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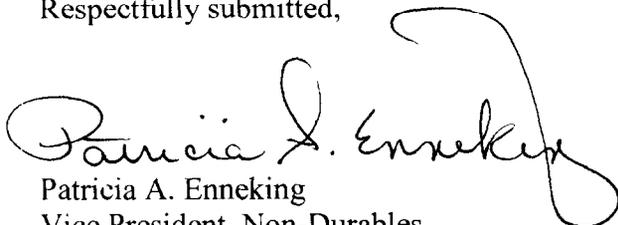
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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

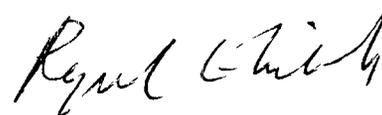
**Re: Proposed Regulations for Prior Notice of Imported Food
FDA Docket No. 02N-0278**

The American Plastics Council (APC) and the Polystyrene Packaging Council (PSPC) submit these comments on the Food and Drug Administration's (FDA) proposed regulation for Prior Notice of Imported Foods under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). APC and PSPC appreciate the important role FDA plays in the protection of the food supply in the United States, and the difficult task it has in implementing the Bioterrorism Act, but this proposed regulation does not further that important purpose. FDA's inclusion of packaging and packaging components, and other food contact articles, not in contact with food at the time of import in its definition of "food" for purposes of the prior notice requirement is improper. FDA's proposed definition ignores explicit congressional expression of intent, and does not further the purposes of the Bioterrorism Act. FDA has underestimated the burden this will cause for industry, and has not shown that it will serve any benefit in increasing the safety of the food supply. Accordingly, as explained in these comments, APC and PSPC request that FDA amend its proposed regulation to exclude packaging, packaging components, and other food contact articles not in contact with food at the time of import from the prior notice requirements. Doing so is consistent with the Bioterrorism Act, congressional intent, and FDA's public safety mandate.

Respectfully submitted,



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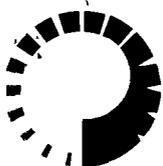
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02N-0278

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**Re: Proposed Regulations for Prior Notice of Imported Food
FDA Docket No. 02N-0278**

These comments are submitted by the American Plastics Council (APC) and the Polystyrene Packaging Council (PSPC), a business unit of APC. APC is a major trade association for the U.S. plastics industry. It is comprised of 23 of the leading resin manufacturers, plus one affiliated trade association representing the vinyl industry. APC's membership represents more than 80 percent of the U.S. monomer and polymer production and distribution capacity. PSPC represents the full scope of the polystyrene industry, from resin producers to finished product fabricators. Because a substantial portion of the production of the member companies of both organizations may be used in contact with food, APC and PSPC are submitting these comments to ensure that the Food and Drug Administration (FDA) considers the full impact of its proposed regulations on the industries.

APC and PSPC appreciate the important job FDA is undertaking in protecting the safety of the United States food supply. The proposed regulations, however, will impose a very large burden

on APC's and PSPC's member companies, with only a very limited and theoretical increase, if any, in the safety of the food supply. In proposing that the import notification requirements apply to packaging materials and other articles not in contact with food at the time of import, FDA has not followed Congress' express intent, and has created an unreasonable and unjustified burden on the industry. The preamble to the proposed regulations provides no food safety justification for the unnecessarily expansive approach. FDA has the clear congressional mandate and authority to define "article of food" for purposes of the import notification to exclude packaging materials and other articles that are not in contact with food at the time of import, and should do so. This would be consistent with the authorizing legislation, the explicit congressional intent, and FDA's mission to ensure the safety of the United States food supply.

I. FDA's Proposed Inclusion of Food Packaging and Other Food Contact Articles in the Definition of Food is Not Consistent with Congressional Intent

Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) requires prior notification for imported "articles of food." For purposes of its proposed regulations, FDA has used a very broad definition of "food." In direct opposition to explicit legislative history FDA has proposed to define "food" to encompass all articles within its statutory jurisdiction under 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA provides examples of products that are technically considered "food" under the FD&C Act, including "substances that migrate into food from food packaging and other articles that contact food." 68 Fed. Reg. 5428, 5430 (February 3, 2003).

