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April 4, 2003

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Via Electronic Submission and Federal Express

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

Re: SPI Comments on Proposed Regulation on Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Docket No. 02N-0276]

Dear Madam or Sir:

The Society of the Plastics Industry, Inc., (SPI)¹ by its attorneys and through its Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC), hereby respectfully submits these comments with regard to the regulation proposed by the Food and Drug Administration (FDA) entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," which was published in the *Federal Register* on February 3, 2003 (68 *Fed. Reg.* 5377). This notice requested public comment on the implementation of the provision for registration of facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. This provision is contained in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act"). Section 305, Pub. L. 107-188 amending Federal Food, Drug, and Cosmetic Act (FFDCA) (codified at 21 U.S.C. 331 *et seq.* (2002)).

¹ Founded in 1937, The Society of the Plastics Industry, Inc. is the trade association representing the fourth-largest manufacturing industry in the United States. SPI's 1,500 members represent the entire plastics industry supply chain, including processors, machinery and equipment manufacturers, and raw material suppliers. The U.S. plastics industry employs 1.5 million workers and provides \$330 billion in annual shipments. The Food, Drug, and Cosmetic Packaging Materials Committee is composed of SPI members with particular interest and expertise in packaging for food and other FDA-related products. The Committee has a long history of working cooperatively with FDA on regulatory issues relating to packaging.

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SPI and its members fully support Congress and the Food and Drug Administration in implementing meaningful steps to protect the U.S. food supply from terrorist acts. The plastics industry stands ready to participate in this important effort. However, as explained more fully below, we respectfully submit that FDA's proposal to extend the registration requirement to facilities that manufacture, process, pack, or hold packaging or other food-contact articles is in contravention of Congressional intent and will unduly burden industry while providing no significant protection against terrorism.

Including Food Packaging Materials in the Registration Provision Is in Contravention of Congressional Intent as Indicated by the Language of the Statute

By way of background, FDA seeks to bring suppliers of food-contact materials (not yet containing food) within the reach of the proposed regulation by referring to the definition of "food" found in Section 201(f) of the FFDCFA, which defines "food" as "(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." 21 U.S.C. § 321(f). Historically, FDA has relied on the FFDCFA's definition of "food," in conjunction with its definition of "food additive,"² to provide a basis for the Agency to assert regulatory authority over any food-contact materials that are also food additives. In this case, the proposed regulation includes a list of examples of products that FDA considers to be covered by the definition of "food," and the list identifies "substances that migrate into food from food packaging and other articles that contact food" as "food" for purposes of the regulation.

The proposed extension of the registration requirement to facilities manufacturing or holding only food-contact materials is contrary to the intent of Congress as evidenced by the specific language of the facilities registration provision in the statute itself. With regard to the registration requirement, the Bioterrorism Act states that facilities that "manufacture, process, pack or hold **food for consumption** in the United States" will be required to register (emphasis added). We consider the term "food for consumption" to be properly interpreted as referring to edible food, not food-contact articles. Based on discussions with Congressional staff and others as the legislation was under consideration, we are quite certain that there was never any intent for the registration provision to extend to facilities dealing with empty food-contact articles. In the case of this provision (unlike the import notification provision discussed in separate comments filed along with these), Congress did not provide legislative history confirming its intent with respect to food-contact materials. We are confident, however, that the absence of such

² Section 201(s) of the FFDCFA defines, in part, "food additive" to include "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." 21 U.S.C. § 321(s). The definition specifically includes substances intended for use in packing or packaging food. *Id.*

statements of intent derives from the assumption by Congress that nobody would misconstrue the meaning of "food for consumption." This conclusion is supported by the difference in language used in the facilities registration provision ("food for consumption") and the more general "articles of food" terminology used with respect to import notification. Since Congress has indicated explicitly that "articles of food" do not include food-contact materials for purposes of import notification, it is apparent that "food for consumption" should not be given a broader interpretation.

Another indication that Congress did not have food-contact articles in mind as triggering facilities registration under the Bioterrorism Act is the legislators' reference to the food categories in 21 C.F.R. § 170.3. The Bioterrorism Act states that FDA may require each facility to submit the general food category, as identified under § 170.3, of the food manufactured, processed, packed, or held at the facility. Indeed, FDA has proposed to include the categories from § 170.3 as a mandatory field on the registration form. However, § 170.3 does not include categories for food-contact materials.

