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Via Electronic and U.S. Mail

Stuart Shapiro
Office of Information and Regulatory Affairs
Office of Management and Budget (OMB)
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Comments of SPI on the Paperwork Burden with Respect to FDA's Proposed Regulations on Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Docket No. 02N-0278]

Dear Mr. Shapiro:

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 submit these comments with regard to the regulations proposed by the Food and Drug Administration (FDA) entitled "Prior Notice of Imported Food 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.* 5428). FDA's notice of proposed rulemaking requested public comment on the paperwork burden with regard to the implementation of the provision requiring that companies importing food to the U.S. provide FDA with prior notice of each shipment. This provision is contained in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act"). Section 307, Pub. L. 107-188

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.

amending Federal Food, Drug, and Cosmetic Act (FFDCA) (codified at 21 U.S.C. 381(m) *et seq.* (2002)).

SPI commends Congress and the Food and Drug Administration for taking actions to protect the U.S. food supply from terrorist acts, and encourages the Agency to continue working with industry to take reasonable steps to protect the public. However, as explained more fully below, we respectfully submit that FDA's proposal to extend the prior notice of import requirement to food packaging and other food-contact articles that do not yet contain food is in direct contravention of Congressional intent and will unduly burden industry while providing no significant protection against terrorism.

With regard to the Paperwork Reduction Act of 1995, FDA specifically invited comments on: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information would have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. SPI will comment on (1) and (2) as they pertain to the industries that provide food packaging and other food-contact articles. We are very hopeful that these comments and subsequent comments to FDA will result in the proposed regulations being revised so as not to apply to food-contact articles. In our view, there are no methods to improve the collected information or the mechanism for collecting the information that would justify an import notification requirement for empty food packaging.

1 Is the proposed collection of information necessary for the proper performance of FDA's functions, including whether the information would have practical utility?

SPI's FDCPMC opposes import notification with respect to food-contact materials (not yet containing food) as imposing burdens on the industry that are contrary to Congressional intent.

By way of background, FDA seeks to bring suppliers of food-contact materials within the reach of the proposed regulation by referring to the definition of "food" found in Section 201(f) of the FFDCA, 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 FFDCA'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.

FDA has attempted to clarify exactly which packaging materials would fall within this description. 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, and rubber, and many other materials, such as colorants, lubricants, preservatives, antioxidants and emulsifiers that are used in food packaging.

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 prior notice of import 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 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 as it does to "components of immediate food packaging," does not limit the coverage of the regulation as FDA apparently intends. The meaning of "immediate food packaging" is even unclear since it could include only the final, completely formed packaging, or also the film or sheet or other bulk materials from which the final packaging is formed.

We were concerned that this type of misinterpretation might be possible because the Bioterrorism Act states that FDA must receive a prior notice of import for each "article of food" that is being imported. Therefore, we sought clarification from Congress that packaging materials were not intended to be subject to this provision of the legislation. As a result of this

² Section 201(s) of the FFDCA 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.*

effort, the Joint Explanatory Statement of the Committee of Conference for the bill included the following language in the legislative history regarding the provision governing prior notice of imported food shipments:

The Managers intend that the requirements of this section [import notification] 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. 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.

In addition, the bill manager in the house, Rep. John Shimkus (R-Ill.), entered into the Congressional Record on May 24, 2002 an extension of remarks stating:

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.

Thus, FDA has disregarded express congressional intent by proposing to require advance notice of importation of food packaging materials not yet containing food.

Including food packaging materials in the regulation also will impose burdens on the industry that are disproportionate to any minimal reduction in risk and will provide no significant protection against terrorism. The uncertainty regarding the packaging materials actually covered by the proposed regulation makes it impossible at this point to even estimate the number of companies and shipments that might be involved. As drafted, the proposed regulation, apparently extending to all components of immediate packaging that migrate to food, would apply to an enormous number of companies and shipments. If, as FDA has indicated, the regulation is intended to cover only finished immediate packaging, this is undoubtedly a smaller part of the packaging industry, but we are not aware of information that would allow us to quantify the impact with any precision.

Additional uncertainty over the magnitude of the paperwork burden derives from the fact that FDA's proposal 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 notice of importation of the articles from which migration occurs, not the migrating substances themselves. Leaving aside that ambiguity,

however, still leaves the apparent requirement for notification concerning imports of 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 paperwork burden on a large number of companies.

Furthermore, prior notice to FDA of the importation of food packaging and other food-contact articles 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 prior notice of the import of 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, but there is no mention of food-contact materials being related to any such occurrences. It does not seem likely that terrorists would attempt to contaminate food indirectly by tampering with empty packaging. Additionally, requiring prior notice of import for food packaging materials would divert FDA attention and resources from activities directed toward more immediate food security risks.

2. Is FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used, accurate?

In estimating the economic burden of the proposed regulation, FDA cites its Operational and Administrative System for Import Support (“OASIS”) database. Using this database, FDA determined that there are approximately 77,427 importers and consignees who receive shipments of food for human and animal consumption in the U.S. The Agency further stated that it will be these 77,427 importers or U.S. purchasers that will be primarily responsible for submitting the prior notice information. It is this figure FDA used to estimate the economic burden of requiring prior notice of imports.

It is doubtful whether all importers of empty food packaging and other food-contact materials are included in the 77,427 figure; as OASIS is an internal FDA database that is inaccessible to the public, we were not able to verify the figure. Since FDA specified that the 77,427 figure represents importers and consignees who receive shipments of “food for human and animal consumption,” we surmise that the figure likely represents importers and consignees of edible food only and, therefore, does not include importers of food packaging materials, except to the extent that there may be some companies in both categories. As a result, FDA’s estimate of the economic burden probably is low, and the Agency should be required to clarify this point.

* * *

In summary, the burden on industry to provide prior notice of importation of “food” should not be extended to any food packaging (not already containing food) or other food-

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contact articles. FDA's proposal is contrary to the expressed intent of Congress, and will not provide protection against terrorism that would justify the burden. 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 before the paperwork burden can even be estimated.

SPI's FDCPMC appreciates this opportunity to comment on the paperwork burden that would be imposed by FDA's proposal.

Sincerely,



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