During the enactment of the Bioterrorism Act, the plastic packaging industry informed Congress that the definition of "food" broadly covers packaging and other food contact materials. If the Bioterrorism Act were to apply to the full range of articles that technically fall within the definition of "food" under the FD&C Act, all the requirements of the Bioterrorism Act, including the prior notice requirement for imports, would apply to manufacturers of packaging and packaging ingredients as well as thousands of other food contact articles. This realization came to Congress late in the legislative process. The congressional response was to insert clarifying language into the legislative history to provide explicit congressional intent on the proper scope of the Bioterrorism Act. Specifically, the Conference Report includes the following language:

The Managers intend that the requirements of this section [307] 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 [FD&C Act].

H. R. Rept. No. 107-481, 107 Cong., 2d Sess. 137 (May 21, 2002). When the packaging industry explained that even this language might not be enough to evidence the clear intent of Congress to exclude packaging materials from the prior notification provisions, Congressman Shimkus, one of the Managers of the Bioterrorism Act, made this statement on the House floor:

Mr. Speaker, in addition to my statement for the record on May 22, 2002 during floor consideration of H.R. 3448 [clarifying other

sections of the Bioterrorism Act], 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.

148 Cong. Rec. E916, (daily ed. May 24, 2002). It is thus clear that Congress intended to limit the scope of "food" for purposes of the prior notice requirement to exclude packaging materials, unless such materials are used in direct contact with food at the time of import. As those packaging materials would be covered by the notice for the packaged food itself, there is no benefit to FDA's intended application of the prior notice requirement to packaging materials.

FDA, as the agency authorized to implement the provisions of the Bioterrorism Act, has discretion in interpreting the terms in that legislation, when interpretation is required. FDA is bound, however, by the language of the statute and clear expressions of congressional intent. When Congress has spoken directly to an issue, the agency (and any reviewing court) must give effect to the unambiguously expressed intent of Congress. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); *Food and Drug Administration v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120 (2000).

For purposes of the prior notice of imports requirements, FDA was directed to develop regulations regarding the import or attempts to import "articles of food." Congress provided

specific and unambiguous direction, however, that the interpretation of this term for purposes of the prior notice requirement is not to include food packaging unless such material is used in food at the time of import. This is consistent with the term “food for consumption” used in section 305 of the Act. Although the language is not identical, this is more likely a result of the expedited enactment process of the Bioterrorism Act than an intentional distinction. In fact, Congress attempted to clarify, and to some extent reconcile the sections, by inserting explanatory language for the prior notice requirement limiting the scope of the packaging to which the requirement applies. There is no other legislative history indicating that packaging and other food contact articles that are not in contact with food when imported are subject to prior notification. FDA has chosen to apply an expansive definition of “food” requiring prior notice in its proposed regulations implementing this requirement, in direct contravention to express congressional intent.

In the preamble to the proposed rule, FDA cites section 801(m) of the FD&C Act, as added by the Bioterrorism Act, as support for its requirement of a notification for “each article of food” in a shipment. The phrase “each article of food” appears nowhere in section 801(m). That section does provide that the Secretary shall by regulation require the submission “of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; . . .” Unlike the legislative history, it affords no explanation of what the “article” encompasses.

II. Subjecting Food Packaging and Food Contact Substances to Prior Notice Will Not Further the Purposes of the Bioterrorism Act

The Conference Report on the Bioterrorism Act states that the intent of the bill is “to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.” H. R. Rept. No. 107-481, 107 Cong., 2d Sess., Joint Statement of the Committee on Conference (May 21, 2002), p. 107. Consequently, all the requirements imposed by the act must further this goal. While many of the provisions of the Bioterrorism Act, when applied to conventional food, will further this purpose, they will not do so if applied to food packaging and other food contact materials. Congress recognized this, and excluded packaging and other food contact articles from the prior notification requirements, and FDA should similarly do so in its regulations.