FDA has indicated that only certain packaging materials are intended to trigger the requirement for facilities registration. In this regard, FDA's proposal states that "substances that migrate into food from food packaging" include "immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food." The terms "immediate food packaging or components of immediate food packaging," however, potentially cover a vast array of products, including plastic resins, glass, paper, metal, rubber and textiles, and many other materials, such as monomers, colorants, lubricants, preservatives, plasticizers, catalysts, antioxidants, defoaming agents, emulsifiers, and adhesives, that are used in the production of food packaging.³ Also, FDA has not addressed the situation in which a packaging material, such as paper or film, may have a coating: would facilities that hold or manufacture the paper or film that is intended to have a coating (but does not yet have a coating) be subject to the registration provision, or just the facilities that apply the coating?

During a February 12, 2003 meeting at the National Food Processors Association, FDA officials attempted to clarify further which packaging would be subject to the registration requirement, and specifically indicated that the intent of the proposal is for the rule to cover only finished packaging that will be in direct physical contact with food. An example used by FDA was that the regulation would apply to liners for cereal boxes, but not the boxes. In response to a question, FDA indicated that the regulations would not cover polymers, additives, or monomers, but only the "immediate" food packaging made from such components. We assume from FDA's

³ For more of an insight into the breadth of materials that possibly could be included, one can refer to the numerous food-contact substances listed in 21 C.F.R. Parts 174-178 of FDA's food additive regulations.

statement that this regulation also was not really intended to apply to the many other components of food packaging, some of which are identified above. The current language in FDA's proposal, however, extending to "components of immediate food packaging," does not limit the coverage of the regulation as FDA apparently intends. It is also unclear whether FDA intends to include only the final, completely formed packaging, or also the film or sheet or other bulk materials from which the final packaging is formed.

Contrary to FDA's declaration of intent, however, the proposed registration regulation is not even limited by its terms to packaging, much less to finished packaging. The Agency's definition of "food" would extend to "substances that migrate into food from food packaging **and other articles that contact food.**" (Emphasis added). We assume that FDA really means to require registration of facilities dealing with the articles from which migration occurs, not the migrating substances themselves. Putting aside that ambiguity, however, still leaves the apparent requirement for registration of facilities that manufacture, store, or otherwise handle food-contact articles other than packaging, such as food processing equipment and glassware, dishware, cutlery, kitchen appliances (and other "houseware" items). If the regulation continues to read this broadly, it will impose a significant burden on a large number of companies.

As discussed above, requiring registration of facilities that manufacture or handle food packaging materials only, not edible food, is contrary to Congressional intent as expressed in the language of the statute. Therefore, the proposed regulation should be revised to exclude facilities dealing only with empty food packaging. In light of the clear evidence that Congress did not intend to include packaging materials facilities in the registration provision of the legislation, and the fact that including food packaging materials in the regulation will unduly burden industry while providing no significant protection against terrorism, we recommend that FDA insert in the regulation language specifically excluding manufacturing and holding facilities for food packaging materials not yet containing food. To accomplish this, we recommend that the phrase "including substances that migrate into food from food packaging and other articles that contact food" be removed from the discussion in Section 1.227(c)(4) of the proposed rule, and that the following language be inserted into this section: "for purposes of this provision, "food" does not include food-contact materials not yet containing food."

Indeed, the proposal requires amendment even to implement FDA's expressed intent to cover only "immediate" packaging. It is SPI's position that the definition of "food for consumption" would need to exclude food-contact materials other than finished food packaging intended for direct contact with food.⁴

⁴ FDA would need to remove the phrase "including substances that migrate into food from food packaging and other articles that contact food" from the discussion of the definition of food in Section 1.227(c)(4) of the proposed rule. The following language should be inserted: "FDA does not intend for all packaging materials to be subject to this provision. Only "finished" food

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The Burden on the Packaging Materials Industry is Disproportionate to any Reduction in Risk

Including food-contact materials in the regulation will impose burdens on the industry that are disproportionate to any minimal reduction in risk and will provide no significant protection against terrorism. Regardless of whether or not the registration requirement would apply only to finished food packaging, it would impose a significant burden on the companies involved. The requirement would apply not just to the facilities that manufacture the products, but also the warehouses where they are stored. Large companies, particularly multinationals, will have to spend an inordinate amount of time simply identifying the facilities that will need to be registered and putting in place mechanisms for meeting their obligations, including the updates FDA proposes to require.

