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Food and Drug Administration
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The Fresh Produce Association of the Americas (FPAA) commends the efforts of the FDA on implementing the facilities registrations requirements. As mandated by the Bioterrorism Act of 2002, the FDA has been charged with securing the U.S. food supply. Members of the FPAA have a long history of supplying the U.S. with safe, quality produce and are proud of their efforts in working with the FDA in enhancing food safety and security. The industry relies on sensible, effective government regulations to ensure the continued advancement of the safety and security of the U.S. food supply. For this reason, the FPAA is submitting comments pertaining to the FDA's interim final rules for facilities registration.

Definitions of Farm, Manufacturing/Processing- The FPAA requests that the FDA further clarify its definitions and exemptions for facilities registration. The illustrative examples that the FDA gives in its proposed rule contain conflicts between activities that are exempt on the farm (i.e. washing and cooling) while simultaneously are specifically defined triggers for registration under the definition of manufacturing/processing. The members of the FPAA believe it would be helpful for the FDA to make more explicit in its rule exactly what activities qualify for a farm exemption and that a statement in the rule is included to explain which illustrative example supersedes the other example.

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Clarification for Filed "Processed" Fresh Fruits and Vegetables- The FPAA has received conflicting information from FDA officials regarding how or what "facility" to register when growers pack and process product in the field according the illustrative examples given by the FDA. Specifically, the FDA should clarify whether firms should register the location where mobile packing equipment is used or should the equipment itself be registered. For instance, items such as pineapples, eggplants and lettuce can be harvested in the field and are passed to a mobile packing operation mounted to a trailer, where activities defined by the FDA as processing are executed. For other commodities such as grapes and strawberries, items are placed into the final consumer packaging using nothing more than a table and a scale as equipment. Ultimately, does the FDA want each table to be registered as a facility or should the field where such equipment is used be the registered facility?

Clarification Needed Regarding Facility Owner vs. User- Information provided by the FDA in its educational outreach programs has been conflicted with respect to who must register under the regulation. One common area of confusion is whether one registration is sufficient for each facility or if it is necessary for each user of a facility to be registered with the FDA. For instance, it is a common practice in Mexico to lease farmland so that a production system using crop rotation, minimizing the use of pesticides and fungicides, is used whereby a vegetable grower will use the land one year, a different corn grower the following year, and a different bean grower in the subsequent year. Given the vegetable grower may "process" in the field as defined by the FDA, the FDA has been unclear whether the grower who is leasing the land should register or if the owner of the land should register. A similar dilemma has occurred where a warehouse that "holds" food under the definition of the rule provides warehousing services to multiple clients, but does not assign specific areas of the floor for the individual customers. Is the single registration by the facility operator sufficient, or must each firm with operations using the facility register as well as presented by the FDA in their outreach programs?

Transportation Equipment and Plastic Shipping Bags Should Not Register- The FPAA disagrees with the interpretation of the FDA (comment 70) requiring the registration of transportation containers that control the ripening of fresh fruits and vegetables. The vast majority of fresh fruits and vegetables are transported in equipment that meets the definition of processing as defined by the FDA in comment 70. Many containers have equipment that controls the temperature, humidity, concentration of ethylene gas, oxygen, etc. The FPAA does not believe that it was the intent of Congress to register millions of cargo containers whose principal use is transportation and not storage. Furthermore, a growing volume of fresh produce is shipped in specially bags that control the respiration and ripening of products that would also need to be registered under FDA's interpretation.

Need for Consistent Enforcement for International Obligations- In order to meets its international obligations, the FDA must consistently enforce the application of its regulations with respect to both foreign and domestic facilities. If the FDA is prohibiting the importation of foods from facilities that have not registered with the FDA, the FDA

must similarly not allow the interstate movement of U.S. foods from facilities not registered with the FDA. To maintain equivalency, The FDA should implant a serious of checkpoints at state lines within the United States to ensure enforcement consistent with international obligations.

The FPAA appreciates the efforts to date by the FDA to minimize the risks to the food supply. The FPAA urges the FDA to make important clarifications in its final rule to improve the transparency of the rule and allow for its consistent enforcement. The FPAA stands committed to improving the safety and security of the U.S. food supply.

Respectfully yours,

Lee Frankel

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President
Fresh Produce Association of the Americas