Flexible Packaging Association

April 3, 2003

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

Re: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Docket No. 02N-0276; 68 Fed. Reg. 5378 (Feb. 3, 2003)

Dear Sir or Madam:

The Flexible Packaging Association (FPA) appreciates this opportunity to provide comments regarding the Food and Drug Administration's (FDA) proposed rule to implement section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act"). Pursuant to section 305 of the Bioterrorism Act, FDA is directed to issue regulations requiring that any facility engaged in the manufacturing, processing, packing, or holding of "food for consumption" register with the agency. FDA's facility registration proposal published in the February 3, 2003 *Federal Register*.

FPA is the national trade association representing all segments of the flexible packaging industry. Flexible packaging, which combines the best qualities of paper, plastic film, foil, and other packaging materials, is used in packaging food, drugs, and cosmetics, among other consumer products, and also is used in agricultural, industrial, and institutional packaging applications. FPA's members include companies engaged in the manufacture of flexible packaging materials for sale to the users or distributors of such packaging for the production of finished packaging for foods and other consumer products, as well as a host of other products. FPA membership is also open to any operation engaged in the manufacture of materials, equipment, or supplies related to the flexible packaging industry. FPA's member companies account for more than half of the 20 billion dollars of flexible packaging produced in the United States each year.

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FDA is to be commended for its commitment to food security and its ongoing efforts to implement the food safety provisions of the Bioterrorism Act. FPA particularly appreciates the relatively short timeframe in which the agency must promulgate regulations to implement the Act, and the difficulty of this task. FPA strongly objects to FDA's facility registration proposal, however, to the extent that it may be interpreted to require facilities that manufacture, process, pack, or hold food packaging materials to register with the agency. If applied to such facilities, the registration requirement will impose a substantial burden on the food packaging manufacturing industry without providing a corresponding benefit to the safety and security of the food supply.

The Registration Proposal

Section 305 of the Bioterrorism Act amends the Federal Food, Drug, and Cosmetic Act (FFDCA or the Act), in relevant part, by directing FDA to require by regulation "that any facility engaged in manufacturing, processing, packing, or holding *food for consumption* in the United States be registered" with the agency. [1]/ In the agency's proposal to implement this section, FDA defines "food" to have the meaning given in section 201(f) of the FFDCA.[2]/ Section 201(f) provides that "food" means "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."

The proposed regulations cite examples of articles that FDA has historically considered to be "food." Among the cited examples are "food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food." [3]/ The preamble to the proposed regulations states that FDA considers "substances that migrate into food from food packaging" to include immediate food packaging (or components thereof), but not outer food packaging. [4]/ As drafted in the February 3 *Federal Register*, the registration proposal could be interpreted to apply to articles of food packaging to the extent that the materials are intended for direct contact with food.

Subsequent to the *Federal Register* notice, at a February 12 outreach meeting, FDA attempted to clarify the intended scope of the registration proposal and its application to food packaging. Specifically, the agency explained its intent to apply the registration requirement to "finished food packaging" only. FDA further explained that a liner used to hold breakfast cereal

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[1]/ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 305 (emphasis added).

[2]/ 68 Fed. Reg. at 5418 (proposed § 1.227(c)(4)).

[3]/ *Id.*

[4]/ *Id.* at 5382. It is factually inaccurate and inconsistent with FDA precedent to equate materials that merely contact food with "substances that migrate into food from food packaging." A substance that contacts food does not necessarily migrate into food.

would be covered by the proposed regulations, but an outer box used for the retail sale of such cereal would not. [5]/

The meaning of FDA's remarks regarding "finished food packaging" is unclear. The plain and commonly understood meaning of "finished food packaging" in the industry is packaging that is formed, filled, and sealed. Thus, FPA considers "finished food packaging" to be packaging that is formed, filled, and sealed, and ready for distribution to the intended consumer. [6]/ In FPA's view, liners and other packaging materials as such (i.e., materials manufactured, held, sold, or distributed prior to finished packaging) are not reasonably classified as "finished food packaging" because they will be subject to further handling, storage, and processing before they can serve the intended purposes. Most importantly, FPA concludes that Congress did not intend the facility registration requirement to apply to the food packaging manufacturing industry. As explained more fully below, this conclusion is based upon the plain language, framework, and legislative history of the Bioterrorism Act, as well as the apparent absence of any appreciable benefit to food security to be gained by registration of facilities that manufacture or hold food packaging materials as such.

