United Fresh Fruit & Vegetable Association

December 23, 2003

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

Re: 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); Submission of comments.

Dear Sir or Madam:

The United Fresh Fruit & Vegetable Association (United) is pleased to provide 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").

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 seriously our responsibility for prevention, detection, and all necessary actions to protect consumers from intentional contamination of our products.

We applaud the FDA for its leadership in ensuring that appropriate steps are in place to minimize the potential of terrorist action to contaminate foods. 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. However, we have serious reservations about certain provisions of the Interim Final Rule for Registration of Food Facilities.

Statutory Authority for Registration Information

The rule will require registrants to submit more information than is required by the Bioterrorism Act. By requiring more information than is specified in the Bioterrorism Act, United believes FDA exceeding its statutory authority. The FDA should only request registration information necessary for oversight.

"Farm" Definition

There are two significant flaws in the development and manner of implementation of the "farm exemption." The first is that the agency is acting without the benefit of an administrative record in developing the parameters of the farm exemption. The second is the chosen manner of implementation reduces the scope of the farm exemption to a nullity.

The general requirement for registration of food facilities is contained in section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 STAT. 594 (June 12, 2002) (hereinafter "Bioterrorism Act"). That section added section 415 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) and directed the Secretary to require by regulation that any facility engaged in the manufacturing, processing, packing, or holding of food for consumption in the United States be registered. Failure to register is a prohibited act, Bioterrorism Act § 305(b), punishable as a misdemeanor with six months' imprisonment and a fine of up to $100,000, or as a three-year felony with fines of up to $500,000 (for organizations) upon a second conviction. FDA also now has the authority to debar persons convicted of a felony in connection with the importation of food. Bioterrorism Act § 304, FD&C Act § 306(b)(1), 21 U.S.C. § 335a(b)(1).

In defining facility, the Congress specifically provided that the term "facility" "*does not include farms*; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels..." *codified at* 21 U.S.C. § 350d(b)(1) (emphasis supplied). There is, however, no legislative history regarding the meaning of the term "farm." In the language of the statute, FDA must register "facilities" that are engaged in "packing" or "holding." At the same time, the Congress directed that

"facilities" do *not* include "farms." It is therefore irrelevant whether farms pack or hold food; they are not "facilities" within the meaning of the Bioterrorism Act.

FDA nevertheless proposed in February 2003, and then modified in the interim final rule, its own definition of "farm."

> Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term "farm" includes:
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> (i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and
>
> (ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

21 C.F.R. § 1.227(b)(3), 68 FED. REG. 58,961. Neither the preamble to the February 2003 proposed rule nor the October 2003 Interim Final Rule describe how the agency arrived at its definition of farm.

In further informal statements, FDA officials have attempted to elaborate on some of the issues raised by this definition. FDA has indicated that a farm that packs or holds crops that were grown on another farm that is leased, but not owned, by the same farmer is required to register. Since farms that engage in "manufacturing/processing" of food are generally required to register, FDA guidance as to what activities constitute "manufacturing/processing" is crucial in defining the scope of the farm exemption. FDA has indicated that the mere act of placing crops in a plastic sleeve, or any other consumer end-use container that directly contacts the crop, constitutes "manufacturing/processing" that would trigger the registration requirement. Finally, FDA has said that is currently considering whether application of pesticides to crops, either pre- or post-harvest, is "manufacturing/processing" that will trigger registration.

United believes that "treating against pests" is an activity on the farm that is consistent with the intent of the Act's farm exemption. 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.

Also, FDA should not distinguish between locations or timing of the pesticide use on the farm. If the pesticide use is a traditional farming activity that is customary across all farms for the growing, harvesting and packing of a specific crop, regardless of whether the treatment

against pests is made pre-harvest to the plants in the field or post-harvest on the commodity in the on-farm packing station, for example, then that pesticide use should be deemed as an activity within the definition of "farm" for purposes of the bioterrorism rules.

Aside from imposing "manufacturing/processing" distinctions that are beyond the statutory authority granted by section 305 of the Bioterrorism Act, these interpretations effectively do away with the farm exemption mandated by Congress in the Bioterrorism Act. The vast majority of farms in the United States engage in one or more of the above "manufacturing/processing" activities. A great many farms, especially produce farms, place harvested produce in consumer-ready packaging (*e.g.*, berries in baskets; apples, oranges, grapes and other produce in plastic bags). Most farms apply pesticides to crops. Many farms pack or hold crops that were grown on other leased farmland. In each of these situations, 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.

It is evident from these examples that FDA is fashioning the Congressionally mandated farm exemption without a proper administrative record concerning how farmlands are owned, leased, and otherwise controlled, and what types of activities traditionally take place on a farm producing fresh fruits and vegetables. This is not surprising, given that FDA traditionally has expended its resources on food production sectors other than basic agriculture. To attempt to define what is a "farm," however, without any inquiry is arbitrary and capricious.

