



GROCERY MANUFACTURERS OF AMERICA

MAKERS OF THE WORLD'S FAVORITE BRANDS OF
FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Registration of Food Facilities
Under the Public Health Security and
Bioterrorism Preparedness and
Response Act of 2002; Notice of
Proposed Rulemaking; Docket No.
02N-0276)

Comments of the Grocery Manufacturers of America, Inc.

Dear Sir or Madam:

The Grocery Manufacturers of America, Inc. ("GMA") is pleased to have this opportunity to provide comments on the proposal of the Food and Drug Administration ("FDA") to implement section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act"), which provides for the registration of domestic and foreign food facilities.

GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than \$460 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

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1. General Comments

Section 305 of the Bioterrorism Act was intended by the Congress to create a minimally burdensome mechanism for the creation of a database of food facilities to enhance the ability of the FDA to communicate with the food industry and allocate its resources to the efficient inspection of foreign and domestic food facilities. Overall, GMA concludes that FDA's food facility registration proposal is consistent with the purposes of section 305 of the Bioterrorism Act. We also conclude, however, that there are several provisions of the registration proposal that are considerably more burdensome than is reasonable or necessary; changes to these provisions – which are described below – would not alter the utility of the registration system, but would minimize the burdens of compliance on the industry and on FDA. In addition, there are some ambiguities that we believe should be clarified in the final regulation.

2. Food Categories Should Not Be Required

In its pre-proposal comments, GMA suggested that FDA not include the food categories as part of the initial registration of food facilities this fall. This suggestion was made in part because GMA was not convinced of the utility of the information and because it was and remains self evident that inclusion of the food category information in the registration process will greatly complicate the registration of several hundred thousand facilities and thus the cost of compliance. Other trade associations, which represent the food industry, included similar observations in their pre-proposal comments.

Nevertheless, in the proposal, FDA concludes that it should require the inclusion of food categories as part of facility registration. Under section 305 of the Bioterrorism Act, FDA is required to make a finding in guidance that inclusion of the food category information is necessary. FDA states that it intends to issue such guidance, which under the agency's regulations would be the subject of comment (21 CFR 10.115). Because FDA has not yet issued the draft guidance, interested persons are not in a position to comment fully on the proposed inclusion of the food categories in the facility registration regulation. FDA's brief discussion in the preamble asserts that having information on the food categories will aid FDA in conducting investigations and surveillance and in communicating with facilities about bioterrorist incidents or other emergencies involving food. FDA also states that the category information may assist it in verifying that the prior notice for a food offered for import and represented, as having been produced at a particular facility is consistent with the registration of that facility. Overall, FDA's principal rationale for inclusion of food categories

appears to relate to the ability that FDA perceives that it would give to communicate effectively and efficiently with the food industry.

GMA is not persuaded that the putative benefits of the inclusion of food category information in the registration system are real or that they outweigh the considerable burden that would be imposed on food manufacturers, especially those that operate multiple facilities that produce a broad array of products. In any system of data collection, the collector of the information must guard against the tendency to assume that more information always produces a better result. In the registration system (and in the proposal on prior notice which is the subject of separate comments by GMA), FDA appears to have fallen into the trap of concluding that the cost of acquiring additional information (to it and to the providers of the information) is relatively slight, while the benefit is real. This conclusion is wrong as the quantity of information that FDA proposes to require in the initial implementation of the facility registration and prior notice proposals creates the real risk of a systemic failure of implementation. In general, GMA believes that a less complex system of registration (and prior notice) will yield measurable benefits while reducing the likelihood of system failure. FDA ought not think that it must create the "perfect" system in the first instance; time and experience will help FDA and the industry to learn what is needed to make the system as functional as possible. Some of the difficulties with the inclusion of the food category information, which are described below, illustrate the potential for systemic failure emanating from the inclusion of unnecessary information.

First, a faulty assumption underlies FDA's apparent belief that the food category information will facilitate useful and targeted communication with the food industry. Suppose, for example, that FDA receives information that suggests that dairy/dairy ingredients have been contaminated by a terrorist. How would the category information aid FDA in determining which facilities to notify? Perhaps it would seem obvious to notify producers of milk, cheese, or yogurt. How could FDA confidently determine, after the obvious categories, where dairy/dairy ingredients were used? Would it know to inform producers of milk chocolate? Salad dressings? Cereal and milk bars? Canned or bottled coffee beverages? Macaroni and cheese? In short, the inclusion of the food categories provides a false sense of confidence about the utility and effectiveness of limited communication. In reality, if the hypothetical situation of a terrorist attack using food were to materialize, the **only** prudent course for FDA would be to notify the food industry at large.

