



2003 12 23 11:40

December 23, 2003

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

RE: Comments on the Interim Final Rule for the 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 October 10, 2003 Federal Register notice (Vol. 68, No. 197) on the interim final 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 importing of bananas into the United States. Virtually all bananas consumed in the U.S. are from countries in Latin America, and there are thousands of banana farms in Latin America that can be responsible for the growing, harvesting and packing of bananas for import into the U.S. On a weekly basis, an average between 3.5 to 4 million forty-pound boxes of bananas is imported into the U.S.

IBA's comments on the interim final rule involve FDA's handling of the "farm" definition as the basis for determining eligibility for the Bioterrorism Act's farm exemption from the requirement to register as a food facility. The Bioterrorism Act specifically exempts farms from the facility registration requirement, and IBA believes that FDA's interpretation of several farming activities is not consistent with the intent of the farm exemption in the Act. In brief, IBA believes that FDA has incorrectly classified certain ordinary on-farm activities to be "manufacturing/processing" and outside the definition of "farm" for purposes of the rule, thereby eliminating the exemption for nearly every banana farm. The scope of the Act's "farm" definition and exemption should cover the customary and necessary activities on farms for the growing, harvesting and packing of food articles.

FDA's decision-making on what constitutes activities within the "farm" definition, as written in the interim final rule and from subsequent FDA outreach communications, appears to be arbitrary and inconsistent with traditional farming practices. FDA should take into account real-world farming practices and apply a reasonable and consistent standard according to traditional farming operations in their interpretation of the "farm" definition.

02N-0276

0212

With these comments, IBA would like to outline two particular activities on typical banana farms that should fall within the scope of the “farm” definition and exemption. And IBA is seeking FDA’s agreement that these activities should not trigger the requirement for that farm to register. The two activities include the post-harvest application of a crop protection product to control fungal pests, and the packing of bananas in bags for sale to consumers.

Immediately after harvest, bananas are transported to a packing shed *on the farm* where they are trimmed, washed, sorted, stickered, treated to control pests, and packed into a plastic wrap-lined box during a systematic operation. One variation of the packing may be that banana clusters are placed inside plastic bags - prior to placement in the box - for their sale to consumers.

The interim final rule defines “farm” to include the harvesting activities of trimming (of outer leaves) and washing. In addition, the rule clarifies that the on-farm “packing” activities of sorting, wrapping, or boxing harvested food for the sole purpose of transporting this food off of the farm” are activities under the “farm” definition and exemption. Finally, in FDA outreach communications following the publishing of the rule, FDA has confirmed that the placement of PLU stickers on individual fruits or vegetables is considered a farming activity. IBA agrees and supports FDA’s decisions on these farming activities; however, two conventional activities on banana farms remain in question. Only the application of a post-harvest fungicide and the potential packing inside an end-use bag remain as banana farm activities not addressed or accepted by FDA to be within the “farm” definition and exemption. IBA is requesting FDA to determine that these farming activities are a part of the “farm” definition for the reasons discussed below.

1. Post-Harvest/Pre-Packing Treatment Against Pests

IBA 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.

It is unclear why FDA includes some on-farm “manufacturing/processing” activities, as defined in the rule, to be within the “farm” definition while excluding other “manufacturing/processing” activities that are just as common and necessary for normal farm operations. FDA has provided examples in public meetings that the type of “manufacturing/processing” activities that would remove a farm's exemption involves actions such as processing oranges into orange juice or processing feed for animal consumption, provided that the orange juice or feed is not consumed on that farm or another farm under the same ownership. These types of non-exempt farm activities are quite different than the application of a pesticide, as the nature and composition of the food or feed is actually changed or manipulated from the manufacturing/processing activity. In fact, FDA makes a distinction when a farm becomes a “mixed-type facility,” in which a farm performs activities that fall both within and outside the “farm” definition. A farm that treats against pests should not be considered as a mixed-type facility, and treating against pests on the farm should not be categorized as a similar non-exempt farm activity.

Furthermore, FDA eliminated “pesticides” from the definition of “food” for the purposes of the bioterrorism rules. As explained in the comment section of the interim final rule, “...pesticides and their residues are subject to substantial and comprehensive regulation by EPA. Where another Federal agency has the types of specific and comprehensive authority described above to regulate the safety of certain substances [here, pesticides], FDA believes that it is appropriate to interpret “food” in section 415 of the FD&C Act to not include such substances.” Therefore, requiring a farm to register because of a conventional use of a pesticide would not only be contrary to FDA’s view that pesticides are not a safety risk needing more FDA oversight from the Bioterrorism Act (versus EPA’s FIFRA authority), but also contrary to the intent of the farm exemption in the statute.

For these reasons pesticide applications made to food *on farms*, whether such treatment against pests is made in the field or just after harvest in the on-farm packing station, should be considered by FDA as within the definition of “farm.” IBA is requesting FDA to provide written confirmation of this interpretation, which would rightfully negate the need for nearly all banana growers to register their farms with FDA.

2. Packing of Food in Consumer Packaging

In meetings with industry representatives following the release of the interim final rule, FDA has indicated that the placement of food in end-use consumer units, containers, or packages (i.e. clam-shells, plastic sleeves, cello bags) during either harvesting or packing is considered “processing” and will result in that farm to register as a food facility. Since the interim final rule already clarifies that the “wrapping” or “boxing” of harvested food is within the “farm” definition, IBA questions FDA’s interpretation that the use of consumer packaging materials would differentiate the packing as an activity outside the farm exemption. Why would the placement of bananas inside a plastic bag before it is placed inside a plastic-lined box require that farm to register, but the placement of the bananas inside the plastic-lined box without the plastic bag be exempt?

The plastic bag itself should not create a new security risk that requires new FDA oversight by applying the facility registration rule. As written in the interim final rule, FDA has determined that it is permissible, for purposes of the registration provision, to exclude food contact materials from the definition of ‘food.’” FDA further defines “food contact materials” to include “food packaging.” Therefore, if the rule clearly excludes food packaging materials from the scope of the regulated article, then why would FDA re-introduce the requirement to regulate food packaging materials when such materials are used in the packing activity of harvested food on a farm?

IBA believes that FDA should clarify that the packing of harvested food on a farm should be within the farm definition and exemption regardless of the type of packaging materials used in the activity.

In summary, IBA believes that the interim final rule and subsequent outreach communications by FDA inadequately categorizes several customary farming activities as “manufacturing/processing” steps that are subject to the facility registration requirement. The *on-farm* application of a post-harvest pesticide and the *on-farm* packing into plastic bags are two such established activities on banana farms that FDA should determine to be within the “farm” definition for the reasons discussed above. This determination would not only be a correct interpretation based on traditional farming practices but also an accurate reading of the farm exemption in the Bioterrorism Act.

IBA appreciates FDA’s consideration of these comments. Please contact me at (202) 303-3400 if you have any questions or wish to discuss these comments in further detail.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tim Debus', written in a cursive style.

Tim Debus
Executive Director