Further, including in the registration requirement facilities that manufacture or hold food packaging material will require registration of many facilities that are principally non-food industrial suppliers but also have a small business in supplying materials being used in food packaging. Also included would be independently owned warehouses that store small amounts of materials used in food packaging. Some owners of these independent warehouses may not even be aware that they are storing food-contact materials that would be subject to the provision. Materials used principally in non-food applications also often have food-contact uses, which may not be known to every facility that handles the materials.

Not only would registration of all of these facilities be exceedingly burdensome, but the information would have limited usefulness in satisfying the purpose of the Bioterrorism Act, which is to “expand FDA’s powers to prevent and respond effectively to terrorist threats against the food supply.” FDA does not explain how registration of the facilities that manufacture and store food-contact materials would deter the intentional contamination of food or assist the Agency in determining the source and cause of contamination. In estimating the benefits of the proposed regulation, FDA discusses five outbreaks of foodborne illness from accidental and intentional contamination of edible food, but there is no mention of food-contact articles being related to any such occurrences. It does not seem likely that terrorists would attempt to contaminate food indirectly by tampering with empty packaging. Further, requiring registration

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packaging intended for direct contact with food, which is in its final form and requires no further processing before food can be added, is intended to be subject to this provision. “Further processing” does not include minor alterations to the exterior of the packaging, such as the application of labels or inks.” SPI is not recommending this definition because Congress did not intend facilities registration to apply where only empty food packaging materials are involved. We simply point out that clarification of the proposed regulation would be needed to implement FDA’s stated intent properly.

of food-contact materials would divert FDA attention and resources from activities directed toward more immediate food security risks.

FDA's Estimate of the Burden on Industry Is Low

FDA's assessment of the number of domestic companies that might need to register in connection with food packaging materials probably is overly inclusive if FDA's true intent is to include only finished packaging since the estimate includes companies supplying basic chemicals. These products may fit within the FFDCa definition of food, but they are not finished packaging.

With respect to foreign firms, however, FDA relies entirely on its proprietary OASIS database, which we do not believe includes many, if any, suppliers of food-contact articles. We expect that the number of foreign suppliers of food-contact materials required to register will be much larger than FDA's estimate.

Furthermore, FDA's cost calculation ignores the effort, discussed above, that will be required of large companies to identify all of the manufacturing and handling facilities covered by the registration requirement. As an example, we have been informed by one large supplier of food packaging materials that approximately 1,000 of its facilities may need to be registered, depending on how FDA defines the products that trigger the registration requirement. With such a large number of facilities affected, both identifying the facilities and managing the submission of change notices would require programming of the company's computer system and a significant commitment of personnel and other resources, none of which was considered in FDA's burden estimation.

FDA also did not consider in its cost calculation the numerous independently owned commercial warehouses, mentioned above, used by companies that manufacture food-contact materials. Not only does the inclusion of these warehouses add to the number of facilities that would need to be registered under the proposed rule, but the owners of these independent warehouses likely would not be aware that the registration requirement applies to them (since they may not be aware that some food-contact materials, particularly materials with additional non-food applications, would be considered "food" under the definition of food in the rule). Both FDA and the manufacturing companies that use these warehouses would need to spend time and resources educating them on the new requirement.

Finally, past experience with other similar situations has shown that a significant number of food processors will require packaging suppliers to also certify that their facilities have been registered properly with FDA, thereby increasing the administrative burden on these companies. This cost also is not included in FDA's cost calculation.

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In summary, the burden of registering facilities that manufacture and store food-contact materials is contrary to the language and intent of the Bioterrorism Act. In addition, such registration will not provide any significant assistance to FDA in deterring or responding to terrorism directed against the food supply. Thus, facilities manufacturing or handling only food-contact materials that are not already in contact with food should be exempt from the regulation. If FDA nevertheless continues to propose inclusion of some food-contact materials within this proposed regulation, the scope of the products to be covered must be clarified.

SPI's FDCPMC appreciates this opportunity to comment on the proposed regulation. SPI and its members also reiterate their willingness to work with FDA and other government agencies to implement significant protection against terrorism.

Sincerely,

A handwritten signature in black ink, appearing to read "R.A. Simmons", with a long horizontal line extending to the right.

Ralph A. Simmons
Legal Counsel for
The Society of the Plastics Industry, Inc.