Adherence to Statute's Plain Meaning and Congressional Intent

As noted above, the Bioterrorism Act mandates that "any facility engaged in manufacturing, processing, packing, or holding *food for consumption*" register with FDA. FPA readily acknowledges that the definition of "food" set forth in the FFDCA is broad, and appropriately so. FDA has long relied upon this definition, together with the statutory definition of "food additive," to regulate the safety of food-contact articles, including food packaging.[7]/ In the context of traditional food additive and related requirements, an expansive reading of the terms "food" and "food additive" is appropriate and necessary to ensure adequate protection of public health. FPA does not believe, however, that the term "food" must, or indeed should, be afforded the same meaning regardless of the context in which it is used. In this instance, Congress prescribes that the expansive definition of food is not appropriate by specifying that it is "*food for consumption*" it intends for FDA to regulate.

In interpreting the meaning of "food for consumption" within the context of the facility registration provision, the agency is required to consider the intent of the provision, as expressed directly in the plain meaning of section 305 and as established through the overall framework

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[5]/ FPA notes that the preamble of the registration proposal expressly references "components of immediate food packaging" and could be interpreted to cover such components, *per se*. In light of FDA's February 12 clarification, FPA assumes that this was not FDA's intent.

[6]/ The phrase "form, fill, and seal" is used throughout the packaging manufacturing, food packaging, and food processing industries.

[7]/ "Food additive" is defined to mean, in relevant part, "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . ." FFDCA § 201(s).

and purpose of the Bioterrorism Act. With regard to the latter, the Supreme Court has stated that "[i]t is a 'fundamental cannon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'" [8]/ A statute is to be interpreted "as a symmetrical and coherent regulatory scheme" in which all parts are to be fit, if possible, "into a harmonious whole." [9]/

Applying these principles, the statutory reference to "food for consumption" in section 305 of the Bioterrorism Act cannot reasonably be assumed to have the same meaning as the definition of "food" set forth in section 201(f) of the FFDCA: FDA must consider not only the qualifying phrase "for consumption," but also whether the structure and purpose of the relevant provisions dictate a more limited interpretation. Indeed, the plain language, framework, and legislative history of the Bioterrorism Act make clear that Congress did not intend the registration requirement to apply to facilities that manufacture, process, or hold food packaging materials, *per se*. Moreover, FPA does not believe that registration of such facilities would serve the statute's intended purpose to enhance food security.

First, the plain language of the registration section refers to "food for consumption." The term "food for consumption" is most naturally and appropriately interpreted to mean edible food intended for direct consumption, not food packaging. Interpretation of the term to include food packaging ignores the qualifying phrase "for consumption" and stretches the language beyond its clear, plain, and common meaning. FDA's proposal does not provide an explanation as to why the phrase "food for consumption" in section 305 should not be given its common meaning.

Second, where Congress intended to include food packaging materials within the requirements established in the Bioterrorism Act, it did so expressly. In the recordkeeping provisions of section 306 of the Bioterrorism Act, Congress authorized FDA to establish—

> requirements regarding the establishment and maintenance . . . of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed . . . to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, *including its packaging*, in order to address credible threats of serious adverse health consequences or death to humans or animals. [10]/

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[8]/ *Food and Drug Administration v. Brown & Williamson Tobacco Corp.*, 529 U.S. 1291, 1301 (2000) (citations omitted) (interpreting the FFDCA definition of "drug" and concluding that the framework of the Act demonstrates that Congress did not intend for tobacco to be regulated as a "drug").

[9]/ *Id.*

[10]/ Bioterrorism Act § 306(a) (adding FFDCA § 414) (emphasis added).

This language is reasonably interpreted to require any "person" that manufactures, processes, packs, transports, distributes, receives, holds, or imports "food" to keep records relating to the immediate previous source and immediate subsequent recipient of the article of food, and if from a different source, the materials used to package the food. If the term "food" included packaging regardless of context, there would have been no reason for Congress to call out packaging specifically in this provision.