Instead of envisioning a communication to a limited segment of the food industry – which runs the real risk of the fatal error of omission – FDA should communicate with the entire industry and seek communication **from** the industry to narrow the scope of potentially affected facilities. If FDA learns that “ingredient x” has been contaminated, it is far more sensible to tell everyone and ask companies which have used that ingredient to inform the agency.

The problem of communication to a limited number of facilities is compounded by the frequency with which companies introduce new or reformulated products. No system of updating registrations could conceivably result in a facility registration database that is precisely current. No harm results from informing facilities of a potential problem that does not affect them, while considerable harm can flow from failing to notify a facility that should have been notified.

Second, the burdens of compliance with the registration requirement will be considerably greater if food category information is required. As proposed, companies would need to update facility registrations within 30 days of a change in the category of product produced or handled at a facility. In many facilities, changes in the mix of products produced is common, as market conditions and seasonal changes in consumer preferences dictate. For the larger food companies with hundreds of facilities to manage, updating the facility registration every time a category is added to or deleted from the product mix at a facility would result in monthly updates.

In sum, there seems to be little to be gained by including the food categories in the registration system while the burden of providing that information and keeping it current is considerable. For these reasons, GMA suggests that FDA eliminate the requirement that the facility registration include food category information. In the alternative, GMA suggests that FDA limit the food categories to: (1) the initial registration of a facility, and (2) an annual update triggered by a communication from FDA to all facilities. This approach would greatly minimize the burdens on the food industry while also providing FDA with a sense of the types of products produced or handled by individual facilities. GMA would still caution FDA against relying on the food category information as a basis to determine what part of the industry to communicate with, but the category information could be of some value to FDA in targeting surveillance or inspections.

Eliminating the requirement for inclusion of food category information or restricting the update requirement to an annual one, would considerably lessen

the data burden on the registration system. If coupled with an acknowledgment by FDA that it will not use the category information as a basis for communication with a segment of the food industry, the risk of system failure in the registration system would be substantially lessened.

3. *Thirty-Day Updates Should Be Limited*

FDA proposes to require that any change in the information contained in a facility registration be provided to FDA in a facility registration update within 30 days of the change. This proposed requirement is unnecessary and burdensome.

FDA has acknowledged that the most important function of the registration information is to permit rapid communication by FDA to registered facilities. GMA suggests that FDA limit the requirement of a 30-day update to changes in the information for the emergency contact person at a facility. GMA further suggests that FDA provide, as an option, for the designation of an "alternate emergency contact" and that if a facility has provided both a principal and alternative emergency contact, it need only do a 30-day update if the information for **both** emergency contacts has changed.

All other information in a registration that has changed during the course of a year would then be provided to FDA in the form of an annual update. GMA further suggests that FDA send a communication to all facilities once a year (perhaps on or about December 1) to remind facilities of the need to update the facility information before the end of the year.

GMA believes that this approach to changes in the information contained in a registration will not diminish the utility of the registration system, but will lessen the burden that would otherwise fall on registered facilities.

4. *Clarification of the Scope of the Registration Requirement is Needed*

In spite of the efforts that FDA has obviously made to implement the registration requirement with little ambiguity, there are several situations that require clarification.

a. *Transportation Vehicles are Not Facilities*

The final regulation should make clear that transportation vehicles - trucks and truck trailers, rail cars, airplanes, barges, and ships - even if used for temporary storage, are not considered "facilities."

FDA has proposed a definition of "facility" in proposed § 1.227(c)(2) as "any establishment, structure, structures under one management at one general physical location, or in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs or holds food for consumption in the United States." The proposed definition does not clearly exclude transportation vehicles from its scope. FDA proposes to define "holding" as "storage of food." (§ 1.227(c)(5)) The examples of holding facilities that FDA provides are consistent with exclusion for transportation vehicles, but the exclusion is not express.

Transportation vehicles are not typically considered to be "facilities" and should therefore be excluded from the definition of facility. A facility is "something that is built, installed, or established to serve a particular purpose."¹ A transportation vehicle typically has no fixed location and its purpose is the movement of goods from one location to another. Not only does a transportation vehicle not logically fit the commonly accepted definition of "facility," but also there is no evidence that the Congress intended to include them in the definition of facility.

