July 7, 2003

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

RE: Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The International Banana Association (IBA) is providing these comments to the May 9, 2003 Federal Register notice (Vol. 68, No. 90, pp. 25188-25240) on the proposed rule requiring the establishment and maintenance of records by certain persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for human and animal consumption in the United States.

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, Inc., 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 establishment and maintenance of records. The following five points summarize our comments for FDA's consideration, with an explanation of each point below:

- IBA agrees with proposed §1.326(a) specifying the foreign facilities subject to the recordkeeping requirements as those facilities that "manufacture/process, pack or hold" food for human or animal consumption in the United States, which is consistent to the same foreign facilities that are required to register under section 305 of the Bioterrorism Act.

- Foreign sites that serve as transitory staging areas for the sole purpose of transporting food, such as container yards and ports, should not be classified as "holding" food and subject to recordkeeping requirements when the possession, custody or control of the food does not change.

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- The inclusion of "immediate food packaging" and "food contact substances" in the definition of "food" creates a difficult and unnecessary compliance effort throughout the supply chain. FDA should remove the requirement to establish and maintain records on "immediate food packaging" and "food contact substances" after such materials are either accompanying or affixed to the food, thus eliminating duplicative tracking and burdensome paperwork.

- IBA agrees with FDA's conclusion that "outer food packaging," if contaminated, does not present a high enough risk to human and animal health to warrant inclusion of outer packaging in the final regulations.

- A twelve (12)-hour period should be the legal maximum timeframe to make available records when a request is made at any time of any day, providing a company with a reasonable and sometimes necessary amount of time to access, verify and provide records to authorities.

§1.326(a) Foreign Facilities Subject to Regulations

FDA is taking a reasonable approach in requiring the same foreign facilities – and only those facilities – that register under section 305 of the Bioterrorism Act (Food Facility Registration) also be required to establish and maintain records under section 306 of the Bioterrorism Act. These are facilities outside the United States that "manufacture/ process, pack or hold food for human or animal consumption in the U.S." IBA concurs with FDA's assessment that "requiring foreign facilities that must register to also establish and maintain records would be the most efficient and effective way to obtain information on food from foreign countries." The proposed scope of foreign facilities that are required to keep records is consistent rulemaking for the purpose of implementing the Bioterrorism Act.

Transitory Staging Areas Not Defined as "Holding" Food

Similar to IBA's comments filed with FDA in consideration for the final rulemaking on section 305 of the Bioterrorism Act (Food Facility Registration), IBA believes that there are certain areas in the supply chain that provide temporary space for the food during transit and that these areas should not be considered as "holding" or "storing" food subject to either the food facility registration and recordkeeping requirements.

In the transportation of bananas, there are two possible transitory staging areas where bananas could be momentarily held inside the sealed container in a secure 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 location where containers or individual pallets are being loaded onto the vessel.

Both locations – the container yard and the port – provide temporary and secure space for the container to sit while the vessel 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 should not be classified as facilities "holding" food, for purposes of requiring registration and recordkeeping, 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.

Furthermore, the proposed rule on page 25193, in explaining proposed §1.327(f), states: "facilities located outside the United States *that take possession, custody, or control* of finished foods for holding, packing, and/or storage prior to export to the United States are subject to these regulations" (italics added for emphasis). FDA's explanation indicates that facilities would be subject to these regulations if there is a change in "possession, custody, or control" of the food. IBA requests FDA to clarify that if food is transported to and from a transitory staging area in the supply chain, such as a container yard and port, and possession, custody, or control of the food does not change, then these areas are not subject to the recordkeeping requirements – as well as the facility registration requirements outlined in section 305 of the Bioterrorism Act.

Recordkeeping for "Immediate Food Packaging" and "Food Contact Substances"

FDA defines "food" in proposed §1.328 as "substances that migrate into food from food packaging," which include "immediate food packaging or components of immediate food packaging that are intended for food use." The proposed rule also explains that "food contact substances" are included in the definition of "food." For the banana industry, conventional interpretation of FDA's far-reaching definition of "food" would mean that the plastic wrapping around the bananas inside the corrugated box and the actual banana brand label (sticker with PLU information) would be considered as "food" and, therefore, subject to the recordkeeping requirements.

Using this broad definition of "food," does FDA intend to require a nontransporter and a transporter in the supply chain to establish and maintain separate records for three items involving bananas: the banana, the plastic wrapping, and the brand label?

The establishment and maintenance of detailed records associated with the manufacture and distribution of plastic wrapping and brand labels would be a burdensome and challenging task for the banana supply chain. The use of the plastic wrapping in packaging and the application of the brand label occur on the farm inside the packing station. The activities involving "immediate food packaging" (the plastic wrapping) and "food contact substances" (the label) are performed inside the packing station on the farm. Therefore, the farm is an "immediate subsequent recipient" in the supply of "immediate food packaging" and "food contact substances."