The specific reference to packaging materials in section 306, when coupled with the lack of any such references in other provisions of the statute, necessarily means (based on appropriate statutory construction) that the other provisions do not encompass "packaging" materials as such. Congress's use of the adjective "its" as a modifier to the noun "food" similarly reflects an understanding that "packaging" is not "food" for purposes of the Bioterrorism Act. This statutory framework reflects a judgment by Congress that packaging materials should be traceable to the immediate previous source, but need not be included within the registration scheme established by the Bioterrorism Act. It also demonstrates that registration of food packaging manufacturing and related facilities would do little to enhance food security, as the "immediate previous source" of food packaging materials will be readily available to the agency through registered facilities that use such materials in the production of finished packaging and finished food products.

Third, the intent of Congress to exclude (with the exception of recordkeeping) packaging materials from the reach of the Bioterrorism Act is further reflected in the legislative history of the prior notice provision set forth in section 307 of the statute. In the Joint Explanatory Statement issued by the Committee of Conference for the bill (H.R. 3448), the Managers advised that—

> The Managers intend that the requirements of this section should not be construed to apply to packaging materials if, at the time of importation, such materials will not be used for, or in contact with, food as defined under Section 201 of the FFDCA.[11]/

The Managers further advised that—

> Nothing in this section shall be construed to alter or amend the regulatory treatment of food packaging materials or food contact substances under the FFDCA. [12]/

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[11]/ H.R. CONF. REP. NO. 107-481, at 137 (May 21, 2002).
[12]/ *Id.*

Finally, to further confirm Congress's intent with regard to the prior notice requirement, Representative John Shimkus (R-Ill.), a member of the Conference Committee for the bill, entered the following remarks into the May 24, 2002 Congressional Record:

> Mr. Speaker, in addition to my statement for the record on May 22, 2002 during floor consideration of H.R. 3448, let me clarify that language included in the Conference Report regarding Section 307 as it relates to food packaging materials. Section 307 dealing with prior notice of imported food shipments should not be construed to apply to food packaging materials or other food contact substances if, at the time of importation, they are not used in food. [13]/

This important legislative history demonstrates that Congress did not intend for packaging materials or other food-contact substances to be subject to the prior notice obligation. More specifically, it demonstrates that the prior notice requirement applies not to food packaging imported as such, but to packaging in its "finished" form (i.e., packaging that has been formed, filled, and sealed). A food packaging material is not "at the time of importation . . . used in food" unless it has been formed, filled, and sealed.

It is also telling that Congress specifically stated that the prior notice provision should not be construed to "alter or amend the regulatory treatment of food packaging materials" under the FFDCA. If FDA were to require prior notice of the importation of unfinished food packaging materials (e.g., bags, pouches, other empty containers, or other materials that have not been formed, filled, and sealed), such a requirement clearly would "alter or amend" the regulatory treatment of packaging materials under the FFDCA by imposing new requirements.

Congress's intent with regard to prior notice is indicative (if not prescriptive) of its intent regarding facility registration because the two provisions serve substantially the same purpose—to facilitate FDA oversight of food security concerns, especially threat investigations. If the Bioterrorism Act is to be interpreted "as a symmetrical and coherent regulatory scheme" in which all parts are to be fit, if possible, "into a harmonious whole," it would make little sense for Congress to exempt food packaging materials from the prior notice provision but to expect food packaging industry facilities to register with the agency.

Fourth, as part of the registration process, the Act authorizes FDA to require, when deemed necessary, identification of "the general food category (as identified under section 170.3 of title 21, Code of Federal Regulations) of any food manufactured, processed, packed, or held at such facility." [14]/ Section 170.3 provides no category for food packaging materials, further

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[13]/ 148 Cong. Rec. E916 (daily ed. May 24, 2002).

[14]/ Bioterrorism Act § 305(a) (adding FFDCA § 415).

confirming that Congress did not intend the registration requirement to apply to facilities that produce, pack, or store such materials.

