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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 Regulations on Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Docket No. 02N-0277]**

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 "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," which was published in the *Federal Register* on May 9, 2003 (68 *Fed. Reg.* 25187). This notice requested public comment on the proposed regulation to require the establishment and maintenance of records by certain domestic and foreign persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended 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 306, Pub. L. 107-188 *amending* Federal Food, Drug, and Cosmetic Act (FFDCA) (codified at 21 U.S.C. 350 *et seq.* (2002)).

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[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.

SPI and its members fully support Congress and FDA in implementing measures to protect the U.S. food supply from terrorist acts. The plastics industry is prepared to participate in this important effort. It is our view, however, that any burdens imposed on industry to prevent terrorist acts should be reasonable when compared to the anticipated protective effect. As explained more fully below, the extension of the recordkeeping provision to suppliers and transporters of packaging or other food-contact articles will unduly burden industry and provide no significant protection against terrorism. Furthermore, FDA has misinterpreted the language of Section 306 of the Bioterrorism Act with regard to the applicability of the provision to the packaging industry. Including the food packaging industry in this requirement is in contravention of Congressional intent.

***Including Food-Contact Materials in the Recordkeeping Provision Is in Contravention of Congressional Intent as Indicated by the Language of the Statute***

SPI's FDCPMC opposes the recordkeeping requirement with respect to food-contact materials (not yet containing food) as contrary to Congressional intent and reflecting FDA's misinterpretation of the statute. On the subject of recordkeeping, the Bioterrorism Act states that FDA may implement regulations to require recordkeeping by persons (excluding farms and restaurants) who "manufacture, process, pack, transport, distribute, receive, hold, or import **food**," to the extent such records are needed to allow FDA 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" (emphasis added). Based on the language of the statute and our knowledge of the underlying Congressional intent (through discussions with those involved in drafting the law), we are confident that Congress was using "food" according to the ordinary understanding of the word, meaning edible food, not packaging.

The reference to packaging does not mandate recordkeeping by packaging suppliers or transporters. Indeed, the reference to "packaging," in addition to "food," indicates a distinction between the two terms in the view of the drafters. The law and Congressional intent would be satisfied by a food processor maintaining records identifying the source of the finished packaging for the food product. In the unlikely event that food packaging is the target of terrorists, records in the hands of food processors regarding their packaging suppliers will allow FDA to follow the history of the packaging and its components. The regulation as proposed by FDA extends far beyond what was intended by Congress. To follow Congressional intent, the proposed regulation needs to be revised to provide only that food processors have records identifying the suppliers of their packaging.

***The Burden on the Food Packaging Materials Industry Is Disproportionate to Any Reduction in Risk***

Including food-contact materials in the regulation beyond the limited extent described above will impose burdens on manufacturers (and transporters) of such materials that are disproportionate to any minimal reduction in risk and that will provide no significant protection against terrorism. Regardless of whether or not the recordkeeping requirement would apply only to finished food packaging (as indicated by FDA in meetings but not so limited in the language of the proposed regulation), it would impose an ongoing, significant burden on the companies involved. Some of the information to be required by FDA unquestionably is already maintained by industry. The proposed regulation, however, would apply to domestic and foreign firms dealing with packaging materials who are not accustomed to having a recordkeeping responsibility with respect to FDA. The firms would need to educate themselves on the new requirements and establish systems not only to keep the records required by FDA, but also to have all of the required information available for FDA within 4 hours of a request made by the Agency between 8 a.m. and 6 p.m., Monday through Friday, or within 8 hours if requested at any other time.

One assumes that the times are meant to be the local times of the facilities that must respond, but the proposal does not address this point. If the times are interpreted to be when the request is made by FDA, then multinational sites would be required to hire additional staff (with the associated increased costs) to be available on a 24 hour, 7 days a week schedule. For example, a request from FDA that is made on Friday at 1:00 pm Eastern Standard Time, will be received in Tokyo at 2:00 pm on Saturday. Likewise, a request from FDA that is made at 4:00 pm, will not be received in Europe until 10:00 pm. Furthermore, even if the information is available from existing records, the 4 – 8 hour window for response certainly will require many companies to establish a procedure dedicated to the records required by FDA, as opposed to relying on existing systems.

In addition, requiring suppliers of food-contact materials to keep these records 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 recordkeeping relating to 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 seems unlikely that terrorists would take such an indirect approach to contaminating the food supply. At the least, this prospect seems sufficiently remote so as not to justify the additional burden that would be imposed on suppliers and transporters of food-contact materials.

***The Proposed Regulation Must Be Revised to Follow FDA's Own Expressed Intent***

Suppliers of food packaging and other food-contact materials are brought within the reach of the proposed regulation by virtue of the proposal's definition of "food," which, as in the previous proposed bioterrorism regulations, is coextensive with the definition of "food" in the Federal Food, Drug, and Cosmetic Act (FFDCA). As SPI has discussed in comments on the previous proposed bioterrorism regulations, the definition of "food" under Section 201(f) of the FFDCA includes both articles used for food by man or animals and **components** (emphasis added) of such articles. A "food additive" is defined in Section 201(s) of the FFDCA as any substance "that is reasonably expected to become a **component** of food" (emphasis added). Therefore, any food-contact substance that meets the definition of a "food additive" also comes within the definition of "food," which FDA has incorporated by reference in the proposed regulation on recordkeeping and the other proposed bioterrorism regulations. In fact, court decisions indicate that a food-contact article or material comes within FDA's authority over "food" even if it is exempt from the need for premarket clearance as a "food additive" (by being a "houseware," for example). In the language of the proposed regulation itself, FDA indicates that the Agency intends "food" to be interpreted as extending to the full breadth of the term's definition under the FFDCA, offering as an example of "food" "substances that migrate into food from food packaging and other articles that contact food." 68 *Fed. Reg.* 25238.

