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December 23, 2003

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

Re: SUBMISSION OF COMMENTS
Docket No. 02N-0276. Interim Final Rule for Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. (68 Federal Register 58,894, October 10, 2003)

Dear Sir or Madam:

The Georgia Fruit and Vegetable Growers Association (GFVGA) representing more than 1000 fruit and vegetable growers in Georgia is pleased to submit these comments on the Interim Final Rule for the Registration of Food Facilities contained in Docket Number 02N-0276. This Interim Final 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").

We compliment the FDA for its leadership to ensure our nation has a safe food supply and appropriate steps are in place to reduce the potential of terrorist action to contaminate foods. GFVGA, along with the entire produce industry is committed to supporting efforts to ensure the safety and security of fresh fruits and vegetables in this country. However, GFVGA has serious reservations about certain provisions of the Interim Final Rule for Registration of Food Facilities.

GFVGA believes FDA is exceeding its statutory authority by requiring more information than is specified in the Bioterrorism Act. The FDA should only request registration information necessary for oversight. As outlined below we are particularly concerned about the "Farm" definition and other registration rules provided in the Interim Final Rule and subsequent communications from FDA to clarify the definition.

1. "Farm" definition – the agency is acting without the benefit of administrative record in developing the parameters of the farm exemption. In defining facility, the Congress specifically provided that the term "facility" "does not include farms; restaurants; other retail……" However, FDA proposed in February 2003, a "farm" definition and then modified the definition in the interim rules.

   Under the modified February 'farm' definition, farm operations which 'pack or hold produce' grown on both owned and leased land would not receive the 'farm' exemption. Leasing farmland is a widespread and common practice in American agriculture. In this area, where FDA has little expertise, the agency should look carefully at how the Department of Agriculture (USDA) views farming operations and farmland leases. Leased farmland carries no higher threat than farmland owned by the farm operator.

2. In communications from the agency, FDA has indicated the act of placing crops in a plastic sleeve, or any other consumer end-use container constitutes "manufacturing/ processing" that would trigger the registration requirement. Many fruit and vegetable farms in the southeast place harvested produce in consumer-ready packaging (*e.g.* peaches in a basket, carrots in a plastic sleeve, blueberries in a clam-shell, apples in a mesh bag). Even if only 10% of the farm's crop is put in consumer-ready packaging, the farm would not qualify for the farm exemption, because it engages in "manufacturing/ processing" and the manufactured/processed food is not consumed on the farm.

3. We understand from informal discussions, FDA is currently considering whether application of pesticides to crops, either pre- or post-harvest, is "manufacturing/ processing" that will trigger registration. Virtually every farm requires some kind of treatment to control pests, using a pesticide as broadly defined under the U.S. Environmental Protection Agency's implementation of the Federal Insecticide, Rodenticide and Fungicide Act (FIFRA). If FDA requires every farm that treats against pests to register, then the number of farms that could actually qualify for the exemption from registration would be minimal. Clearly this is not the intent of Congress in writing the farm exemption into the statute.

4. We applaud FDA for amending its definition of "food" in the interim final regulation to exclude food equipment and packaging materials. Including these types of products would have created substantial burden upon both the agency and the produce industry in submitting registrations.

5. From the definitions, we understand the term "facility" does not include transport vehicles if they hold food only in the usual course of business as carriers. However, vehicles, including "mobile facility" that are used to manufacture/process, pack, or hold food "beyond the usual course of its business as a carrier," are required to register. The definition of "facility" and "mobile facility" are still open for interpretation. Further clarification from FDA concerning these definitions is requested.

   Under the guidelines a farmer with a "mobile facility" has to register individual plots of land where the 'mobile facility' is used. This is unnecessarily burdensome and irrelevant in the protection of our food. If a farm is required to register due to some activity used

in the harvesting of produce, e.g. packaging, and is now considered a "facility," the address of the farmer should be sufficient.

6. The 60-day timeframe for updating registration information in the Interim Final Rule is more workable for our industry. However, the updates should be required when a **significant** event occurs such as change in ownership, location closing, changing the location of a facility, etc. The 60-day rule becomes a burden for minor changes such as an area code, management change, product addition, etc. Registrants should be permitted to notify FDA of these types of changes biannually or annually.

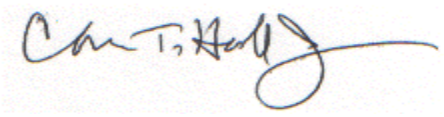
In conclusion, FDA should not disregard the intent of Congress to exempt farms from registration as this regulation is developed. FDA's interpretation of the farm exemption could potentially require almost 100% of the farms in the US to register under these guidelines. We believe FDA has acted in a manner that is arbitrary and contrary to Congressional intent. Congress' exemption of farms from the registration requirement must rest on a more definitive definition of a farm than:

- Is the orchard (a) leased (and therefore required to be registered) or (b) not leased (and exempt),
- Or whether the grower/shipper decides to place apples in (a) three-pound bags (required to be registered) or (b) forty-pound cartons (exempt),
- Or possibility in the future, does the grower follow best management practices (a) to apply pesticides, at the levels as specified on the label, to protect their bell pepper from insect damage (required to be registered) or (b) applies no pesticides (exempt).

FDA should revisit the definition of farm by undertaking fact finding regarding current fruit and vegetable production and packing practices.

Thank you for this opportunity to comment. Our industry is proud of the contribution fruit and vegetables make to the health of Americans. We want to do everything reasonable and prudent to provide a safe and wholesome product to the American people. We look forward to continuing to work together with FDA on these very important issues.

Sincerely,



Charles T. Hall, Jr.
Executive Director

Cc: Georgia Congressional Delegation
Donnie Morris, President, GFVGA
Donna Garren, Vice President, United

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