The potential list of food contact articles is tremendous. A review of the broad array of materials FDA regulates in its food additive regulations, 21 C.F.R. Parts 170 through 189, reveals the scope of materials FDA considers “food” under the statute becomes clear. These sections do not cover articles typically referred to as “housewares,” which are food contact articles such as plates, utensils, and cookware used in the home or retail establishments. These items have traditionally been considered outside the scope of FDA’s food additive authority, but are still considered “food” under the FD&C Act. Under FDA’s proposed definition of “food” for purposes of the prior notice requirements, all of these articles, and any of their components, would require prior notification. Thus, all of these items, and any component of these items, would be subject to prior notification if possibly used with food: paper, paperboard, plastics, most industrial chemicals, metals, glass, pottery and china, rubber products, lubricants, food processing equipment, as well as all utensils. None of these could reasonably be considered “food for consumption.”

Applying the prior notice requirement to this broad variety of products will overwhelm both industry and FDA resources, with no benefit as far as increased security for the United States food supply. It is difficult to believe that a terrorist attack on the food supply will be carried out through packaging. As a technical matter, it would be virtually impossible to insert a poison in packaging with a sustained release mechanism to contaminate food, without the full cooperation of the packaging manufacturer. Even putting aside the technical and logistical complexities that would be involved, such an indirect approach would have virtually no impact before discovery. All food processors have routine procedures in place to ensure that their packaging materials are suitable for use with food. Any possible threat to the food supply from packaging would be uncovered at this stage.

FDA states in the preamble to its proposed regulation that "with respect to articles that can be used for food and non-food uses, FDA believes that prior notice is required if the article is being imported for use as food." 68 Fed. Reg. at 5430. This comment creates an immense burden for the packaging industry, as most food packaging materials are imported in a form other than finished food packaging which can have many uses in addition to use with food. If food use is only one of the many intended uses of a product upon import, it is clear from FDA's comment that prior notice would be required for all packaging, food contact articles, and any material that may be an ingredient of these, as it is impossible to segregate material that will be used with food from material that will not be used with food within bulk shipments. Because of the significant burden created by imposing the prior notice requirement on these imports, with no food safety

benefit, food packaging and other food contact materials should not be subject to the prior notice requirements.

III. Separate Notification for Food Packaging and Food Contact Articles is Duplicative

FDA's proposed regulation requires that the notification contain the complete FDA product code. Proposed 21 C.F.R. 1.288(e)(1)(i). FDA further explains in the preamble that the complete product code includes information about the "container/packaging" of the food. 68 Fed. Reg. at 5436. Consequently, FDA will receive information about the packaging used in contact with food through the notification submitted for the food item. Given Congress's express intent to limit the prior notice requirement to food packaging and other articles in contact with food at the time of import, there is no need for a separate notification for the packaging. Such a requirement would be duplicative, and unnecessarily burdensome on both FDA and industry.

As noted above, the technical difficulty involved with carrying out a terrorist attack through packaging is very high. To think a contaminant could survive in packaging that does not already contain food through shipment, import, further processing to package food, shipment of the food, the shelf-life of the food, and finally consumption, strains credulity. Congress wisely limited the prior notification requirement to packaging and other articles that already contact food at the time of import, as there is absolutely no risk from material that does not contact food. Further, as FDA proposes to implement the prior notification requirement to include the FDA product code, FDA will receive information about the packaging of all imported food. The purpose of the prior

notification is to “enable[e] such article to be inspected at ports of entry into the United States.” Bioterrorism Act section 307. If FDA has a concern about a particular packaging type presenting a risk to food, FDA already will be receiving the information necessary to identify and inspect those articles without requiring a separate notification for the food contact article.

IV. FDA Underestimates the Financial Burden of the Proposed Regulation

FDA estimates the cost of the prior notice system using the OASIS codes for food imports (codes 02-52, 54, and 70-72). 68 Fed. Reg. at 5440. Because these categories only cover those items that are traditionally considered “food,” this analysis underestimates the impact that FDA’s proposed definition of “food” will have on imports, and thus the cost of the prior notice proposal. The categories in the OASIS system do not cover the imports of bulk chemicals, polymers, bulk papers, and other precursor materials that are used in other areas as well as food packaging and other food contact articles. Under FDA’s proposed regulation, importers of these materials will be required to submit a prior notification if they are aware that the materials may be used with food. Because it is difficult to know for certain every possible use of a bulk chemical, the prudent importer will be forced to submit a notification to ensure that, if the product is to be used with food, it is legal to do so. This creates an unnecessary burden on several levels. For industry, notifications will be required for a vast quantity of material that will not contact food. For FDA, unnecessary resources will be spent processing notifications for materials that may never contact food. FDA should avoid this unnecessary expenditure of resources by following the clearly defined legislative intent and not requiring notification for food contact materials unless, at the time of import, the materials are used in direct contact with food. Based on

industry data regarding the value of imports, APC and PSPC conservatively estimate that the value of imports in the plastics industry is approximately \$16 billion. Under FDA's proposed definition, this entire amount is likely to be subject to notification.