The way the proposed recordkeeping regulation is drafted, then, it would apply, at a minimum, to all food-contact substances that meet the definition of "food additive," and, possibly, to literally all food-contact articles and materials. The preamble to the proposed regulation and FDA's public statements, however, suggest that such broad coverage is not really the Agency's intent. Specifically, the preamble states as follows with respect to food packaging.

> FDA interprets packaging in section 306 of the Bioterrorism Act [the recordkeeping provision] to mean the outer packaging of food that bears the label. FDA is not interpreting packaging to include food contact substances, which are included in the definition of "food." Outer packaging would include, for example, the outer cardboard cereal box that bears the label of the cereal, but would not include the inner lining that holds the cereal. Outer packaging would also not include the outer shipping box in which the cereal boxes are shipped.
>
> FDA has tentatively concluded that the risk to human and animal health from contamination of outer food packaging is relatively small compared to the risk from contamination of the immediate packaging that comes in direct contact with food. Therefore, FDA is proposing not to require covered persons to keep records regarding outer food packaging. However, the agency also recognizes that there may be instances where it may be necessary for FDA to be able to investigate agents that could lace outer

> packaging and could thereby contaminate a food for which the immediate food contact may not provide an adequate barrier. In addition, outer packaging could be intentionally diverted and used to package food that has been tampered with. FDA seeks comment on whether the level of risk to human and animal health from potential contamination of outer packaging is high enough to warrant inclusion of outer packaging in the final regulations.

68 *Federal Register* 25190.

SPI appreciates FDA's statement in the preamble that the Agency "is not interpreting packaging to include food contact substances, which are included in the definition of 'food' [in the FFDCA]." This stated intent, however, is not implemented by the wording of the proposed regulation, which encompasses the full breadth of the statutory definition of "food," explicitly "including substances that migrate into food from food packaging and other articles that contact food." The proposed regulation must be revised to follow FDA's own expressed intent not to require recordkeeping by suppliers of "food contact substances." 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 Section 1.328 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."

Based on the remainder of the preamble, it appears that FDA intends to apply the recordkeeping requirement only to suppliers of finished packaging for direct contact with food. While FDA has interpreted the recordkeeping provision of the Bioterrorism Act to include so-called "outer packaging," the Agency has proposed in the preamble to exempt such "outer packaging" from the regulation on recordkeeping. SPI certainly agrees that suppliers of "outer packaging" should be exempt from this proposed regulation, along with all other packaging suppliers. Once again, however, the language of the proposed regulation does not follow FDA's stated intent. Under the proposed regulation, suppliers of "outer packaging" would be subject to the recordkeeping mandate along with all other packaging material suppliers.

If FDA intends this proposed regulation to apply to finished packaging for direct contact with food, the regulation must so state. As SPI has indicated in prior comments on the first two regulations proposed under the Bioterrorism Act, the following revisions would be needed to have the recordkeeping regulation apply only to finished packaging for direct contact with food. SPI is not recommending this definition because Congress did not intend for the recordkeeping requirement to apply to manufacturers and transporters of food packaging materials. We simply point out that clarification of the proposed regulation would be needed to implement FDA's stated intent properly. The proposed regulation should be revised to implement the intent of the Congress, which was not to extend the Bioterrorism Act to any packaging or packaging materials not yet containing food.

***FDA's Estimate of the Burden is Low***

In attempting to estimate the number of food packaging companies affected by the proposal, FDA used counts of facilities found in the County Business Patterns (CBP), which was created by the U.S. Census Bureau. Data in the CBP is tabulated by industry as defined in the North American Industry Classification System (NAICS) Codes. A particular NAICS Code corresponds to a specific industry or subset of industry.

In the discussion of the estimate of firms affected, FDA references twenty NAICS Codes for the food packaging industry. *See* 68 *Fed. Reg.* 25201. These codes correspond to general categories of finished packaging manufacturers, such as "Plastics Bottle Manufacturing," "Paperboard Container Manufacturing," and "Glass and Glass Product Manufacturing." Thus, many manufacturers of the materials used in the production of food packaging are not included in the estimate. As a result, FDA's estimate of the burden is unrealistically low if the regulation remains as drafted, meaning that it applies to all domestic and foreign manufacturers and domestic transporters of food-contact materials.

Further, FDA has not identified the transporters (of food-contact materials, as opposed to food products). In addition, FDA again has used its proprietary Operational and Administrative System for Import Support (OASIS) database to identify foreign companies that would be subject to the proposed regulation. Although SPI cannot obtain information on the precise coverage of the OASIS database, we are reasonably certain that it does not cover imports of all food-contact materials

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In summary, the burden of recordkeeping relating to all food-contact materials is contrary to the language and intent of the Bioterrorism Act. In addition, such recordkeeping will not provide any significant assistance to FDA in deterring or responding to terrorism directed against the food supply. 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 FDA's recordkeeping proposal. SPI also reiterates the commitment of the plastics industry to work with FDA and other agencies to combat the threat of terrorism.

Sincerely,

Ralph A. Simmons

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