Accordingly, FDA should exclude transportation vehicles from the definition of facility.

b. *An Exclusion for Certain Temporary Storage Facilities is Warranted*

The final regulation should clarify that the temporary "holding" of food in one's home or in temporary storage (as, for example, in leased "self service" public storage) does not convert the home or the public storage into a "facility" for purposes of registration. This exclusion is needed because the proposed definition of "facility" in section 1.227(c)(2) seems to suggest that an individual home becomes a facility if food that is "manufactured/processed, packed, or **held**" enters commerce (emphasis added).

¹ Webster's New Collegiate Dictionary 406 (1980).

Sales personnel will often have substantial quantities of product in their possession, especially if they service rural areas of the country. These individuals will take possession of product from a food manufacturer for purposes of distribution to retailers. For relatively brief periods of time, the sales personnel may store product in their homes, in a portion of a public "self storage" warehouse, or in another small storage location. This storage of product is clearly incidental to the sales function of the sales personnel. Requiring these individuals to register their homes or a portion of a public storage warehouse would serve no obvious regulatory purpose: communication with them would be redundant of communication to the food manufacturer whose products they distribute and it is inconceivable that FDA would use scarce inspectional resources to examine limited product stored in the living rooms of sales personnel.

Because there is no value in having sales personnel register these temporary storage locations, FDA should expressly exempt "storage locations, including homes, which are used for the temporary storage of food as incidental to the activities of sales personnel."

c. *The Definition of "Facility" Should Exclude Quality Analysis and Research and Development Locations*

Under the Bioterrorism Act, facilities are subject to the registration requirement only if food is manufactured, processed, packed or held "for consumption in the United States." (Section 415(a)(1), 21 U.S.C. § 350d(a)(1)). Because of the "U.S. consumption" requirement, quality analysis and research and development facilities would typically be exempt from registration, as food that might be produced or analyzed in such a facility is not intended for consumption in the United States. In addition, a foreign facility that produces a food product for analysis within a quality analysis or research and development facility is not required to register (assuming that the foreign facility does not otherwise manufacture, process, pack or hold food for consumption in the United States). The final regulation should clarify that these types of "facilities" are exempt from registration.

In our comments on prior notice, we suggest that FDA provide for a blanket prior notice for quality analysis or research and development samples. Our suggestion includes the proposed requirement that, in order to file a blanket prior notice for these types of samples, the quality analysis or research and development facility be registered. Such a facility that does not wish to use the

blanket notice provision would not, under our suggested change to the registration regulation, need to be registered.

d. Facilities Subject to USDA Jurisdiction Should Be Exempt From Registration

Under the proposal, FDA would exempt from registration those facilities that are "regulated exclusively" by the U.S. Department of Agriculture (proposed section 1.226(g)). We suggest that this exemption should be expanded to include all facilities that are subject to USDA jurisdiction, even if those facilities are also subject to FDA jurisdiction.

5. *Miscellaneous Suggestions To Improve the Registration System*

Given the large number of facilities that will need to register and the amount of information that will need to be collected in the registration system, GMA has several suggestions to facilitate the registration process:

- a. The electronic registration system should permit the registrant to save the registration form in draft for completion at a later date.
- b. The electronic registration system should provide for multiple individuals from the same company to register facilities at the same time. This feature will be particularly useful to large companies with multiple facilities that are to be registered at the parent company level.
- c. FDA should provide for the uploading of registration information through a spreadsheet format. For companies with multiple facilities, this option would reduce the time and cost of registration and the potential for data entry errors.
- d. FDA should provide a secure mechanism for the updating of registrations, perhaps through a password system, that will minimize the ability of unauthorized individuals to make changes to an existing registration.
- e. FDA should send a communication to all registered facilities annually to remind the facility of the need to provide an annual update if one is required. As noted above, GMA suggests that

all changes other than those related to the emergency contact, be included in an annual update.

- f. In order to minimize confusion for facilities that may hold registration numbers for other purposes, FDA should create an acronym for the "food facility registration" (perhaps FFR #) so that facilities can ensure that they reference the correct number in their general business practices.

6. *Conclusions*

FDA's proposal provides the basis for a workable facility registration system and quite obviously reflects a great deal of effort and thought on the part of FDA. With a few important modifications, which are described in these comments, GMA believes that FDA will have faithfully and effectively implemented section 305 of the Bioterrorism Act. GMA appreciates the opportunity to participate in this rulemaking and requests that FDA consider these comments carefully.

Sincerely yours,



James H. Skiles
Vice President, General Counsel