In an area such as this, where FDA has little expertise, the agency should look carefully at how the U.S. Department of Agriculture (USDA) views farming operations and leases of farmland. Leasing farmland is a widespread and common practice in American agriculture. In administering farm programs, such as direct and counter cyclical payments, the leasing of farmland does not compromise government benefits. That is, a farm still remains eligible to receive payments even when the owner leases the land to someone else. In fact, the underlying statutory authorities for farm programs typically recognize that farmland is often leased and clearly differentiate the roles of and decisions that can be made by a farm's "owner" and "producer". *See, e.g.*, 7. U.S.C. § 7911 ("owners" make decisions on establishing a farm's base acres and payment acres) and 7 U.S.C. § 7913 ("producers" receive direct government payments).

It is correct that an agency's construction of its governing statute is entitled to deference provided Congress has not directly addressed the precise question at issue. *Chevron U.S.A., v. Natural Resources Defense Council*, 467 U.S. 837, 847 (1984). Administrative constructions that are contrary to Congressional intent, however, must be rejected. *Id.* at 847 n.9. Because it would effectively negate the farm exemption, FDA's present definition of farm is contrary to Congressional intent. The Congress meant *something* when it exempted farms from registration. As the Supreme Court reiterated this term, "It is a 'cardinal principal of statutory construction' that 'a statute ought, upon the whole to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.'" *TRW Inv. v. Andres*, 534 U.S. 19, 31 (2001) (quoting *Duncan v. Walker*, 533 U.S. 167, 174 (2001) (some internal quotation marks omitted)), *cited in Virginia v. Maryland*, 72 U.S.L.W. 4093, 4098 (Dec. 9, 2003).

By including such a significant portion of farms in the registration requirement, FDA has eviscerated the Congressional intent to exempt traditional agriculture. FDA's interpretation of the farm exemption could exponentially multiply the number of registrations from an agriculture segment that the Congress meant to exempt. FDA has therefore acted in a manner that is arbitrary, capricious, and contrary to Congressional intent. Congress' exemption of farms from the registration requirement must rest on something more than whether an orchard is (a) leased (and therefore required to be registered) or (b) not (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). Registration and its consequent recordkeeping obligations cannot turn on such distinctions.

FDA should revisit the definition of farm by undertaking fact finding regarding current fruit and vegetable production and packing practices, and by using its enforcement discretion over facilities that claim exemption from registration and recordkeeping under the farm exemption.

"Food" Definition

We commend FDA for amending its definition of "food" in the Interim Final Rule to exclude food equipment and packaging materials. Inclusion of these types of products in the definition would have created a substantial burden upon the agency and the food industry needing to submit registrations.

"Facility" Definition

The term "facility" does not include transport vehicles (*e.g.*, trucks, railcars, cargo vessels, airplanes) if they hold food only in the usual course of business as carriers. However, if a vehicle is used to manufacture/process, pack, or hold food "beyond the usual course of its business as a carrier," it is a facility and must register. As stated by FDA, a vehicle, including a "mobile facility" that is used to manufacture/process, pack, or hold food "beyond the usual course of its business as a carrier," is required to register and should use the address of the vehicle's owner or operator as the address of the "facility" on the registration form. The definition of "facility" and "mobile facility" are still open for interpretation. Clarification from FDA concerning these definitions is again requested by United.

In addition, if a farm is required to register, FDA should provide additional guidance regarding how to register farms. A single farmer may own, lease, or operate many separate plots of land scattered over a wide area. In the event of a food security problem, the farmer is the person that FDA will want to contact. Therefore, it would make sense for FDA to allow farmers to submit a single registration for all their farms, even though their farms may not be in the same general physical location.

FDA should clarify that sites that serve as transitory staging areas where produce is momentarily held prior to transportation are not facilities that "hold" food under the 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. United has received verbal advice from some FDA officials that such staging areas are required to register, regardless of the length of time food is present at such sites. Therefore, United once again requests that FDA confirm that such transitory staging areas are not facilities that hold food and, therefore, are not required to register.

Flexibility for the Registration Process

The 60-day timeframe for updating registration information in the Interim Final Rule is more workable for our industry than the 30-day timeframe originally proposed. However, for a farmer who may tend many different farms and may work on a seasonal basis, even a 60-day timeframe is often not feasible. United requests that the final rule be revised to require that the 60-day timeframe for updating required registration information only applies to *significant* events. Significant events would include a change in ownership of a facility, a change in the location of a facility, or the closing of a facility. For other changes in required information, such as management changes, area code changes, or addition or subtraction of a product line or trade name, registrants should be permitted to submit an update biannually or annually.

Conclusion

In conclusion, FDA should not in the development of this regulation disregard the intent of Congress to exempt farms from registration. Also, the registration process should 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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Vice President, Scientific and Technical Affairs