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July 7, 2003

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

**Re: Proposed Regulations for Establishment and Maintenance
of Food Records
FDA Docket No. 02N-0277
68 Fed. Reg. 25188 (May 9, 2003)**

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 Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (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 application of the recordkeeping requirement to food contact facilities is unjustified in light of the remoteness of the possibility that food contact substances could pose a threat to health. 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 regulations to exclude food contact facilities from the recordkeeping requirements. Doing so is consistent with the Bioterrorism Act, congressional intent, and FDA's public safety mandate.

Respectfully submitted,

Handwritten signature of Patricia A. Enneking in black ink.

Patricia A. Enneking
Vice President, Non-Durables
American Plastics Council

Handwritten signature of Raymond Ehrlich in black ink.

Raymond Ehrlich
Director, Environmental & Public Affairs
Polystyrene Packaging Council
A business unit of the American Plastics Council

Attachment

02N-0277

050



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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 rules 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. While APC and PSPC and their members agree with FDA's decision not to apply the proposed regulations to outer packaging, the same rationale that supports that exclusion applies equally to food contact materials. In proposing that the recordkeeping requirements apply to food contact articles, FDA has created an unreasonable and unjustified burden on the industry and its suppliers. Under FDA's proposed approach, there is no limit to the suppliers of components and precursor substances who would be required to establish and maintain records. Removing food contact facilities from the scope of the recordkeeping regulations is consistent with the language of the authorizing legislation and FDA's mandate to ensure the safety of the United States food supply in the least burdensome means possible.

I. Applying the Recordkeeping Requirements to Food Contact Materials Will Not Further the Purpose 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, 107th Cong., 2d Sess. 107 (May 21, 2002). Accordingly, all the requirements imposed by the Act must be directed at achieving this goal. While the proposed recordkeeping rules might further this purpose when applied to conventional food, they will not do so when applied to food contact materials.

In particular, Section 306(b) of the Bioterrorism Act, which the proposed rules purport to implement, authorizes FDA to establish recordkeeping requirements only where such records are necessary to identify the immediate previous source and immediate subsequent recipient of food “in order to address credible threats of serious adverse health consequences or death to humans or animals.” FDA claims in the preamble to the proposed rules that the regulations “would result in a significant improvement in FDA’s ability to respond to and help contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.” 68 Fed. Reg. 25188 (May 9, 2003). However, FDA has failed to show that food contact materials could present any such threat or that the application of the proposed regulations to these materials would help the agency respond to or contain such a threat.

It is illogical to believe that a terrorist attack on the food supply will be carried out through food contact substances. As a technical matter, it would be virtually impossible to insert a poison in contact materials with a sustained release mechanism to contaminate food, without the full cooperation of the materials manufacturer. Even if such tampering were remotely feasible, such an indirect approach would have virtually no impact before discovery. Food contact manufacturers and food processors have routine procedures in place to ensure that their contact materials are suitable for use with food. Any possible threat to the food supply from packaging would be discovered at this stage. Accordingly, there is no reason to believe that applying the recordkeeping requirements to food contact substances would further the purpose of the Bioterrorism Act or FDA’s stated goal of the proposed regulations.

APC and PSPC fully agree with FDA's determination not to extend the recordkeeping requirements to outer food packaging, as there appears to be no actual risk that harm could be perpetrated through outer packaging. However, FDA fails to provide any basis for distinguishing the level of risk posed by food contact substances and outer food packaging, other than its statement 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." 68 Fed. Reg. at 25190. This bare assertion is plainly insufficient to justify imposing the substantial obligations of the proposed recordkeeping regulations on the food contact industry. Further, without an explanation, this unsupported distinction between the dangers posed by outer packaging and food contact materials appears to be arbitrary and capricious, in violation of the Administrative Procedure Act.

Significantly, there has not been any adverse health incident attributed to adulterated food packaging. The examples of foodborne outbreaks that could be averted by the proposed requirements, to which FDA refers in the preamble, demonstrate that the appropriate realm for these regulations is conventional food. Beginning on page 25225 of the preamble, FDA sets out the cost of these outbreaks. The "vehicles" for these five outbreaks are all conventional foods, and have nothing to do with packaging or food contact articles. If FDA seriously thinks that food contact materials pose a potential threat from an intentional attack on the food supply, FDA would have estimated the cost of such an attack and would have shown that these provisions will minimize that risk, in an attempt to justify the immense burden being placed on the industry. FDA has provided no such cost minimization justification. The safety history of food packaging demonstrates that the current system is working to protect public health. While FDA must

accurately implement the Bioterrorism Act, this proposed regulation goes too far, and imposes a burden without a proper estimate of the benefit or any cost minimization achieved by the proposal. In the absence of such an estimate, FDA's inclusion of food contact materials is completely unjustified.

II. FDA Vastly Underestimates the Burden of the Proposed Recordkeeping Regulations

In its Analysis of Economic Impact, FDA estimates that 73,813 packaging facilities will be subject to the recordkeeping requirements. 68 Fed. Reg. at 25201. The agency explains that the data used for this analysis reflects the number of manufacturers and distributors of the following types of packaging:

Paperboard containers, paper bags and treated paper, plastic bags, bottles, laminated plastics and other plastic materials, polystyrene and urethane foam products, glass products, and metal and aluminum can, sheet, plate and products. Furthermore, printing services and label producers are included such as lithographic, gravure, flexographic, screen, digital, and quick printing services.