Fifth, it is unclear how registration of food packaging manufacturing and related industry facilities would further the objectives of the Bioterrorism Act. Congress intended the facility registration requirement to assist FDA in responding to threats to food safety that may involve facilities that manufacture, process, pack, or hold food for consumption. [15]/ As FDA itself has advised, registration information is expected to enable the agency to act quickly in response to threatened or actual terrorist attacks affecting the food supply, or to other food-related emergencies. [16]/ For example, in the event of an outbreak of food-borne illness, collected information may help FDA and other authorities to determine the source and cause of the event, and to notify affected facilities quickly. [17]/

FPA is aware of no appreciable food security benefit to be gained by subjecting the packaging industry to a facility registration requirement, nor are any packaging-specific benefits described by FDA in the proposal. FPA finds it noteworthy that three recent reports addressing the potential vulnerability of the food supply to bioterrorism and related threats make no mention of packaging as a potential vehicle for the intentional contamination of food. [18]/

To the extent that FDA believes that packaging materials may pose food security concerns, such concerns would be most relevant and credible at the point that the packaging materials are transformed into "finished food packaging"—packaging that has been formed, filled with a food product, and sealed. Prior to this point, the security risk posed by packaging materials is extremely remote, and even if intentional acts of tampering did occur, any affected unfinished packaging materials would be subject to further handling, processing, and examination that would provide ample opportunity to detect evidence of contamination.

Moreover, in the unlikely event of an intentional attack on the food supply, and in the even less likely event that such an attack involves food packaging materials, FDA will be able to readily identify affected food packaging industry facilities through traceback records that will be required pursuant to the Bioterrorism Act. The agency's source of such records will be food processors and packers that will be registered with the agency and that will be required to maintain records of the "immediate previous source" of the food, including its packaging, handled therein. Indeed, in FPA's experience, food processors and packers already keep such

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[15]/ 148 Cong. Rec. H2857-8 (daily ed. May 22, 2002).

[16]/ 68 Fed. Reg. at 5379.

[17]/ *Id.*

[18]/ GAO, Rep. No. GAO-03-342, *Food Processing Security: Voluntary Efforts Are Under Way, but Federal Agencies Cannot Fully Assess Their Implementation* (Feb. 2003); National Resource Council of the National Academies, *Making the Nation Safer: The Role of Science and Technology in Countering Terrorism* (June 2002); Centers for Disease Control and Prevention, *Public Health Assessment of Potential Biological Terrorism Agents, Emerging Infectious Diseases* (Feb. 2002).

records and are currently able to trace supplied packaging materials to the immediate previous source. In light of the minimal risk posed by food packaging materials and the traceback capability that will be mandated by the Bioterrorism Act, it is not clear how application of the facility registration requirement to the food packaging manufacturing industry will enhance food security.

FPA believes strongly that FDA and industry resources will be most effective in protecting food security if such limited and finite resources are focused on those industry segments that produce food intended for consumption and intentional components of such food. Extending the registration requirement to food packaging manufacturing and related packaging industry facilities adds to the burden faced by both industry and FDA, but does not enhance food security in any meaningful way.

Summary and Recommendations

Based upon the plain language, framework, legislative history, and purpose of the Bioterrorism Act, FPA believes that Congress clearly did not intend for packaging materials to be subject to the registration requirement established in the legislation. Application of the registration requirement to facilities that manufacture, process, pack, or hold packaging materials would impose substantial burdens on both industry and FDA, without providing any corresponding benefit to food security. FPA urges the agency to revise the definition of "food" in proposed 21 C.F.R. § 1.227 to specifically exclude food-contact articles as such, including food packaging and components thereof.

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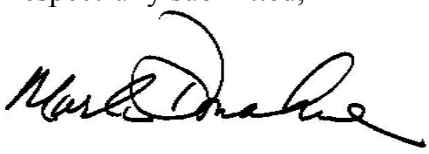
FPA appreciates this opportunity to provide comments concerning FDA's proposal to require registration of facilities that manufacture, process, pack, or hold food for consumption. FPA looks forward to working cooperatively with the agency on this and other food security proposals and initiatives. Please do not hesitate to contact us if it would be desirable to discuss these comments or if FPA may provide additional information.

Respectfully submitted,



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