purpose of its transport, such as name and address. There are thousands of cargo containers that are used for transporting bananas from farm to retail. Not only would the initial registration of these containers be a cumbersome task, but the maintenance of registration records as containers are replaced in the system would be unmanageable.

It is apparent that the proposed rule does not attempt to require registration of cargo containers and ocean vessels. FDA's tables in the proposed rule, which calculate the number of potential facilities affected by this rule and the estimated compliance costs, give no indication that containers and ships are being considered under the rule. This is the right approach. But due to some ambiguity in the definition of "Facility," IBA is asking FDA to clarify "mobile facilities" and to specifically exclude in the rule mobile structures that hold food for the lone purpose of its transport from one location to another in the supply chain.

§1.227 (c)(5) Definition of "Holding"

In the transportation of bananas, there are two possible transitory staging areas where bananas are momentarily held inside the sealed container in a secured location awaiting the next transportation step. The first area may be the container yard, which is typically near the port of export. The second area may be the actual port facility where containers or individual pallets are being loaded onto the ship.

Both locations – the container yard and the port – provide temporary and secured space for the container to sit while the ship and port operations are being prepared for loading. Given the perishable nature of the product and the desire to rapidly transport the fresh commodity, bananas move from these staging areas as quickly as possible. IBA believes that container yards and ports do not qualify as facilities "holding" food since (1) these locations are designed to move the cargo, not store the cargo, (2) these locations are sites along a consistent and continuous transportation route, and (3) there is no unauthorized access to these locations and the cargo containers.

Therefore, IBA requests that FDA distinguish in the rule facilities that serve as staging areas for the next step in the transportation route as different from facilities that hold food as "storage." In the proposed rule the definition of "holding" includes such examples as "warehouses, cold storage facilities, storage silos, grain elevators, or liquid storage tanks." 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. In the case of container yards and ports, the intent is to move the product to the next point along the distribution chain. The definition of "holding" should exclude the transitory staging areas of container yards and ports.

§1.227 (c)(6) Definition of Manufacturing/Processing

The proposed rule defines “manufacturing/processing” to include “synthesizing, preparing, treating, modifying or manipulating food.” Based on these terms, the activity of commercially *ripening* fruit may fall within this definition, which may require facilities that ripen fruit to register under the rule. IBA is requesting FDA to specify in the rule whether ripening is an activity covered under the “manufacturing/ processing” definition, thereby requiring ripening facilities to register as a food facility.

If ripening is indeed a “manufacturing/processing” action under the rule, FDA should be aware of a developing ripening technology that presents a unique question concerning the prior notice rule. Cargo containers are being equipped with technologies to help ripen fruit while in transit. In other words, specially configured containers now possess the ability to artificially ripen fruit like bananas while the containers are being moved via trucks from one location to another, such as from the U.S. port facility to a retail distribution center. While cargo containers should not fall under the scope of this rule as a mobile structure (see discussion above), many containers are performing activities such as ripening while in transit in which the activity may fall under the “manufacturing/ processing” definition. IBA believes that such technological advancements should not change the interpretation of what defines a facility under the rule. FDA should determine that cargo containers are not facilities when transporting food from one specific location to another, regardless of any manufacturing/processing, packing, or holding that may occur inside the container.

§1.232(a) Required Information: Address

FDA needs to take into account address formats that are unique from the conventional address forms used in the U.S. In Latin America, for example, 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 address information that is unconventional to U.S. formats.

§1.241(f) Failing to Register: Responsibility of Costs Incurred

This section of the proposed rule requires that “transportation and storage expenses shall be borne by the owner, purchaser, importer, or consignee” if FDA determines that an imported article of food must be held at the port or removed to another storage location.

The holding of perishable food commodities can be detrimental to the quality and value of the product. The consequences of food products being held as a result of non-compliance to the rule can be costly, but IBA agrees that in such cases of non-compliance it is the responsibility of the private parties to cover all costs incurred in the transportation and storage of those products.

However, if by some rare occurrence FDA is imperfect in the enforcement of the rule and mistakenly holds imported product because of an oversight in the government's records of a registered facility, then FDA should be accountable to such errors and assume the responsibility of not only the transportation and storage fees but also any lost value as a result of damage to the quality of the food product.

Thank you for the opportunity to participate in the rulemaking process by presenting the above comments. Please contact me at (540) 314-3214 if you have any questions or wish to discuss these comments in further detail.

Sincerely,

A handwritten signature in black ink, appearing to read 'T. Debus', written in a cursive style.

Tim Debus
Executive Director