68 Fed. Reg. at 25202-3. In assuming that these are the only categories of food contact materials that would be affected by the proposed regulations, FDA ignores several considerations that result in an underestimate of the burden imposed.

First, FDA adopts an expansive approach to the definition of "food." It would include all "substances that migrate into food from food packaging and other articles that contact food." 68 Fed. Reg. at 25238. The potential list of food contact articles considered "food" is vast, as demonstrated by the broad array of materials FDA regulates in its food additive regulations, 21

C.F.R. Parts 170 through 189. Articles typically referred to as "housewares" -- which are food contact articles such as plates, utensils, and cookware used in the home or retail establishments -- have traditionally been considered outside the scope of FDA's food additive authority, but are still "food" under the FD&C Act. Under FDA's proposed regulations, all facilities manufacturing, processing, packing, or holding these articles must establish and maintain records. Thus, all firms engaged in any of the following industries would be subject to the recordkeeping requirements: paper, paperboard, plastics, most industrial chemicals, metals, glass, pottery and china, rubber products, lubricants, food processing equipment, and utensils. Applying the recordkeeping requirements to this broad variety of products will overwhelm both industry and FDA resources, with no benefit to the security of the United States food supply.

Second, FDA's estimate of the burden of its proposal fails to account for the broad range of "upstream" manufacturers that make ingredients and components that go into food contact articles -- a substantial portion of the membership of APC and PSPC. The agency's extension of the definition of food to everything that may possibly be considered food would expand the burden of the recordkeeping requirements exponentially. Any facility engaged in the manufacture, processing, packing, or holding of any component or precursor substance of food contact material would be subjected to the recordkeeping requirements, as any ingredient of an ingredient of something that may migrate into food is considered a "food" under FDA's approach. There is no logical end to this chain. For example, all of the distributors and suppliers of raw materials for the constituents of food contact substances would be included. This paperwork and logistical burden will be immense, with no comparable increase in the safety of the food supply.

Third, most of APC's and PSPC's members and their suppliers produce both food and non-food products and product components. Because a facility may not know at the time it ships a substance or material whether it is destined for food use, the facility may be required to establish records in any event to ensure compliance with regulatory requirements in the event that the substance is in fact used for food at some point down the chain of commerce. This approach will result in a tremendous waste of resources, perhaps leading to the establishment of records for every shipment of every chemical substance that might possibly have a food use.

Fourth, FDA's requirements for transporters fail to consider transporters of food contact substances. These transporters are unlikely to be aware that the materials they are transporting -- for example, chemical precursors to these substances -- are deemed "food" by FDA. They will have no reason to think that they are obligated to establish and maintain records regarding the shipment of these materials. If FDA assumes that the facility from which the materials are being sent should advise the shipper of the recordkeeping requirement, then the agency would be imposing an additional notification requirement on the food contact industry that goes beyond what is required by the conventional food industry. There is no justification for this disparate treatment, particularly given the fact that any security risk to the food supply is likely to be posed by conventional food.

Finally, the tremendous burden posed by the proposed regulations will not fall only on large paper, packaging, and chemical suppliers. Many of the facilities are small independent establishments. The recycling industry will also be affected, because many food contact articles

make use of recycled input. This would include all curbside recycling programs, which are clearly sources of raw materials for food packaging. The paperwork burden imposed by the proposed recordkeeping requirements would overwhelm many of these small facilities. Applying these rules to the recycling industry is simply bad public policy, for it may lead many establishments to leave the business of turning recycled materials into food contact materials because they would be unnecessarily overburdened by the recordkeeping requirements.

Given the tremendous costs of this proposal, FDA should focus on the area in which there is the opportunity to benefit the safety of the United States food supply -- conventional food itself. There is no benefit to applying the recordkeeping requirements to food contact materials, and doing so amounts to nothing more than a waste of resources. FDA has been charged with an immense obligation, ensuring the safety of the United States food supply, and it must focus its attention on areas where the expenditure of effort will yield returns in increased safety. Requiring recordkeeping for food contact substances will not achieve this purpose.

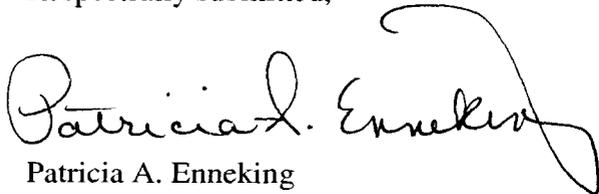
III. Recommendations

For the reasons described in detail above, FDA should not impose recordkeeping requirements on food packaging and food contact facilities at all. The recordkeeping obligation with respect to food contact substances should begin with the first conventional food establishment to receive the materials. These companies will document receipt of these materials as part of their obligation to establish and maintain records regarding the immediate previous source of food components. Such records will provide all the information FDA might need in the highly

unlikely event that a foodborne health emergency would be traced to food contact materials, because any possible tampering with contact materials would only become relevant when those materials are applied to conventional food.

For the reasons set forth in these comments, FDA should revise its recordkeeping proposal to exclude food contact materials and should focus only on conventional foods. This approach is consistent with the statute, the legislative history, and the 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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