In estimating the total cost as stated in the preamble to the proposed regulation, FDA based its calculations on improper assumptions. FDA states that there were 4.7 million OASIS import lines that it used to establish its base line cost for this proposal. 68 Fed. Reg. at 5442. FDA further states that the average imported entry contained 2.6 lines. "An 'entry line' is an FDA term used by the OASIS reporting system, which refers to a line on an invoice that reflects a certain article specific to manufacturer or packaging: e.g. 100 cases containing 48 six ounce cans of tuna." *Id.* FDA then calculates that, because there is an average of 2.6 lines per import entry, and there were 4.7 million lines, there were 1,807,692 entries that would require notification. What this ignores is FDA's definition of "article of food" for purposes of this regulation. FDA states that if the manufacturer, or size of the container differs, even though the products are in the same shipment, separate notifications will be required. Therefore, assuming FDA's use of the 4.7 million entry lines is correct, the proper number for FDA to use in estimating the cost of this proposal should be the 4.7 million lines. This will increase the cost of the proposal 2.6 times, to \$155,193,974. APC and PSPC do not consider the 4.7 million lines to accurately reflect the burden of this proposal, however, as it ignores the impact of FDA's proposed definition on materials not in contact with food. Adding the ignored cost of prior notification for the packaging materials that may be used with food but are not in contact with food at the time of import to the \$155,193,974 demonstrates the excessive burden of this regulation on industry and FDA.

FDA further underestimates the burden of this proposal by not considering the upstream component manufacturers. Because FDA's proposed definition of food would also apply to all ingredients of food packaging and other food contact articles, notification must be submitted for the import of all these items. This extends FDA's notification requirement far beyond the categories FDA considered to include all the inputs used to manufacture these articles. And because these items and the ingredients used to manufacture them are primarily shipped in bulk, with no way to distinguish between the food use and non-food use material, notification will be required for all of it. Thus, the number of notifications required will be much larger than FDA estimates, with an enormous cost to industry and FDA. Also, given that none of these materials will be allowed to cross the United States border without proper notification, there will be a tremendous impact on commerce.

Given the extraordinarily high cost of this proposal, FDA should focus its resources where there is the opportunity to benefit the safety of the United States food supply - food itself. There is no benefit to applying the import notification requirements to food packaging, and doing so amounts to nothing more than a waste of limited resources. FDA has been tasked with an immense obligation, ensuring the safety of the United States food supply, and it must focus its resources on areas where the expenditure of resources will yield returns in increased safety. Prior notice of imports of food packaging and other food contact articles will not achieve this purpose.

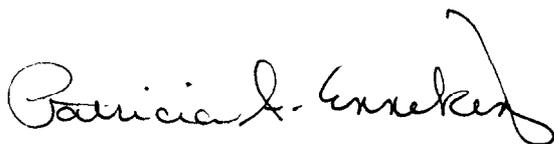
The examples of foodborne outbreaks to which FDA refers in the preamble that could be averted by these requirements have nothing to do with food packaging. Beginning on page 5454 of the

preamble, FDA sets out the cost of five foodborne outbreaks. The “vehicles” for these outbreaks are all conventional foods, and have nothing to do with packaging or other food contact articles. If FDA seriously thinks that food packaging or other food contact articles pose a potential threat from an intentional attack on the food supply, FDA would have estimated the cost of such an attack, in an attempt to justify the immense burden being placed on the industry. In the absence of such an estimate, FDA’s treatment of food packaging and other food contact materials is completely unjustified.

IV. Conclusion

FDA should amend its definition of “food” for purposes of the prior notice requirement to exclude food packaging and other food contact articles not in contact with food at the time of import. Doing so is consistent with congressional intent, as well as FDA’s mission to protect the safety of the United States food supply under the Bioterrorism Act.

Respectfully submitted,



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