Since farms are exempt from the requirement to establish and maintain records per §1.327(a), a break in the recordkeeping chain occurs. Information such as the date that the material was received, the lot number and quantity – all proposed information

requirements in the proposed rule under §1.337 – would likely not be available at the farm location. Thus, records on the plastic wrapping and labels would need to be first documented at some point further in the supply chain at a facility yet to be determined, perhaps even at time of import into the United States. The separation between the supply of packaging and labeling materials to the farm and the receipt of the packaged product at the next person or facility subject to these regulations could be distant enough to make recordkeeping difficult for "immediate food packaging" and "food contact substances."

Banana producers and farm locations have standard and fixed suppliers of these packaging and labeling materials. The identification of the source of these materials would not be a difficult process. However, the detailed tracking of each supply for each lot of bananas, including delivery dates, lot numbers and quantities, would be a burdensome task. If farms do not track and keep this information, which person or facility in the supply chain could provide all of the data required in the proposed rule for complete and separate traceability of these packaging and labeling materials? And if the "immediate food packaging" and "food contact substance" is accompanying and affixed to the food, respectively, then why would separate records be necessary when traceback and traceforward capabilities of the food would also trace the packaging and labeling, for example?

IBA believes that requiring records to effectively traceback the food to farm level should be sufficient to also effectively traceback potentially contaminated "immediate food packaging" and "food contact substances" to their source. The supplier relationship and purchase orders of packaging and labeling materials would identify the likely source. Furthermore, because the manufacture of these packaging and labeling materials would be registered facilities under section 305 of the Bioterrorism Act, where records would be kept, FDA would be able to quickly access information required from the initial source to traceforward to the farm in response to a potential threat.

IBA encourages FDA to remove the requirements to establish and maintain separate records for "immediate food packaging" and "food contact substances" once these materials are accompanying or affixed to the food. If records are kept on the food, then those same records could be used to trace the packaging and labeling materials to the farm and point of initial contact with the food. From there, the material's original manufacturing/processing facility can be identified, where detailed records on the immediate subsequent transporter and recipient (likely the farm) will be maintained according to the regulations.

The requirement to establish and maintain records on "immediate food packaging" and "food contact substances" can be duplicative, burdensome and unnecessary for the reasons described above. IBA requests FDA to eliminate the need establish and maintain separate records on these materials once they are accompanying or affixed to the food.

Recordkeeping for "Outer Food Packaging"

FDA is seeking comment "on whether the level of risk to human and animal health from potential contamination of outer packaging is high enough to warrant inclusion of outer packaging in the final regulations."

For bananas, "outer packaging" would be the forty-pound corrugated box. Separating the bananas from touching the box is a plastic wrapping. Due to the minimal direct contact that bananas have with the inner lining of the box, the likelihood of any cross-contamination from the outer packaging to the food would be negligible.

IBA agrees with FDA's conclusion that "the risk to human and animal health from contamination of outer food packaging is relatively small compared to the risk from contamination of the immediate packaging that comes in direct contact with food." Therefore, outer packaging should not be included in the final regulations.

§1.361 Timeframe To Make Records Available

The proposed rule requires records "to be made available within 4 hours of a request if the request is made between 8:00 a.m. and 6:00 p.m. (local standard time), Monday through Friday, or within 8 hours of a request if made at any other time...."

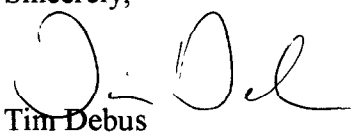
Four (4) hours is too short of time to legally require turnaround of complete documentation of records for a food item. The availability of knowledgeable personnel to access specific records, the verification of completeness and accuracy of the records, and the transmission of data to appropriate authorities may require additional time. What if the foreign facility primarily speaks a language other than English? Would translation of FDA's request, or the translation of the records, be required? What if technology fails in the ability to access and transmit the records?

While it is likely that four (4) hours will be sufficient in many cases, as all responsible parties will quickly respond to an emergency, there may be some circumstances when more time will be needed. Setting a maximum time limit for a lawful response needs to take into account these circumstances. IBA proposes that twelve (12) hours should serve as the maximum amount of time for response with complete and accurate data. And twelve (12) hours should serve as the single standard, regardless of what time of day the FDA request is made.

As stated in the proposed rule, FDA's experience in receiving records to a request is "2 to 3 days." In fact, FDA admits that "rarely do firms make records available within 24 hours." Thus, a mandatory twelve (12) hour turnaround time would greatly improve current conditions. This timeframe is much more reasonable and manageable for a legal limit of time when violations and penalties can be assessed for those exceeding the limit.

Thank you for the opportunity to participate in the rulemaking process by presenting the above comments. Please contact me at (804) 379-1466 or tdebus@uffva.org if you have any questions or wish to discuss these comments in further detail.

Sincerely,



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